Organisation of a Clinical Laboratory

Peter O’Loughlin
SA Pathology
5. Laboratory Management

(a) Organisation of a Clinical Laboratory (FAACB)

- Hospital Management Structure and the Clinical Laboratory\textsuperscript{1,2}
- Personnel management;\textsuperscript{1} staff recruitment and retention, job descriptions, rostering, performance appraisal


- Requirements for continuing education and professional development
- Resource and Financial management;\textsuperscript{1} budgeting, capital expenditure, cost accounting and reimbursement
- Information management; productivity, test utilisation – see Information Technology and the Laboratory
- Key Performance Indicators;\textsuperscript{3} turnaround times, error rates
- LEAN and Six-Sigma principles. Quality Management Systems\textsuperscript{4}


Requirements for Medical Pathology Services (First Edition 2013)

This document is intended to apply to all medical pathology testing.

The Requirements for Medical Pathology Services is intended to apply to all medical pathology testing. The overarching document sets out key requirements for best practice in pathology laboratories and allows the technical requirements in specific areas of pathology testing to be more streamlined subsidiary documents.

This document has a date of effect of 1 December 2013.

In this section

- National Pathology Accreditation Advisory Council (NPAAC)
- Accreditation
- NPAAC Membership
- NPAAC Functions
- Best Practice Pathology Guidelines
- Guides to understanding NPAAC publications
- NPAAC Errors and Contingency
- NPAAC Meeting Dates
- NPAAC News
- NPAAC Publications
- NPAAC Strategic Plan and Document Hierarchy
- NPAAC documents under review
- NPAAC Documents for Public Consultation

Share this page
NPAAC Standards

- Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002
- Requirements for Medical Pathology Services (First Edition 2013)
- Requirements for the Supervision of Pathology Laboratories (2007 Edition)*
- Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection) (Third Edition 2013)
- Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)
- Requirements for Information Communication (Third Edition 2013)*
- Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs) (Third Edition 2014)
- Requirements for Enrolment and Participation in External Quality Assessment (Fifth Edition 2013)
- Requirements for the Retention of Laboratory Records and Diagnostic Material (Sixth Edition 2013)
NATA

- AS ISO 15189 Medical Laboratories – Particular requirements for quality and competence
- NATA (Field Application Document) Medical Testing - Requirements for Accreditation*
- NATA (Field Application Document) Amendments Sheet*
- ISO 14971 Medical Devices-Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices Quality Management Systems – Requirements for Regulatory Purposes
Your lab and local regulations

- AS ISO 15189:2013 Medical laboratories - requirements for quality and competence
- AS ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- AS/NZS 4308: 2008 Procedures for Specimen Collection and the detection and quantitation of drugs of abuse in urine
- NPAAC Requirements for Quality Management in Medical Laboratories (2007)
- PIC/S Guide to Good Manufacturing Practice for Medicinal Products (2009)
- Department of Agriculture, Fisheries and Forestry (DAFF; formerly AQIS) 2011, General Policies, Quarantine Approved Premises (QAP)
- DAFF 2008, Quarantine Approved Premises Criteria 5.1 for Quarantine Containment Level 1 (QC1) Facilities.
- DAFF 2008, Quarantine Approved Premises Criteria 5.2 for Quarantine Containment Level 2 (QC2) Facilities.
- Australian Government Department of Health and Ageing Health Insurance Act 1975 and Human Services (Medicare) Regulations 2017
What is lab management

• Planning/Strategy
• Organization
• Leadership
• Staff management
Skills for management

• Well organised
• Good time management
• Interpersonal and relationship-building skills
• Delegation
• Forward-planning and strategic thinking
• Communication
• Problem-solving
• Administrative and financial skills
• Leadership
Organisational structure of a chemical pathology service

- PATHOLOGY DIRECTOR
  - CHEMICAL PATHOLOGIST (CLINICAL LEAD)
  - OPERATIONAL MANAGER

- OTHER DISCIPLINES
  - Pathologists
  - Quality Manager
  - Admin staff

- BUSINESS MANAGER

- SITE 1
  - HEAD OF DEPARTMENT

- SITE 2
  - HEAD OF DEPARTMENT

- SITE 3
  - HEAD OF DEPARTMENT

- SITE 4
  - HEAD OF DEPARTMENT

- SITE 5
  - HEAD OF DEPARTMENT
Quality Management system

- Monitor and report quality performance and identify opportunities for improvement across entire process:
  - Documented
  - Monitored
  - Reviewed
  - Updated
  - Audited
Brain-to-brain loop

Request-Test-Report cycle

Doctor

Patient

Need for pathology test

pre-analytical

analytical

post-analytical

Biggest challenge is with the pre- and post-analytical steps that happen outside the box

Adapted from Graham Beastal
Accreditation

• Accreditation is required to offer a service
  – AS ISO 15189:2013
  – AS/NZS 4308: 2008
  – AS 4760 etc.
Personnel

Most important laboratory resource

• Recruitment
• Retention
• Training and continuing education
• Competency and competency assessment
• Performance appraisal
• Personnel records
Facilities and equipment

FACILITIES:
• Engineering controls for staff safety
• Safety equipment

EQUIPMENT:
• Contemporary
• Maintained – records kept
• Safe

Learn how to write a business case
Workflow

• Optimise
• Understand REAL limitations – geography, equipment, training
• Apply LEAN thinking
• Map
• Identify bottlenecks
• Consider alternatives
Process maps
Design KPIs for performance monitoring

• Indicators of patient safety - errors
• Staff - competencies
• Business performance
• Marketing
• etc
KPI - TAT

• Clinical expectations (patient outcomes)
• Commercial contracts
• Sentinels to monitor lab capabilities
• Select meaningful indicators
• LIS – automated reports need to reflect true time of receipt and time of resulting
• Pre-analytical – collection to lab
KPI - Activity

• Activity
  – Workload management
  – Financial reporting
  – Business performance
  – Strategic planning
    • Business cases
  – Marketing
KPI - Errors

KIMMS – pre- and post-analytical errors
• Wrong blood in tube
• Precious samples rejected –TM, intra-op etc
• Haemolysed sample
• ID failure
• Retracted reports
• Customer complaint

Errors must be managed - CAR/OFI
Continuing education

Internal:
• Seminars, journal club,

External:
• AACB – CPC, webinars, tutorials, seminars, lectures, conference etc
• AACC – Learning Lab ($12-$15 per month)
• IFCC – eAcademy coming soon
• Post-graduate
Business Continuity Plan

Loss of: power, LIS, internet, phones, instrument, supply

• Business Impact Assessment – BIA
  – Categorise functions into Tiers of criticality

• Develop CLEAR plans for critical functions
  – Relocate to other lab within your organisation
  – Forward to other provider

• Recovery strategies

KEEP CUSTOMERS IN THE LOOP
WHS
Protect our most valuable resource

• Safe facilities
• Active staff involvement
• Training
• Clear information
  – Biosafety Manual
  – Chemical Management Manual
• Incident reporting and management
Risk Management
DANGER
Do not enter

UNSTABLE CLIFFS
You may fall and
DIE

Please stay behind the fence
Risk Management

• Iterative process
• Rate risks realistically – avoid emotional rating
• Maintain a risk register
  – Track actions
  – Record controls – rate controlled risk
  – Monitor effectiveness
  – Propose treatments – rate treated risk (hypothetical)
• Close risks
• Distinguish issues from risks
Chemical Pathology service delivery is highly subject to change

Manage it!