Accreditation of Clinical Laboratories

Symposium on Traceability in Laboratory Medicine

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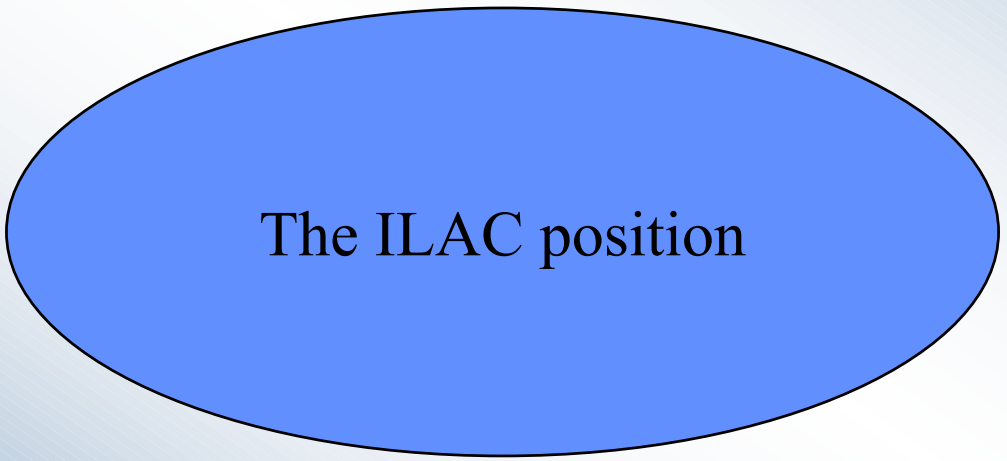
Presentation Summary

- **Linking metrology with accreditation- the ILAC position**
- **An overview of the accreditation process, areas covered and the value of accreditation**
- **Current and future issues relating to clinical laboratory accreditation**
- **Two examples of clinical laboratory accreditation schemes - South Africa and Australia**
- **Traceability in clinical laboratories?**

Linking metrology with accreditation



What is the Value of Accreditation?

Accreditation provides, among many other things:

- **confidence that a laboratory is operating to current best practice**
- **a benchmarking facility for the laboratory**
- **an incentive/opportunity to continually improve practices**
- **continuing internal and external review processes**
- **comparability of results between laboratories**

The accreditation process...

- uses “peer review”
- ensures compliance with:
  - defined standards
  - good measurement practice
- evaluates the adequacy and appropriateness of the service relating to the patient
- reviews ongoing professional education
- assures an impartial and consistent approach to assessment

Assessments include review of...

- **Methods**
  - selection, validation, verification, comparative studies
- **Equipment**
  - calibration (traceability), maintenance
- **Internal quality control**
  - definition of action limits, frequency, review, action taken
- **Proficiency testing**
  - use as laboratory management tool

Assessments include review of...

- **Records and reports**
  - **review of clinical interpretations**
- **Staff**
  - **qualifications, experience, training, competence, continuing education**
- **Management systems**
- **Accommodation**
- **Safety in laboratory practice**

Assessments also include review of...

- Adequacy and appropriateness of service offered
- Effect of laboratory results on patient management and other clinical outcomes
- Specimen collection:
  - conditions and safety
  - identification, handling and transport of specimens
- Laboratory reception:
  - specimen condition and identification
  - sub-sampling and labelling
  - provision of clinical notes

The international scene - now

- **Clinical laboratory accreditation programs exist in:**

  Australia, Canada, many parts of Europe, Hong Kong, Japan, New Zealand, South Africa, USA, UK

- **Strong "national" flavour**
- **Similar but varying:**
  - **accreditation processes, team composition, assessment coverage, "standards" used**
- **Some intercomparisons have been carried out through IMEP**
- **Strong national PT program support**
- **Not all clinical accreditation bodies are ILAC members**

The international scene - in the future

- **Greater harmony in approach and practice is expected, due to :**
  - **publication of ISO 15189 (“medical” ISO/IEC 17025)**
  - **supporting standards for traceability eg EN ISO 17511, ISO 15193**
  - **EC directive on IVD medical devices and other such drivers**
  - **recognition of value of accreditation and ILAC MRA**
  - **regulatory and trade pressures**
  - **increasing age and expectations of travelling public**

Pathology Laboratory Accreditation in the Southern African Context

SADC
HEALTH SECTOR PROTOCOL

Policy Proposal for laboratory service in support of Regional strategies:

Laboratory accreditation

- **Education and training for laboratory personnel**
- **Monitor optimal use, evaluation, standardization and maintenance of instruments, diagnostic kits and reagents**

SADC
MAIN POLICY OBJECTIVES

Define and formulate a regional proposal for laboratory accreditation including blood transfusion service

Develop policy on supply and quality control of blood and blood products

Harmonize curricula for education and training and accreditation/registration of personnel and institutions

Regulations in SA concerning Pathology Laboratory Accreditation

MEDICAL AND DENTAL SUPPLEMENTARY HEALTH SERVICE PROFESSIONS AMENDMENT ACT NO 89 1997

- **61.1 THE MINISTER MAY IN CONSULTATION WITH THE COUNCIL MAKE REGULATIONS RELATING TO:**
- **(i) The accreditation by the Council of Pathology Laboratories providing services which fall within the ambit of this Act, laying down of conditions with which such laboratories must comply to obtain accreditation and the determination of fees to be paid by such laboratories in the process**

Regulations in SA concerning Pathology Laboratory Accreditation continued:

NATIONAL HEALTH BILL 1997:

The Minister may make regulations concerning:

(b) the accreditation and licensing of laboratories

No regulations, due to formation of the National Health Laboratory Service, therefore process voluntary at present

ACCREDITED LABORATORIES IN SOUTH AFRICA

- First assessments January 2000. June 2002, 138 accredited laboratories
- 5 Main Laboratories from Private Pathology Groups, incorporating all major disciplines, including Clinical Trial Laboratories. 115 Peripheral Laboratories associated with these Main Laboratories
- 8 Main laboratories from the National Health Laboratory Service
- Reference Laboratory - National Institute for Communicable Diseases
- 1 Main and 3 Peripheral Laboratories in Namibia

SA INITIATIVES ON TRACEABILITY IN LABORATORY MEDICINE

- Via EQA Provider, SA Laboratories participating in IRMM International Measurement Evaluation Programme (IMEP – 7): Inorganic components in human serum
- Via EQA Provider, SA Laboratories performance compared against values assigned by Germany based reference laboratory
- NHLS Laboratories participating in RCPA Programme Flinders Medical Centre, Adelaide Australia
- NHLS to establish further National Reference Laboratories

The Australian medical accreditation scheme

- **Joint professional and accreditation body initiative- NATA/RCPA**
- **Established as voluntary program in 1982 to:**
  - **raise standards**
  - **provide additional means of education**
  - **deal with community concerns about poor practice**
- **Became mandatory for purposes of federal funding in 1986**
- **RCPA provide extensive and regular PT support in all disciplines**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NATA/RCPA Coverage

- All disciplines
- Public and private pathology laboratories
- “Office pathology”
- ICU facilities
- Blood transfusion services
- IVF facilities
- Parentage testing
- Other specialist areas eg endocrinology

Current issues for NATA/RCPA

- **Implementation of ISO/IEC 17025**
  - **particularly measurement uncertainty and traceability**
- **Crossover to ISO 15189 when published**
- **National review of pathology legislation**
- **Robust notification systems for poor performance in PT**
- **Expansion of point-of-care testing outside of "laboratories"**

Traceability in clinical laboratories?

- **ISO 15189 recognises the need for traceability:**
  - **specific standards on traceability in the medical field have also been produced (ISO 17511, ISO 18153, ISO 15193)**
  - **the same calibration requirements apply as for other fields**
  - **the same difficulties apply as for chemical/biological measurements**
- **Progress will depend on:**
  - **a clear definition of the measurand**
  - **availability of appropriate reference materials**
  - **education of all parties**