

MS ISO 15189: ASSESSMENT FOR COMPETENCE & QUALITY

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What is Accreditation?

- Procedure by which an authoritative body (STANDARDS MALAYSIA) gives formal recognition that a body (laboratory) or person (signatory) is competent to carry out specific tasks (scope)
- Procedure assesses conformity to required levels of competence
 - ◆ National criteria / standards
 - ◆ International criteria / standards
- Impartial evaluation
- Ensures quality



Medical Laboratory Accreditation - what does it mean?

- **The laboratory is competent & has quality**

- ◆ Optimal medical testing
- ◆ Has suitable organizational set-up, management & facilities
- ◆ Work performed by qualified & trained staff
- ◆ Work performed according to approved procedures
- ◆ Work place is safe for staff

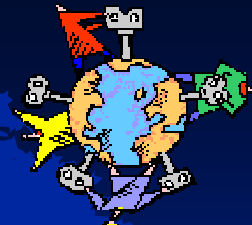


Accreditation - benefits to the laboratory

- **Improvement to lab management & performance**

- **Competitive advantage**

- ◆ Mark of quality & competence
- ◆ Credibility & recognition
- ◆ Reimbursement of fees in healthcare financing/insurance schemes
- ◆ Increase prospects for international market (AFTA & WTO)



Accreditation - benefits to the Public

- **Getting your money's worth**
- **Better medical care**
 - ◆ International standards
 - ◆ Don't mess around with substandard laboratories
 - Inaccurate results = wrong diagnosis, inappropriate treatment, prolonged illness (even death).



WHO ACCREDITATES?

- NATA (Australia)
- IANZ (New Zealand)
- RNE (France)
- CAP (USA)
- UKAS (UK)
- HOKLAS (Hong Kong)
- STANDARDS MALAYSIA (Malaysia)



Department of Standards Malaysia, MOSTI



- **Established through Standards of Malaysia Act, 1996**
- **Functions**
 - ◆ Development & promotion of Malaysian Standards
 - ◆ **Accreditation**
 - Skim Akreditasi Makmal Malaysia (SAMM)

Standards used in SAMM

- MS ISO/IEC 17025 “General Requirements for the Competence of Calibration and Testing Laboratories”
- **MS ISO 15189 “Medical Laboratories – Particular Requirements for Quality and Competence”**

Accreditation

- **Criteria – MS ISO/IEC17025;
MS ISO 15189**

- ◆ Assures the client that the procedures are technically valid
- ◆ Recognises the technical competence of laboratory staff
- ◆ Endorses the quality management system
- ◆ Assures the client that the results are technically valid

Why MS ISO 15189



- **In what ways do medical testing laboratories differ from calibration & testing laboratories?**



ISO 15189

- **An international standard for the development of quality systems and accreditation for medical / clinical laboratories**
 - ◆ Takes into account contribution of medical laboratory service to patient care
 - ◆ Not only testing, also advisory, interpretative and educational services

A Medical Laboratory cannot function outside the context of patient care

- **An integral service in Medical & Healthcare**
 - ◆ Not purely analytical
 - ◆ Has clinical function
- **Investigation of patients for:**
 - ◆ Presence of disease
 - ◆ Risk of disease
 - ◆ Extent of disease





The difference between a medical laboratory and an analytical laboratory

- **Performs relevant and useful tests**
 - ◆ As requested by primary doctor
 - ◆ As advised by pathologist (laboratory doctor)
 - What types of samples?
 - When to collect?
 - How to transport?
 - ◆ Interpretation requires relevant clinical information
 - ◆ Rapid versus standard testing (e.g. intra-operative vs post-operative)



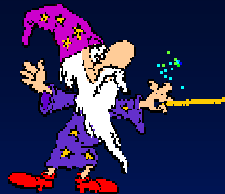
The difference between a medical laboratory and an analytical laboratory

- **Choice of tests often depends on pathologist**
 - ◆ Most appropriate technology for the problem
 - ◆ What additional tests to perform (e.g. to elucidate a subtype of cancer)
 - Special stains, electron microscopy, etc
 - Prognostic and predictive parameters
 - ◆ What and how many sub-samples to take (e.g. to assess the extend of spread of a cancer)
 - Sampling of surgical margins and lymph nodes



The difference between a medical laboratory and an analytical laboratory

- **Transmission of findings in a meaningful way for patient care**
 - ◆ Are clarifications needed from primary doctor?
 - ◆ Is another sample needed?
 - ◆ Transmission of urgent findings
 - ◆ The philosophy of team-work
 - Clinico-pathological discussion to decide on patient management
 - ◆ Code of professional conduct
 - ◆ Medico-legal responsibilities



What is expected of a Medical Testing Laboratory

- **Performs relevant and useful tests**
 - ◆ Relevance to medical problem
 - ◆ Choice of tests
- **Results can be trusted**
 - ◆ Accurate, consistent & reliable
 - ◆ Performed & interpreted by qualified persons
- **Timely & Affordable**
- **Ethical**
 - ◆ Pathologist subject to Code of Professional Conduct & Medical Act
- **Does not pose a danger to staff and public**

MS ISO 15189



Standards for Medical Testing Laboratories have some specific requirements:

- ◆ Use terminology needed that can be understood by the medical community.
- ◆ Include pre and post-analytical phases.
- ◆ Include safety and ethics.

SAMM documents produced for MS ISO 15189



- **SC2 -Specific Criteria for Accreditation in the field of Medical Testing**
- **Specific Technical Requirements**
 - Anatomical Pathology (Cytopathology) – STR 2.1
 - Anatomical Pathology (Histopathology) – STR 2.2
 - Chemical Pathology – STR 2.3
 - Haematology – STR 2.4
 - Medical Microbiology – STR 2.5
 - Medical Microbiology (Virology) – STR 2.6
 - Assisted Reproductive Technology – STR 2.7
 - Cytogenetics – STR 2.8

Development of 6 Professional Practice Guidelines by CPath (2005)

- Retention of Pathology Records and Materials
- Minimum qualification, training and experience of professional personnel working in a pathology laboratory
- Laboratory construction and design
- Maintenance and operation of equipment in a pathology laboratory
- Safe laboratory practice
- Sample management



Standards still need to be prescriptive

- **Countries where accreditation culture is established**
 - ◆ Standards merely refer to National guidelines/ norms established by professional bodies
 - ◆ Consensus development
- **Local situation**
 - ◆ Many National guidelines/ norms not yet developed or established
 - ◆ CPath has developed 6 guidelines
 - ◆ CPath in process of developing workload norms

MS ISO 15189 accreditation: Current status (May 2009)

- **Assessors**
 - ◆ 107 registered assessors (total)
 - ◆ 6 lead assessors
 - ◆ 35 technical assessors
 - ◆ 66 trainee technical assessors
- **Laboratories**
 - ◆ 10 accredited
 - ◆ 17 in the process

**MS ISO 15189
ASSESSMENT:
COMPETENCE &
QUALITY ISSUES**

Assessment of competence

- **Qualifications strictly in compliance with SC and STRs?**
 - ◆ Minimum requirements must not be less than Pathology Act 2007
- **More important**
 - ◆ Training & retraining should match testing needs
 - ◆ Review of staff performance with competence in focus
 - ◆ Continuing Professional Development
 - ◆ External Quality Assurance

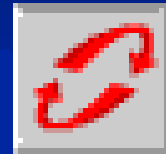
What is Quality?



- **Good quality does not necessarily mean the highest quality.**
- **Quality is “fitness for purpose”**
 - ◆ Quality is a product that meets the customer's requirements or expectations
 - ◆ A quality product does the job at an economic price
 - ◆ Suppliers of a product do not decide upon its quality, their customers decide
- **Quality is “getting it right the first time”**

Poor Quality is Expensive

- **Lost productivity**
 - ◆ Have to undo a mistake or repeat the test
 - ◆ Results in delays
 - ◆ Processing complaints
 - ◆ Recall of reports
- **Demoralises staff**
- **Undermines client confidence**
 - ◆ Loss of commercial edge
- **Failure costs may far exceed prevention and appraisal costs**



How to achieve Quality?

- **Have a quality management system**
- **Have a monitoring system**
- **Prevent things from going wrong**
- **Improve as you go along**



Assessment for quality: Is there a quality culture?

- Commitment to quality by the highest level of management
- Clearly defined organisational structure including clear assignment of responsibilities and authorities
- Participation and cooperation by all staff working as a team
- Focus on people processes as well as system content
- Focus on prevention rather than correction
- Does Quality concern everyone?

Is there an appraisal system?

- Checking to confirm that testing was right
 - ◆ Monitoring
 - ◆ Internal and external QC/QA
 - ◆ Internal and external audits
 - ◆ Feedback & complaints
- Controlling and monitoring every step in a production process leads to a quality product



Is there preventive action?

- **Prevent things from going wrong**

- ◆ Planning the system
- ◆ Documenting the plan
- ◆ Training staff
- ◆ Equipment management
- ◆ Reviewing the system



Is there Quality Improvement?

- Quality assurance Vs Quality improvement
- Focusing on quality improvement leads to better outcomes than focus on quality assurance activities alone
- **Quality improvement is like a race without a finish line**



Quality & competence issues:

- **EQA and Continuing Professional Development**
 - ◆ Subscription just to fulfill requirements of standards?
 - ◆ Need to develop culture of professional development and continuous improvement

Quality & competence issues:

- **Who is in charge of the laboratory?**
 - ◆ Administrative vs professional leadership
- **Clinical role of the laboratory**
 - ◆ Pathologists not assuming sufficient clinical responsibilities
 - ◆ Deficient forum for clinico-pathological / patient care discussion

Quality & competence issues:

- **Referral to outside labs**
 - ◆ Currently few labs are accredited
 - ◆ How are competence & quality assessed in non-accredited labs?
- **Contract review**
 - ◆ Evaluation for appropriate requests
 - ◆ Insufficient professional advice & interaction with customers

Quality & competence issues:

- **Why can't whole chain of labs be accredited through assessing one model lab**
 - ◆ Same methodology, same organisational system, why not just sample branch labs
 - ◆ Fail to realise that it is not only the analytical aspect that is important
 - ◆ Deliverance of relevant and effective service for patient care

Quality & competence issues:

- **Workload**

- ◆ Most lab personnel are overworked
- ◆ Pathologist: population ratio = 1:90,000
- ◆ Need to develop national norms
- ◆ Need to appreciate the effect of excessive workload on quality & CPD

Future

- **Increasing acceptance of accreditation**
 - ◆ Competitive advantage
 - ◆ Health care financing
 - ◆ Globalization
- **Establishment of practice guidelines and norms by the Profession to support accreditation**
 - ◆ More consensus development
 - ◆ Better acceptance by all
- **The Pathology Act**
 - ◆ Legislative requirements imposed on laboratories
- **Revision of MS ISO 15189**
 - ◆ Less need to be prescriptive on qualifications of staff and norms
 - ◆ More focused on competence & quality issues

Focus on Quality Improvement

In the long run, the benefits include

- Improved staff confidence and self esteem
- Improved client satisfaction
- Easier and more consistent training
- Fewer mistakes
- More profits
- Just plain better business

