European Journal of Logistics, Purchasing and Supply Chain Management
Vol.4, No.1, pp.19-31, February 2016
Published by European Centre for Research Training and Development UK (www.eajournals.org)

# LABORATORY QUALITY MANAGEMENT SYSTEM FOR A MEDICAL TESTING AND DIAGNOSTIC LABORATORY: A REVIEW OF AN AVENUE TO ACCREDITATION AND BEYOND

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**ABSTRACT:** *This review attempts to clarify the concepts of Laboratory Quality Management System (Lab QMS) for a medical testing and diagnostic laboratory in a holistic way and hopes to expand the horizon beyond quality control (QC) and quality assurance. It provides an insight on accreditation bodies and highlights a glimpse of existing laboratory practices but essentially it takes the reader through the journey of accreditation and during the course of reading and understanding this document, prepares the laboratory for the same. Some of the areas highlighted include: requirement for accreditation consultants, laboratory infrastructure and scope, applying for accreditation, document preparation. This paper is well supported with details like preparation of a standard operating procedure and a quality manual. Concept of training and privileging of staff has been clarified and a few of the QC exercises have been dealt with in a novel way. Finally, a practical advice for facing an actual third party assessment and caution needed to prevent post-assessment pitfalls has been dealt with.*

**KEYWORDS:** Accreditation, Laboratory Quality Management System

## INTRODUCTION

Laboratory Quality Management System (Lab QMS) has evolved through several phases in western countries in the past 40 years and has been comprehensively assessed previously [1] but this aspect has not received its full credit in Nigeria, till now. This in itself shows the existing need to excite an interest and invite a debate on this vital topic. Among the existing work, review by Arora[2] on quality assurance (QA) and Basu *et al* [3] on quality control (QC) of culture media are very informative but undoubtedly the most exhilarating piece in terms of what exactly was required to bring in the concept of quality was written way back in 1992 by Rao.[4]

Information about accreditation process is available through Medical Laboratory Science Council of Nigeria (MLSCN) and SLIPTA documents, which are extremely well written, but these documents make a dry reading and are theoretical. Hence, the current endeavour is to explain the whole process in an easy to follow practical way.

The road map to article is as follows: accreditation bodies, need for accreditation, existing practices in different laboratories, do it yourself or hire consultants?, applying for accreditation, quality plan and preparation of documents, quality system procedures (QSPs), quality manual, internal QC in examination procedures, facing accreditation some practical tips and post-assessment pitfall and conclusions.



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

## Accreditation Bodies

An accreditation body is a statutory organization that is usually established by an act of parliament and is internationally recognized through "Mutual Recognition Arrangement" An accreditation body promotes development and maintenance of good practices in testing and calibration, i.e. technical requirements and competence, establishes and maintains international recognition for its national programs.

## Global level

International Organization for Standardization (ISO) is a worldwide federation of national standards body which was conceived in 1947 (in the form of NATA: National Association of Testing and Accreditation of Laboratories); at present it comprises 140 members with at least one member in each country. ISO publishes its guidelines as International Standards. [5] The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) deal specifically with laboratories. [6] The ILAC delegates the broad tasks via ISO standards to regional bodies like Asia Pacific Laboratory Accreditation Cooperation (APLAC) for Asian countries. To make these guidelines acceptable globally and to draw a uniformity all over the globe, there is a memorandum of understanding (MOU) quoting complete recognition and agreement among two international accreditation bodies (ILACandIAF)andISO(MRA).

## National Level

The Medical Laboratory Science Council of Nigeria (MLSCN) in Nigeria is the National Accreditation Board for Testing and Calibration of Medical Laboratories registered under the Act 11 of 2003. It is the sole authorized Medical Laboratory accreditation body in Nigeria. Its objective is to provide third party assessment of quality and technical competence.

## Laboratory accreditation: A step further than quality assurance and quality control

Accreditation is a procedure by which an accreditation body (like MLSCN) gives formal recognition that a body (laboratory) or person (signatory authority) is competent to carry out specific tasks (scope). [7] The procedure imparts official credit, authorization and registration of a laboratory and that it has demonstrated its capability, competence and credibility to carry out its specified scope. [8] It is a philosophy of principles and a voluntary process including a wide array of quality tasks beyond QA and QC. Advantages of accreditation include the following. [9]

- Reports are accepted internationally implying the concept "Once Tested, Accepted everywhere."
- Overseas business is improved.
- Quality of reports is not affected by individuals once the systems are in place.
- User confidence increases.
- Productivity increases as error and wastage decrease.

## Need for Accreditation

We all know that by running a successful QA program we can deliver reliable reports in an agreed upon time frame and hence achieve customer (which may be the physician or the patient) satisfaction; and once we systematize this process, the system can be assessed,



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

evaluated and improved upon which is comprehensively called the Lab QMS. Accreditation re-enforces and reassures quality by creating an opportunity for the laboratory to look back upon the pitfalls which eventually creep into the system as soon as we take our eyes off it.

National level guidelines for good laboratory practice, issued by Medical Laboratory Science Council of Nigeria (MLSCN) have existed since long, [10] but poor response from the laboratories has led to making of a new directive wherein accreditation is a must-have for CGHS empanelment benefits; [11],[12,17] and this has served as the biggest driving force for the private laboratories to opt for accreditation. Nevertheless, initiatives taken and efforts put in by the laboratories undergoing accreditation have been lauded by the government. [13, 17]

**Existing Practices in Different Laboratories**

Laboratories may be divided into two broad categories: first those which are run by government organizations among which a few are attached to medical colleges and second are the private sector laboratories wherein again we find a divergence: (a) the class-apart independent laboratories run by big corporate giants or the in-house laboratories of private/corporate hospitals/clinics and; (b) many small scale run-of-mill laboratories which do not even have the basic laboratory structure for doing Medical Laboratory tests.

If we talk about government organizations, then those which are not associated with teaching/CME programs are the least followers of the painstaking path which quality is. On the other hand, laboratories associated with teaching hospitals, which shape up the coming generations of Medical Laboratory Scientists, are enigmatic because of the presence of iconic Medical Laboratory Scientists who may not strictly follow the Medical Laboratory Science Council of Nigeria guidelines. Their experience makes this science look like an art as they avoid those traps which are circumvented through Lab QMS, but this makes the system persondependent.

If we discuss the lacunae which exist in an un-accredited laboratory they would be many and would vary with each laboratory, so instead we would like to refer to the article by Rao which quotes "Most of the medical colleges, Medical Laboratories are in poor state due to lack of funds, shortage of staff, etc. the responsibility for this sorry state of affairs, we should admit, is partly ours". [4] This reference reviewed most of Lab QMS in six advises which we would like to state with reference to the existing state of affairs and see where we have come since 1990s.

- "Reference manuals (quality documents in current parlance) should be prepared": Most non-accredited laboratories either lack or have poorly prepared documents not in accordance with ISO 15189:2007.
- "National type collection centre on the lines of American Type Culture Collection (ATCC) should be there": This issue has largely been resolved as one can now easily procure ATCC strains.
- "Quality check on production companies (media, disc etc)": although many agencies have come up as custodians responsible for upholding quality but now it is within easy reach to check the quality of these products at our own laboratories.
- "Quality control of laboratory equipments": SLIPTA has already accredited a large number of calibration laboratories by 2011 but one should be careful in choosing and interpreting what these agencies report.


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

- "Mushrooming of private clinical laboratories should be checked": this is where this branch of medicine gets discredited the most.
- "Quality control should be taught to students at appropriate levels": this is being done at most teaching institutions but mostly theoretically.

**Do it yourself or hire consultants?**

Undoubtedly, there are many good Medical Laboratory Scientists but yet it is our opinion that those undergoing accreditation for the first time would be greatly helped by private consultants, at least in the area of writing a quality manual and documentation. This review will help in greatly minimizing the dependence of a laboratory on the private consultants but may not remove it. This appraisal would prove fruitless for a reader who has not read or not understood the SLIPTA documents or is unable to make manuals and SOPs, which would be plenty in any case. It is important to remember that the actual process of quality management is in our hands and overdependence on the consultant may lead to issue of an accreditation certificate but not necessarily quality.

**Getting started**

First requirement is appointing a Quality Manager (QM) but there are no specific guidelines for selection. The QM should be sent for training on LAB QMS and Internal Audit program as per ISO 15189:2007 standard. These programs were earlier conducted by SLIPTA, but now a few SLIPTA accredited government and private training institutes independently conduct it, as a 4-day course, for which one may refer to the SLIPTA website. [19] The QM must write down all documents as per ISO 15189:2007 standard and train other lab personnel accordingly. All the lab personnel should have gone through and understood these documents.

ISO 15189:2007 is the standard guideline for developing Lab QMS in medical testing laboratory and it can be purchased from the ISO website. [14, 15] The document verbatim of ISO 15189:2007 standard is the NABL 112. It is available, free of cost, from MLSCN website [17] and can also be used as a working tool.

**Applying for accreditation**

Under ideal conditions, one must first set up a laboratory, establish a Lab QMS, start processing, perform an internal audit, improve the system as per ISO 15189 or MLSCN guidelines, apply for External Quality Assurance Scheme (EQAS) and once having achieved satisfactory results, apply for accreditation, but if we follow this, we may never get accreditation as the intended state of perfection aimed by the above standards may never exist with no training or external assistance; so the most practical way would be to apply for accreditation and develop alongside because as the date of inspection, for accreditation, comes near, an intense pressure to improve mounts.

The best thing about MLSCN is the large number of self-help publications freely available on its website for the purpose to facilitate people opting for a "Do it Yourself" policy and to reduce dependence on private consultants. Therefore, even if consultants are hired, the first step is to download and read thoroughly the following documents from MLSCN website besides MLSCN: Application form for Medical Laboratories. [17] and a Guide for Unlocking SLIPTA checklist & ISO 15189 [19] which is a preparation tool for 5-star performance


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

towards international accreditation of medical laboratories that provide details necessary documents required to apply for accreditation. The following aspects need to be looked into.

- Laboratory registration under "The Companies Act."
- Laboratory must apply for EQAS. One needs to register by pre-assessment but till final assessment this system should be fully functional.
- Scope: A list of tests, for accreditation, is to be prepared and send to the NABL office. Before deciding the scope of the test one must ensure availability of relevant space and equipments as highlighted below.

**Laboratory area**

- Front office: Reception area where patients make the first contact here; this should display all the tests carried out in-house and / or those out-sourced (i.e. the DOS: Directory of Services), turnaround time (time calculated from subtracting time of reception of samples from expected time of delivery of reports), names of the various Medical Laboratory Scientists and working hours of the laboratory. There should be a system for lodging complaints (a complaint box, complaint forms) and receiving feedback from customers.

- Sample collection room and a toilet: For essential requirements of this area one may refer to the SLIPTA check list & ISO 15189. [19]

- Processing area: This would need careful evaluation as this would largely influence the scope of tests

**Organization Chart**

It clearly depicts the hierarchy of the laboratory personnel. It needs to be present in the Quality Manual and may also be displayed in the laboratory front office.

**List of Equipments**

A list of equipments has to be provided to the MLSCN office in a format. The format should include manufacturer's name, model no., year of make, year of installation, availability of operation manual and procedure, details of periodic maintenance/ calibration / validation of all equipments being used in the laboratory.

**Details of Last Internal Audit and Management Review**

Management review meetings (MRMs) can be conducted by QM in the presence of Technical Manager, Chairman and the Medical Laboratory Scientists of various specialties. The minutes of the meeting have to be documented. Internal audits have to be conducted for each specialty by internal auditors from a different specialties, at least yearly, and the non-compliances as well as the corrective action taken have to be documented. The laboratory is required to keep a photocopy of the Medical Laboratory Scientist’s certificate issued by the MLSCN.

**Quality plan and preparation of documents**

Preparation of documents is easier if one begins with the lowest tier among the hierarchy of documents i.e. "end point documents" This would include the pre-analytical (test requisition



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

form and consent form), analytical (worksheets/registers) and post-analytical (test reports, records) documents along with others like feedback/complaint forms and formats for QC tests. [16] As Medical Laboratory Scientists, we are aware about the standard operating procedures (SOPs) but we do not have them in print at least not in the format prescribed by ISO 15189: 2007 guidelines; so we can start first with the end point documents and once these are streamlined we may start writing our SOPs. Obviously one would keep on improving the end point documents as and when one gains more experience.

Standard operating procedure: An SOP should incorporate the following points which are being addressed here through the example of culture of aerobic bacteria in blood by automated system, Bactec 9050. ™ This SOP along with commensurate references must also include a copy of the Bactec 9050 ™ manual:

- Purpose: To culture aerobic bacteria in blood.
- Principal of examination: Fluorescence-based detection.
- Performance specifications (unit of measurement): positive (if growth is detected) and negative (if no growth).
- Primary sample system: Blood (however, the laboratory may have a separate SOP/policy to use the Bactec system for samples from normally sterile sites like CSF, synovial fluid, pleural fluid, etc).
- Container: Bactec bottle; type depending on the patient [adult / pediatric].
- Equipment and reagents required: Biosafety cabinet-IIA, Bunsen burner, bacteriological loop, incubator, sheep blood agar, MacConkey agar, peptone water, antibiotic discs, Mueller Hinton Agar (MHA), McFarland standard, ATCC control strains.
- Calibration procedures: For calibration requirements of equipments refer to the section j of Quality manual. Machines like Bactec 9050 cannot be calibrated by MLSCN certified laboratories and hence have to be placed under periodic maintenance contract with the manufacturer.
- Procedural steps: This should include the criteria for processing (whenever the Bactec signals a positive growth.
- Responsibility: To be operated by authorized Medical Laboratory Scientist.
- Safety precautions: Follow standard safety precautions.
- Turnaround time: Described in detail in scope of tests.
- Internal quality control (IQC): Bactec 9050 bottles: each batch should be tested for both positive and negative results (refer to the Bactec 9050 manual).
- Interferences: Laboratory can write a comment that isolation rate of Bactec 9050 increases with three culture samples
- Critical alert value: all Bactec positives samples should undergo a Gram stain and the report should be communicated, at the earliest, to the treating physician.

**Quality System Procedure**

Conceptually different from SOPs, Quality System Procedures (QSPs) include procedures meant to execute policies and also serve as guide to streamline laboratory work (especially handling of ambiguous situations). One would have to use a bit of common sense to make these QSP documents. They are nothing but how one must essentially approach a situation: Be it any important laboratory finding, a reporting error or staff selection etc. For example, reporting Bactec positive blood culture (critical alert): One may make a QSP stating that all Bactec positive cultures would be subjected to culture and Gram stain and if an organism can



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

be observed on Gram stain, the same is to be reported to the doctor. Next day after observing the growth and recording results of preliminary tests, a second feedback is given. Third day, the organism with its identification and sensitivity are finally communicated to the doctor. This system helps in guiding treatment and also ensures quick transfer of critical information.

**Quality Manual**

The most important step toward the process of accreditation is to prepare a quality manual. This is the most exhaustive part and to prepare this one can take help of SLIPTA checklist & ISO 15189 document [19] which is the Guide for Preparing Quality Manual or a private consultant if required. Ironically, the Quality Manual of the laboratory is the most vital document that has to be sent first to the MLSCN along with the laboratory "scope" when applying for accreditation. A few tricky points are being discussed here; it should be noted that these points are not discussed in the order given in MLSCN application form.

- General features: One may refer to Version 2 of 2015 of SLIPTA checklist & ISO 15189 document [19]
- Introduction
    - Scope and purpose: Only those areas which are being aimed for accreditation should be mentioned in the scope along with its turnaround time. For example the laboratory may have culture for Mycobacterium *tuberculosis* their scope but not its drug susceptibility testing, even though it may be performing the latter.
    - Nomination of technical manager (TM), Quality Manager (QM) and their job description:
    - Job description of TM: Smooth functioning of laboratory on day to day basis, daily analytical work and trouble shooting, reporting of results, inventory management, recruiting staff, training and commencement of new test.
    - Job description of QM: To develop QMS, organize participation in proficiency testing program and ILC, daily QC, vendor selection and analysis, training of staff, organize internal audits and planning of MRMs.
- Description of the organization (one may refer to Act 11 of 2003 of MLSCN [17] ), legal identity (registration with registrar of companies), resources and main duties.
- Quality policy: an example, "The laboratory is committed to provide services in the field of Medical Laboratory Science and is competent to produce accurate and precise results in a manner necessary to ensure appropriate and timely patient care. The laboratory is managed by highly qualified and trained personnel who understand quality policies as laid by ISO 15189".
- Quality assurance: this part has been covered under the section QC in Medical Laboratories.
- Document control: the laboratory has to make a list of all the documents that have to be prepared and controlled by the Laboratory Head. This list which reflects all the necessary documents to be prepared, can be categorized as: document control system, work sheets, general safety, biosafety, QSPs, operation of various laboratory equipments, staining techniques, media preparation and testing, biochemical preparation and testing, various cultures (technique vary with kind of sample and


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

requisition), antibiotic sensitivity testing, in-house calibration if any and maintenance of ATCC strains. It should give a method of reflecting revisions and reviews done till date.

- Accommodation and environment: a few points are worth describing here:
    - Manufacturer supplied data sheet (MSDS): this is available on the internet for all chemicals and describes in length various hazardous properties of the chemical (inflammability, corrosiveness, etc), ways and means to store, control spill and treat body exposure. A document listing all hazardous chemicals, used in the laboratory, should be prepared by the QM and it should cater to the above-mentioned aspects.
    - Records of temperature, humidity, housekeeping, disinfection activities, pest control, safety of electrical appliances, fire safety have to be maintained.
- Instruments, reagents and other relevant consumables: these are the single most important aspects which QM should understand and implement them totally. One also needs to refer to SLIPTA check list & ISO 15189 document. [19] Few practical aspects are being touched upon:
    - A list of laboratories accredited by MLSCN for calibration is available (MLSCN accreditation document). [17] One needs to get equipments calibrated from accredited laboratories to maintain measurement traceability. Few types of equipment can be validated in-house through calibrated equipment.
    - Once the equipment is purchased the following list of procedures have to be done: entry in an inventory register, marking with labels carrying date of purchase, make, date of calibration and due date, name and phone number of service engineer and preparation of maintenance charts (for example, temperature and cleaning records).
    - All chemicals are to be labelled for date of purchase, date of opening, date of expiry, storage conditions and special handling/safety instructions, if any.
- Maintenance of records and archiving.
- Review of contracts: the laboratory should have written policy on what all services they are providing so that requests can be addressed according to the laboratory ability. Any change in the service (addition or deletion of a test) has to be notified to the users.
- Selection of referral laboratory: while selecting a referral laboratory, one must make sure that the test outsourced falls within its scope. A Memorandum of Understanding (MOU) has to be signed between to the two laboratories.
- Purchasing services and supplies: the laboratory has to design criteria for selection of its vendors. This may include price, market reputation, maintenance of cold chain and ability to deliver products in a proper timely manner. A list of suppliers is to be made along with the evaluation scores using above criteria.
- Control of non-conformities, improvement and preventive action: to handle this important aspect, one has to nominate a person (maybe a deputy QM) who would note any non-conformity brought to notice by any personnel of the laboratory. For example


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

if the zone of inhibition of doxycycline is out of range, as per CLSI, for *Staphylococcus aureus* ATCC 25923, one should perform a root cause analysis for it (which could be a alteration with pH of the media, cation concentration, incubatory conditions, turbidity standard, or the disk antibiotic concentration) as mentioned in the CLSI M-100 document. [24] Once the problem has been identified next step is to take a corrective action which at the first go is stopping the release of results for doxycycline and then finally make a preventive action plan. All these activities should be documented.

- Personnel
    - Organizational chart: Delineates the designation and hierarchy in the organization.
    - Job description: Has to be described specifically in a QSP.
    - Credentialing: Certificates of professional education, experience certificates of previous employment and on-going training programs have to be maintained with the QM. Along with this vaccination and health records should also be kept.
    - Staff education and privileging: The QM should make a syllabus regarding what needs to be taught to the staff. A typical syllabus should include: collection, handling, transport and storage of samples; QSPs; general and biosafety; sterilization and disinfection; waste management; media preparation; sample processing; staining and direct examination; identification of isolate; antimicrobial sensitivity testing and QC. Each worker should be assessed on the skill he/she is intended to perform. After the worker is assessed on the whole syllabus, we can get to know his skill matrix or competency map. This is the right way of privileging (allowing the staff to work in specific areas as per skill) and appraisal of the staff. The laboratory should conduct tests at regular intervals and preserve these documents as proofs of training.
- Pre-examination procedures
    - Designing a test requisition form (TRF) and consent forms, examples of which are been provided in the SLIPTA document. [19]
    - Sample collection manual for which one may again refer to SLIPTA document. [22]
    - The laboratory would have to prepare QSPs for sample reception area which should include sample rejection criteria [25] sample numbering system, billing system (if done at laboratory), labelling of urgent requests (this can be highlighted on the TRF), written policy on verbal requests, delivery of critical information (a placard, to display what consists of critical information, should be present in the reception area), storage of samples and handling of complaints. To monitor quality, one should prepare records of incompletely filled forms, rejected samples, sample label errors and lost samples.
- Examination procedures


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

- Internal audit and management review: The readers are advised to refer to SLIPTA. [20]

**Internal quality control in examination procedures**

Once we have addressed the procedural and document requirements, this section addresses the QC during examination procedures.

- **Media preparation:** Both Basu *et al.* [2] and Arora [3] have reviewed this topic, especially Basu whose article had gone to great details, but both have overlooked an aspect. We have covered the entire features in a practical way and have also evolved our own method to check for the ability of media to support growth. The following QC tests should be conducted:
    - pH testing (use pH meter) of every batch. The laboratory can use hydrochloric acid and sodium hydroxide for adjusting the pH. The pH meter can be calibrated in-house with help of at least two buffer solutions covering the test range.
    - Sterility testing: [26] A simple thumb rule is to incubate the prepared media at 35°C for 24 h and 25°C for 2 days; one needs to test only one unit for media which are poured and then autoclaved, while those which are autoclaved and then poured the entire lot needs to be tested (more than 10% contamination warrants discard of the entire lot).
    - Performance testing: This is done whenever a new lot is procured. If one gets more than one unit of the same lot, then testing is done only for one unit. Ability to support growth: most laboratories quantify isolates on blood agar and use Mueller Hinton agar (MHA) for sensitivity testing. Hence, we would require testing the ability of these media to appropriately support growth. Indicator and selection properties, for which a media is being used, would have to be demonstrated at the time of procurement by a set of American Type Culture Collection (ATCC) strains.
- **Staining:** Stains should be checked by a known positive and negative control (ATCC strains) at the time of procurement and these records should be preserved. Procedure of staining can be checked on control slides whenever we perform a staining (at least from a culture smear). These slides can be made in-house and have a smear of a positive and negative control (ATCC strains) at two ends.
    - Reagents and other consumables: New lots are tested by known ATCC and in-house controls as highlighted in a previous review. [2] All these quality exercises should be documented and the results preserved in the records.
    - Antibiotic sensitivity testing (AST): Quality check on antibiotic disks should be done at the time of procurement and thereafter once weekly. CLSI guidelines on QC of disks with help of ATCC strains can be referred to for making this SOP as well as an SOP on QSP to follow if zones of inhibition are out of range. This is one of the most important aspects of quality check in AST as many-a-times antibiotic disks may not give zones in the required QC range. For QC of media see above. One must use 0.5 McFarland turbidity standard


ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

for inoculum preparation (for QC of McFarland, one can refer to CLSI M-100 document [24]).

- EQAS and Inter Laboratory Comparison (ILC): MLSCN make it compulsory for one to perform ILC by sending a portion of same sample to a MLSCN accredited laboratory (quarterly testing of all investigation not covered under EQAS is considered adequate). MLSCN recognizes EQAS program run by various institutes like MLSCN itself and NIIRC which is a Research Centre situated in Lagos, Nigeria.

**Facing accreditation: Some practical tips**

No matter how well the laboratory follows its QMS, there are always a few gaps left and it would be wise that the laboratory head, well versed with the MLSCN standards, conducts a self-audit (not to be confused with internal audit which should not be done by lab head themselves) as per the check-list (SLIPTA & ISO 15189) which the assessors also make use of. After this self-audit, one should conduct a MRM and discuss the non-conformances observed; alongside one can use this opportunity to have a dialogue with the management about the transportation and accommodation for the assessors. Minutes of all MRMs should be maintained as records.

It is often observed that there may be a change of manpower just around the assessment time and therefore the QM needs to be vigilant in addressing to the training needs and privileging of this new staff. Such ambiguous situations may be addressed as separate QSPs. And finally, it is just another examination and it would be wise to project what we actually do and sometimes even with our best efforts some lacunae remain, one should admit them and these can be corrected later.

## CONCLUSION

A common problem with most laboratories is that within a day of receiving the status of an accredited laboratory their quality practices fall back to primitive levels till a few months from next assessment when they again wake and make a dash for quality. Likely cause is the change in existing staff with most worrisome being change in the Quality Manager (QM). This problem can be prevented by creating a backup like a deputy QM. The QM holds the key to uphold quality by remaining very vigilant and creating a system for periodic self-audit and a continuous laboratory management education. Human resource department should also chip in with policies on retaining good staff by linking their appraisals to their privileging. Accreditation is a philosophy and by inculcating the principles of excellence within ourselves, we can uphold and sustain both quality and the accredited status of our laboratories.

## REFERENCES

Application form for Medical Testing Laboratories (MLSCN) Available from: http:// www.mlscn.gov.ng

Arora DR. (2004). Quality assurance in microbiology. *Indian J Med Microbiol* **22**:81-6.



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

Assessment Forms and Checklist (Based on ISO 15189: 2007) (NABL 217; Issue No: 02, Issue Date: 01.02.2008, Amendment No: 05, Amendment Date: 01.09.2008). Available from:http://www.nablindia.org/nabl/asp/users/documentMgmt.asp?cp=4anddocType=both

Bartlett RC, Sullivan MM, Tetreault JZ, Lobel S, Nivard J. (1994). Evolving approaches to management of quality in clinical microbiology. *Clin Microbiol Rev* **7**:55-88.

Basu S, Pal A, Desai PK. (2005). Quality control of culture media in a microbiology laboratory. *Indian J Med Microbiol* **23**:159-63.

Clinical and Laboratory Standards Institute. Performance Standards for Antimicrobial Susceptibility Testing; Twenty First Informational Supplement 2011; M100-S21. Wayne, USA.

Directory of Accredited Calibration Laboratories (NABL 500; Issue Date: 03.01.2011). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=4anddocType=both.

Duguid JP, Collee JG, Frase AG, Aikman KW. Organization of the clinical bacteriology laboratory; Quality assurance. In: Mackie and McCartney Practical Medical Microbiology. 14 th ed. Collee JG, Fraser AG, Marimon BP, Simmons A, editors. London: Churchill Livingstone; 1996. p. 1-16.

Fresh empanelment of Private Diagnostic Laboratories / imaging center and revision of package rates applicable under CGHS, Delhi. Available from: http://www.du.ac.in/fileadmin/DU/DUCorner/pdf/CGHS_Diagno_Imagingcentres_64.2011.pdf.

General Information Brochure (NABL 100; Issue Date: 17.08.2010). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=1anddocType=both.

Guide for Internal Audit and Management Review for Laboratories (NABL 161; Issue No: 03, Issue Date: 25.03.2008, Amendment No: 00, Amendment Date: 00). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=3anddocType=both.

Guide for Preparing a Quality Manual (SLIPTA) Available from: *www.who.int/.../afro-**slipta**-checklist-guidance*

Guidelines for Good Clinical Laboratory Practices (GCLP). Available from: http://www.icmr.nic.in/guidelines/GCLP.pdf.

Introduction to NABL Training Courses. Available from: http://www.nabl-india.org/nabl/html/train-course-intro.asp

ISO 9000 (QMS) - FAQ's. Available from: http://www.bis.org.in/cert/faqmscd.htm9000-q1

ISO Store, Purchase ISO 15189: 2007 document online. Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42641.

ISO/IEC Guide 2: 2004 (Standardization and Relative Activities - General Vocabulary:. Availablefrom:http://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+Guide+2%3a2004andsource=googleandadgroup=iso10andkeyword=ISO%2FIEC%20guide%202andgclid=CO2HuKLImKwCFUkb6wodMUBGPQ.

Issue Date: 02.11.2005, Amendment No: 04, Amendment Date: 01.03.2008). Available

Kanagasabapathy AS, Rao P. (2005). Laboratory accreditation- procedural guidelines. Indian J Clin Biochem 20:186-8.

Kimothi SK. (2009). The handbook of laboratory quality management and accreditation ISO/ IEC 17025 and ISO 15189: 1 st ed. Jaipur, India: Raj Publishing Housep. 19-20.

NABH / NABL Certification of Hospitals / Diagnostic Centers empanelled under CGHS.



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)

NABH accreditation lauded. Available from: http://www.qcin.org/nbqp/qualityindia/Vol-2-No5/health_page_4_9.php.

Rao RS. Quality control. *Indian J Med Microbiol* 1992;10:141-2.

Specific Criteria of Accreditation of Medical Laboratories (NABL 112; Issue No: 03, Issue Date: 01.02.2008, Amendment No: 01, Amendment Date: 01.09.2008). Available from: http://www.nabl-india.org/nabl/asp/users/documentMgmt.asp?cp=2anddocType=both.

Terms and Conditions for Maintaining NABL Accreditation (NABL 131; Issue No: 05,

Winn Jr. WC, Allen SD, Janda WM, Koneman EW, Procop G, Schreckenberger PC, et al. Color Atlas and Textbook of Diagnostic Microbiology: 6 th ed. Baltimore and Philadelphia, USA: Lippincott William and Wilkins; 2006. p. 14-5.



ISSN 2054-0930 (Print), ISSN 2054-0949 (Online)