The Role of ISO 15189 in Australia

First American Congress for the Accreditation of Medical Laboratories, Blood Banks and Haemopoietic Progenitor cells

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What will be covered:

- **Context - A brief history of Medical Testing Accreditation in Australia**
- **The regulatory framework**
- **The use of Accreditation Standards**

A brief history of Medical Testing Accreditation

- NATA was established in 1947 by the Commonwealth Government of Australia
- Authority in the assurance of technical standards
- Responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials & proficiency testing scheme providers throughout Australia (and overseas)
- NATA is recognised by Memorandum of Understanding (MoU) with the Commonwealth Government as The National Accreditation body
- NATAs primary role is to serve the national and public interest by facilitating the provision of reliable calibration, measurement, testing and inspection infrastructure to government, industry and the wider public

A brief history of Medical Testing Accreditation

- Medical Testing Accreditation program was established in 1982
- Upon discussion with Australian Government a voluntary scheme was established in conjunction and upon request from the Royal College of Pathologists of Australasia (NATA/RCPA) – Joint NATA/RCPA Accreditation program
  - the aim was to *encourage* medical laboratories to meet acceptable standards
  - Accreditation voluntary at that stage
- 1985 first laboratory accredited in Medical Testing

A brief history of Medical Testing Accreditation

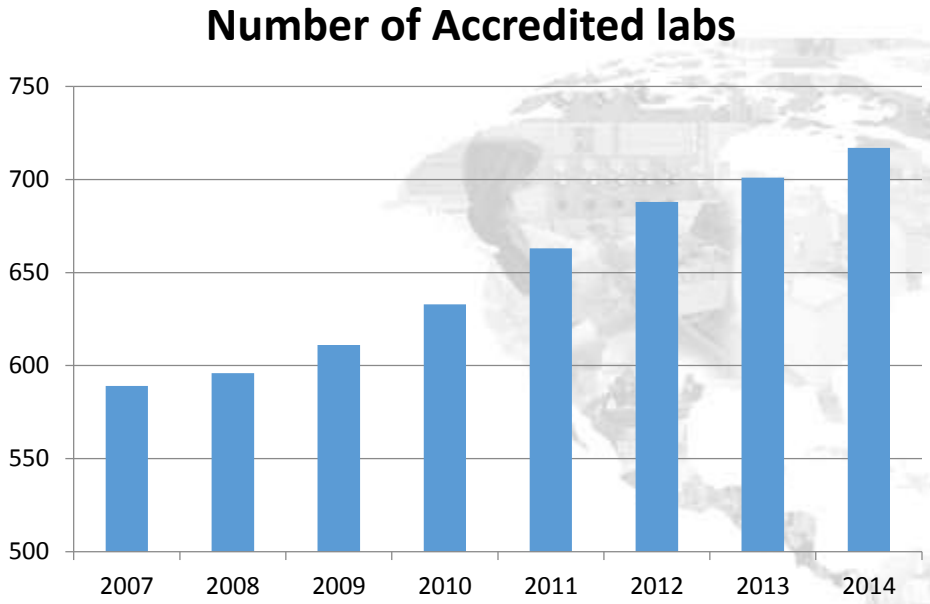
- Following a Federal enquiry into allegations of medical fraud and over-servicing mandatory accreditation for Medicare payments was proposed
- Federal Government chose NATA/RCPA as sole provider of accreditation for pathology
- 1986 - Mandatory scheme linked to Health Insurance Act (Commonwealth Department of Health) was approved through legislation
- All pathology laboratories in Australia receiving funding through Medicare must be accredited through the NATA/RCPA Laboratory Accreditation Program.
- NATA has a Deed of Agreement (contract) with Commonwealth Government to provide Medical Testing Accreditation

NATA/RCPA Medical Testing Accreditation program

- Currently there are a total of 717 Accredited laboratories
- All accredited to ISO 15189
- These numbers do not include >100 NSW Health Pathology Emergency Department Point of Care Testing sites)

NATA/RCPA Medical Testing Accreditation program

Year	Accredited facilities
2007	589
2008	596
2009	611
2010	633
2011	663
2012	688
2013	701
2014	717



Main increase in types of Accreditations :

- **Haemopoietic Apheresis collection sites**
  - **35 Progenitor cell Collection units linked to**
  - **28 Progenitor cell transplantation procedure laboratories**
- **PoCT**
- **Workplace Drug testing organisations**

The use of Accreditation Standards

The Standards hierarchy in use in Australia

International Standards

ISO/IEC 17025, ISO 17020, ISO/IEC 17043, ISO Guide 34, ISO 15189

National Standards

Usually associated with regulatory requirements

National Pathology Accreditation Advisory Council

Requirements for Procedures related to the collection, processing, storage and issue of Human Haemopoietic Progenitor Cells

Requirements for Transfusion Laboratory Practice

The use of Accreditation Standards

The Standards hierarchy in use in Australia

Other Standards and Guidelines

Standards Australia

AS 3864-2012

Medical refrigeration equipment-For the storage of blood and blood products

Part 2: User related requirements for care, maintenance, performance, verification and calibration

Australasian and New Zealand Society for Blood Transfusion

ANZSBT Pretransfusion laboratory practice

The role of ISO 15189

ISO/IEC 17025 used for medical testing assessments until ISO 15189 was published

Standards Australia represents Australia at ISO and IEC level and is represented on ISO TC 212 - Clinical laboratory testing and in vitro diagnostic test systems

Australia is a full Participating "P" member on ISO TC 212

NATA and RCPA usually send representatives to TC 212 WG1

Australia had an important involvement in the development of ISO 15189 and continues to do so

The role of ISO 15189

However ISO 15189:2003 was not adopted in Australia until 1 January 2005

Reason: ISO version was not adopted and rebadged by Standards Australia until December 2004

Republished by as Australian Standard AS4633-2004 (ISO 15189:2003)

ISO 15189:2007 republished and adopted by Standards Australia in August 2009 as AS ISO 15189:2009

Implementation by NATA on 1 January 2010

The role of ISO 15189

ISO 15189:2012 republished and adopted by Standards Australia in May 2013 as AS ISO 15189:2013

Implementation by NATA on 1 July 2013

ILAC requirement for all laboratories to be transitioned to

ISO 15189:2012 before 1 March 2016

The role of ISO 15189

ISO 15189 is used to accredit a diverse range of Laboratories where Medical Testing is performed

NATA does not limit accreditation to ISO 15189 to "traditional" Pathology Laboratories

Nor does it limit accreditation to testing performed by Pathologists and/or Medical Scientists

Wherever Medical Testing occurs NATA can accredit as a Medical Testing laboratory

Types of laboratories currently accredited:

Large tertiary teaching hospitals

Service Acute/Chronic public pathology

Staffed by Clinical Specialists, Pathologists, Clinical Scientists and Medical Scientists

Small regional hospitals

Service Acute/Chronic public pathology

Usually staffed by only Medical Scientists (with Supervision from parent sites above)

Large and small private metropolitan and regional laboratories

Community pathology

Staffed by Clinical Specialists, Pathologists, Clinical Scientists and Medical Scientists

Types of “laboratories”

Hospital wards performing PoCT without laboratory oversight

Emergency departments/ ICU etc

Outreach clinics for Aboriginal communities

General practitioners

Mobile testing vehicles – Ambulances

“Hospital in the home” services

Workplace Drug Testing

Mobile vans, permanent sites, client sites e.g. Pilots, train drivers, mines, power plants, Shipping Docks etc

Military services – Field hospitals

Services provided:

- **Microbiology**
  - Bacteriology
  - Parasitology
  - Virology
  - Mycology
  - Mycobacteriology
  - Serology of infection
  - Molecular Microbiology
    - Sanger (organism identification) & Massively Parallel Sequencing (epidemiology)
- **Immunohaematology**
  - Transfusion laboratories
- **Blood Donor Services**
  - Australian Red Cross Blood Service

Services provided:

- Haematology
- Immunopathology (including Tissue typing)
- Anatomical Pathology
  - Histopathology
  - Cytopathology
  - Autopsy Services (including coronial autopsies)
- Chemical Pathology
  - General Chemistry
  - Biochemical genetics
  - Newborn Screening Services
- Medico-legal drug testing
- Genomics
  - Cytogenetics (including Microarray)
  - Molecular genetics (including whole exome and whole genome sequencing by MPS)
- Assisted Reproduction Techniques

The Surveillance cycle in Medical testing and the scope of each visit type

- The Surveillance cycle was amended in 2013 to meet ISO 17011
- 2 year cycle for new accreditations
- 4 year cycle for existing accreditations
- The visit types include
  - Reassessment
  - Surveillance visit
  - On-line activity

The Surveillance cycle in Medical testing and the scope of each visit type

2 year cycle for new accreditations

- **Surveillance visit at 12 months post initial assessment**
- **Reassessment at 24 months post initial assessment**

4 year cycle

- **Surveillance visit at year 2**
- **Reassessment at year 4**
- **On-line activity years 1 and 3**

The Surveillance cycle in medical testing

Scope of assessment visits

Surveillance visits

- **Predominantly an assessment of the Quality System elements including a comprehensive Quality Manual Document review (Section 4)**
- **Limited technical review includes**
  - **specific technical issues including pre-analytical activities; the methods/procedures in use; status of equipment calibrations/checks; quality control procedures and records; enrolment, participation and performance in proficiency testing; records and reports; and continuing suitability of the facility's accommodation**
- **NATA Lead assessor visit only**

The Surveillance cycle in medical testing

Scope of assessment visits

Reassessment

- **Predominantly a full reassessment of the technical aspects of the laboratory (Section 5)**
- **Limited quality system review**
- **Technical assessors and NATA Lead assessors**

- **Both visit types are On-site**
- **But NATA is trialling “Virtual” assessments for uncomplicated testing such as PoCT**

The Surveillance cycle in medical testing

On-line activity

Introduced I July 2014

- **Touch base activity**
- **Selective technical and management system requirements are reviewed**
- **The activity may result in selected material being sent to a technical assessor for review and comment**
- **Follow up of major findings from the previous visit**
- **Major changes in staffing or testing capability**
- **Validation/verification records**

The Surveillance cycle in medical testing

On-line activity

- **Selected PT/QAP records**
  - **Participation summary reports since previous on-site visit - only if sub-optimal history is evident.**
  - **Previous QAP performance and participation history be considered**
  - **Where enrolment, participation or performance was sub-optimal these QAP programs should be prioritised and more completed records be requested.**
  - **For testing with the greatest risk to public health such as Immunohematology, Histology, Gynaecological Cytology and all in-house Class 3 and 4 IVDs PT/QAP must be requested**

Use of ISO “like” Standards in NATA Accreditation programs

- NATA/RANZCR Medical Imaging Program
  - Use of Sector specific standards based on ISO/IEC 17025
- NATA/ASA Sleep Disorders Services
  - Use of Sector specific Standards based on ISO 15189

Sleep Disorders Services

- **"New" program of accreditation**

- **An accreditation process for sleep services has been available since 1997 to foster excellence in the approach to management of sleep disorders.**
- **The Thoracic Society of Australia and New Zealand (TSANZ) initially managed the program**
- **the Australasian Sleep Association (ASA) took over governance of this process in July 2009**
- **The ASA has been working with NATA for the last couple of years to update the program**
- **with the aim that NATA would take over the management of the program**
- **Now known as the NATA/ASA Sleep Disorders Services (SDS) Accreditation Program.**

Sleep Disorders Services

- In 2012, the ASA Standards were amended to include the principles from the international standard ISO 15189 (2007) Medical laboratories – Particular requirements for quality and Competence
- Standards were renamed ASA Standard for Sleep Disorders Services
- The inclusion of the ISO requirements to the existing ASA standards brings sleep disorders services accreditation to an internationally recognised level
- The accreditation program is based on a 4-year cycle with a surveillance activity midway through the cycle and a full re-assessment at four years
- The assessments involve peer review and the assessment teams include at least one sleep physician, one sleep technologist and a NATA Lead Assessor
- 11 SDS laboratories are currently accredited

Standard for Sleep Disorders Services

Developed from the requirements of ISO 15189: 2007

4 Management requirements

4.1 Organisation and management

4.2 Quality management system

4.3 Document control

4.4 Review of appropriateness of request and patient preparation

4.5 Subcontracting of tests and services

4.6 External services and supplies

4.7 Feedback

4.8 Resolution of complaints

4.9 Identification and control of nonconformities

4.10 Corrective action

4.11 Preventive action

4.12 Continual improvement

4.13 Quality and technical records

4.14 Internal audits

4.15 Management review

Standard for Sleep Disorders Services

5 Technical Requirements

5.1 Personnel

5.2 Accommodation and environmental conditions

5.3 Equipment

5.4 Pre-examination procedures, including handling of patient referrals

5.5 Sleep disorders services methods

5.6 Assuring the quality of the service

5.7 Post-examination procedures, including ongoing patient care

5.8 Reporting of results

1er. **Congreso Interamericano para la acreditación de**
Laboratorios Clínicos, Bancos de Sangre y células Progenitoras Hematopoyéticas

Thank you for your attention

Any Question?