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Change necessary in lab accreditation

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The infrastructure of industrial laboratory in India has improved with the advent of the concept of quality in testing. A look at the early ’90s shows that the most of the industrial testing laboratories were not aware about the role and importance of the quality in testing.

Globalisation and impact of GATT agreement helped industrial laboratories to improve the infrastructure. Many government organisations and multinational companies followed these policies to hire the services of accredited laboratory. This compelled industrial testing laboratories in India to improve their infrastructure.

In the clinical laboratory sector, inspite of the technological upgradation, the overall quality awareness and infrastructural development has not improved, unlike the industrial sector, which got a boost from the popularity of accreditation concept.

Accreditation of medical colleges

Though the concept of accreditation has been initiated in the clinical sector for last seven years, it is yet to become popular for various reasons. Firstly, Indian clinical laboratories are not prepared for it.

Accreditation means technical competence to carry out the specific task, but accreditation system can work perfectly, if major resources are also available with accredited sources. Medical colleges who are engaged in imparting this education and training are not well equipped with the changing scenario of global path lab practices.

Medical colleges and training institution must come under accreditation. Educational course should cover the requirement of global accreditation criteria and other variables of a clinical laboratory in the Indian scenario.

The Indian Council of Medical Research (ICMR) can take the initiative for standardisation of the course for pathology professionals and technicians. Because of rapid changes in clinical lab technology and its practices, government should involve major accredited health care diagnostic centers and laboratories in education and training. Online training programmes can also be started where various institutes can come under a network-based system.

Setting up of model nodal lab

At a time, when the Government of India is planning to establish healthcare institutions like AIIMS in the various parts of the country, establishment of at least five nodal laboratories is essential. These nodal labs can play key role in research, development, formulation of various policies and criteria for standardisation of pathological laboratory. They can also be the key institutes in education, training, inter-laboratory comparison of testing including proficiency testing.

Need for liberalisation of insurance coverage and stringent policy accreditation movement will also not be encouraging until insurance sector plays key role during the registration of laboratory.

In countries like the US and Australia, accreditation of laboratory is compulsory for test expenditure disbursement. In India, however, the medical insurance industry is still not providing the coverage of the test expenditure in domicile case (except for domicile hospitalisation).

Because of this, relationship between laboratory and insurance sector has not been strengthened. Accreditation should come in force and only insurance sector can make it successful.

Accreditation system in the US

In the US, accreditation bodies like COLA and CAP do not provide accreditation to clinical laboratories on the basis of quality system standard ISO/IEC 17025. The focus in this accreditation process is on technical proficiency and safety. Their accreditation is followed by a self-assessment of the laboratory, which is assessed through a technical checklist supplied by accreditation body.

The accreditation body renders technical advice to bridge the gap and they conduct onsite assessment after the self-assessment by laboratory. Besides this, they deliver online training for lab director-this makes a person fully conversant with accreditation process and its implementation. This training is compulsory for the accreditation. The accreditation body prescribes quality system after the accreditation, which is voluntary.

In India, National Accreditation Board for Testing and Calibration Laboratories (NABL), New Delhi is providing accreditation to clinical laboratories. And a few laboratories have taken accreditation from NABL and CAP (College of American Pathologists). NABL is providing accreditation on the basis of quality system standard ISO/IEC 17025 which will be superseded by new quality system standard ISO 1589.

Need for changes in NABL accreditation process

1) Conceptually quality system cannot be ignored but practically it becomes a burden on paper. Correction of grammar, spelling, clause, sentence of quality manual and others by a non-clinical assessor make a clinical lab embarrassed in their regular working schedule.

It is not practical for laboratory to maintain the descriptive ISO/IEC 17025-quality system regular basis. It is observed from the experience that it is mostly a paper exercise and laboratory prepares it before the audit.

The system should be brief and checklist type to save the time and no scope of generating unnecessary papers for standard compliance or satisfaction of the auditor.

2) Quality system based accreditation system should be removed. Specific requirement for technical competence should be checklist type. NABL-112 is a guideline for assessor. It is not a checklist for the assessor. The fact to be considered is that COLA and CAP both are not member of ILAC or APLAC but their accreditation in USA is very popular. So NABL can think it separately.

3) The accreditation process should begin with developing and guiding technical and safety proficiency of the laboratory. Accreditation level or gradation system can be introduced to attract all types of clinical laboratory. It should be in such a way that a laboratory rendering service in rural area can join the accreditation process.

Accreditation of the accreditation body

The accreditation of accreditation body is also essential. APLAC accreditation to NABL is basically established on industrial importance. It has no clinical standing. If any suitable national medical body is not found or doesn’t take responsibility,

then other international organisations can be approached.

Need for development of infrastructure & resources

1)The assessment team coming for assessment is trained on quality system requirement. NABL doesn't conduct clinical workshop or training on technical requirement for their assessor. Assessors are not given training on technical requirement on clinical competency (clause 5.1-5.10 of ISO/IEC 17025 is a general technical system).

This creates confusion in the post audit phase when report is delivered to the NABL technical committee. Auditor's training should cover specialised test discipline following the technical and safety requirement of the clinical laboratory. A technical team can be sent to other international accreditation body to learn their technical audit.

2) NABL doesn't have any clinical cell where applicant laboratory can get their technical clarification. Technical cell should be developed on specialised discipline that will assist the laboratory for development of technical proficiency and close the technical gap before the on-site assessment. Programm co-ordinator should be very efficient and competent about accreditation policy and procedure.

3) Appointment of local assessor: Assessor is to be trained locally for assessment of the laboratory. Government incentive support SISI of Government of India is providing a subsidy of Rs.75, 000/- against ISO 9000 certification for small scale industry but no such incentive is provided for NABL accreditation. If this is started for small and medium scale laboratories, this would thrust the accreditation movement.

Support needed from ICMR

If NABL policy doesn't permit to withdraw quality system based accreditation, ICMR can take key role in providing accreditation.

There can be more than one accreditation body and prospective laboratory can choose what kind of accreditation is suitable for them. ICMR being a leading and national body have full resource and infrastructure on development of accreditation policy and procedures.

Task Ahead

Accreditation process and concept of commissioning needs to be reviewed again. A committee should be formed under the leadership of ICMR,

where consultants of repute of present clinical laboratory accreditation system should be invited. Committee will prepare draft accreditation concept to commissioning.

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