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Towards accreditation of clinical biochemistry in the public sector on the island of Mauritius

Received: 23 October 2005
Accepted: 19 November 2005
Published online: 14 January 2006
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Abstract Medical laboratories of the public sector as well as of the private sector on the island of Mauritius are preparing for accreditation. The clinical laboratory of the Central Health laboratory of the Ministry of Health and Quality of Life has undergone a pre-assessment by experts of the International Atomic Energy Agency (IAEA) through the aegis of a project targeted to members of the Africa Region. Several shortcomings were identified and respective corrective actions were recommended for implementation within a given time

frame. In addition to ensuring the competence of the laboratory, accreditation has various positive aspects such as an increased awareness of the staff to quality and better training opportunities. The pre-assessment exercise has provided a gap analysis, which is an important aspect in the preparation towards accreditation.

Keywords Clinical biochemistry . Accreditation. ISO/IEC 17025 . Technical competence. Quality Policy. Quality Management

Introduction

The medical laboratory service of the Republic of Mauritius has evolved significantly during its 60 years of existence. The health authorities are eager to provide a laboratory service that is sound and reliable, and, as such, they endeavor to ensure high-quality health care. Therefore, since 1987 the clinical biochemistry laboratory participates in the external quality assessment scheme organized by the World Health Organization (WHO) Collaborative Centre of Wolfson Laboratories, Birmingham UK. The scheme includes over 200 medical laboratories in Europe and elsewhere that receive quality-control samples from the centre on a monthly basis for the analysis of selected constituents. A feedback report, retrievable from the Website, compares the performance of the particular laboratory to the rest of the group. Statistical data are provided, and indicators of poor and good performance for the particular month as well as for the running months are given. In this respect, the performance of the Mauritian laboratory is comparable to the group of the well-performing laboratories of Europe.

The process of preparing for accreditation was launched in 2000 as the spectrum of laboratory tests offered increased significantly and included assays based on radioactive tracers. In the latter type, thyroid-function tests and assays for tumor markers were already offered on a routine basis and they were all exclusively based on radioimmunoassay (RIA) procedures.

At a workshop comprising laboratory personnel, researchers, and officials of the Ministry of Health, the first draft of the Quality Manual was examined and modifications proposed thereto. Courses on accreditation and internal auditing were offered by the national body for accreditation, the Mauritius Accreditation Service (MAURITAS). The Steering Committee of the latter body has set up an Action Plan on accreditation. Seminars were also organized for interested parties under the aegis of the IAEA. Technical documents on accreditation are provided by the Mauritius Standards Bureau.

Meanwhile, under a specific project of the IAEA, an expert team has come to carry out a pre-assessment exercise on the department in 2004.

A brief on the present quality system and on the outcome of the assessment exercise is described next.

Table 1 Observations

<u>Management requirements</u>	<u>Score</u>	<u>Max score</u>	<u>Technical requirements</u>	<u>Score</u>	<u>Max score</u>
Organization and management	26	35	General	5	10
Quality system	11	20	Personnel	22	25
Document control	5	40	Accommodation and environmental conditions	15	25
Review of requests and contracts	15	15	Test methods and validation	29	65
Subcontracting 0 Purchasing	13	0	Equipment	26	35
Service to the client	5	15	Measurement traceability	13	20
Complaints	3	5	Sampling	0	0
Control of non-conforming work	2	5	Test items	16	20
Corrective action (CA)	4	10	Quality control	23	40
Preventive action	2	20	Reporting	21	25
Control of records	35	10			
Internal audits	23	40			
Management review	3	25			
Total	147	10		170	265
Ratio (%)	58.8	250		64.2	
Global Ratio (%)	61.6				

Results

Quality policy of the laboratory

The aim of the Biochemistry Department is to provide clinically useful information through laboratory analysis of samples from patients, taking into account the resources allocated by the Ministry of Health. The reported data should be reliable and their uncertainties should be in accordance with the clinical needs and the appropriate technical standards of the profession.

Observations

In their report, the IAEA assessors summarized the observations in Table 1.

The Quality Policy is implemented by the following means:

- Proper sample collection, stabilization, transport, sample preparation, and identification;
- Reliable analytical work, so that systematic and random errors do not exceed specified limits;
- Turnaround time within specified limits, inter-alia for emergency measurements within 1 hour, and for rare routine measurements within 1 week after receipt of samples;
- Data reported in a clear form and supplemented with relevant information, including reference intervals, to allow reliable clinical interpretation;
- Appropriate communication with clinicians, so that results will be interpreted and logically integrated into further (clinical and laboratory) evaluation of the patient,

and the clinicians become aware of the unexpected problems and errors;

- Materials and reagents used within the laboratory for all investigations are safe to the environment and to the personnel working within the department;
- Wherever hazardous materials are used such as toxic and radioactive items, appropriate measures must be taken to protect the personnel and the environment.

The quality system of the Biochemistry Department is described in the Quality Manual. The goals of the department are outlined in the Quality Policy section of the manual.

There is a specific structure of documents relating to all procedures as is detailed in the ISO/IEC 17025 [1].

The above table shows the scoring awarded by the assessors for the key requirements of the ISO/IEC standard 17025 (1999 version). There are two main sections: Section 4 (the management requirements) and Section 5 (the technical requirements). Aspects of laboratory organization, document and record control, internal audit and management review are found in Section 4. The Technical Section deals mainly with all the main factors that have a significant impact on the test result. In other words, the technical competence is assessed principally from the latter section. In their assessment, the experts noted a significant weakness in the document control, in procedures in place to prevent occurrence of non-conformances, as well as on the procedure of management reviewing. The aspect of quality control did not satisfy the assessors. The global ratio was 62%, which, in the present case, is encouraging in that appropriate corrective measures were taken within the given time frame and accreditation of the schedule presented could be ensured.

Discussion

The accreditation of medical laboratories is based on requirements as per ISO/IEC 17025, though the ISO 15189 [2] is more specific for these laboratories. The services have to cater to the needs of patients as well as for the clinical personnel responsible for the care of the patients. Among the services required, patient preparation, patient identification requisition and collection of samples, and their transport and storage are considered as pre-analytical considerations. Post analytical factors will include the validation of test results, their interpretation, reporting, and advice. The ISO/IEC 17025 clearly lays down the specific requirements to ensure competence in the laboratory. Given the wide scope of activities in this particular clinical chemistry laboratory, it is essential to appoint a quality manager who will be responsible for proper implementation of the quality system.

The main objective of seeking accreditation is to warrant technical competence of the laboratory. When a quality system as per the ISO 9000 series is in place and the laboratory conforms to that system, the laboratory is said to be certified. This is different from accreditation where the laboratory should comply with requirements for technical competence. It is now becoming important (particularly in the medical field) to have ways and means to ensure that the right test result is provided to the right customer at the

right time. One is now more concerned with the quality of test results to ensure that appropriate health care is provided. One example is the new requirement for diagnosing diabetes mellitus, as recommended by the WHO, which recommends that relevant assays be performed by an accredited laboratory [3]. Most of the medical laboratories are therefore getting prepared to satisfy the requirements of the customer.

The present exercise has identified positive aspects. The laboratory personnel are competent in their respective tasks; there are sound procedures for equipment use and maintenance, handling of test items and so on. The main shortcomings were noted in the area of quality control and in method validation procedures.

The preparation for accreditation has provided an opportunity for the personnel to become more aware of various aspects of total quality management. There has been a definite commitment from management (in this case the health authorities) as well as from the laboratory personnel to ensure good quality in the service. In addition, through the aegis of the MAURITAS, training has been possible in key areas such as for internal auditing, the various clauses of the ISO/IEC 17025 standard, and on documentation such as guidelines for the preparation of quality manuals. More importantly, the particular interest of the IAEA to help and ensure accreditation of laboratories in the Africa Region performing nuclear technologies cannot be overlooked.

References

1. ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
2. ISO 15189 Medical Laboratories- Particular Requirements for Quality and Competence
3. Reinauer H, Home PD, Kanagasabapathy AS Heuck CC (2002) WHO Laboratory Diagnosis and Monitoring of Diabetes