Laboratory Organization, Lab Direction, Staff, Choice of Equipment, Physical Layout

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Introduction

- 70% of medical decisions are based on laboratory tests
- Thus the quality and accuracy of tests is of vital importance
- Quality is very much related to the manner in which the laboratory is organized and managed
Management

- “Management” comes from the Old French ménagement which means “the art of conducting, directing”. It also finds its origin in Latin from manu agere which means “to lead by the hand”.
- It characterises the process of leading and directing all or part of an organisation, through the use of human, financial and intellectual resources.
ISO STANDARDS

- The gold standard for the medical laboratory, in particular, is ISO 15189:2007.
- ISO 15189:2007 defines the particular requirements for quality and competence.
- It specifies the quality management system requirements specific to medical laboratories.
Key Role of Management

- Organization of laboratory and its structure
- Quality Management System
- Personnel and Staff
- Equipment
- Workflow and Laboratory Layout
Organizational Structure

The Organizational Structure needs to be clearly defined.

To avoid assumptions, an

- Organizational chart should be drawn up with the responsibilities at all levels clearly defined.
- Assignment of responsibility
- The management team is responsible for strategic planning. The planning process should be based on the vision and goals set.
Quality Management System

- A series of processes in motion set by Mx that will ensure the quality of the laboratory. This is termed as the quality management system (QMS).
- Consist of 5 pillars
5 Pillars of QMS

- **Quality Policies**
  A statement of the goals of the organization with respect to its Quality Management System.

- **Quality Procedures**
  The details of the QMS, including the specific processes, procedures and staff responsibilities.

- **Work Instructions**
  The actual instructions for performing tasks that affect the quality standards of the organization.

- **Quality Records**
  Documents that demonstrate conformance to the specified requirements of the QMS.

- **Corrective Action Requests**
  Controlled documents that specify how problems with the organization’s QMS are to be fixed.
Process of Planning

- Time management – Turnaround time of reports
- Who is going to do what - roles should be defined and responsibilities spelt out
- Use of human resources – the management needs to ensure adequate staffing
- Management of workflow – so that all processes are supervised and monitored for quality performance
- Financial resources
- Set benchmarks or standards – the team should have a goal set that would achieve the
- Necessary standards. No compromises on quality will be allowed and benchmarking should be against the internationally accepted standards
STAFFING

- The staff are the single most important asset in any laboratory.
- The laboratory shall be directed by a person or persons who have executive accountability and the competence to assume responsibility for the services provided.
Primary Responsibilities of Director

- Interaction with users of laboratory
- Quality issues
- Future planning
- Education
- Research
Specific Duties : Director

- Staff operates according to the regulatory environment
- Staff are adequate in number, competent, trained appropriately and evaluated.
- Staff operate in a safe environment
- Methods and instruments are validated and verified
- Lab conforms to all internal quality procedures and enrolled in EQA program
Staff qualifications

- Laboratory management shall ensure that there are appropriate numbers of staff, with the required education and training, to meet the demands of the service and appropriate national legislation and regulations.
- Registration of staff shall be in accordance with current national legislation and regulations.
- The staffing shall include an individual(s) with the following roles:
  - a) quality management
  - b) training and education
  - c) health and safety
Personnel Management

- Personnel management ensures that staff contribute fully and effectively to the service, while receiving fair and consistent treatment from laboratory management.
- Laboratory management shall ensure that procedure(s) for personnel management include:
  - a) staff recruitment and selection
  - b) staff orientation and induction
  - c) job descriptions and contracts
  - d) staff records
  - e) staff annual joint review
  - f) staff meetings and communication
  - g) staff training and education
  - h) grievance procedures and staff disciplinary action.
Job descriptions and contracts

- Written job descriptions and contracts enable staff to know their duties, responsibilities, and rights.
- Laboratory management shall ensure that all staff shall have job descriptions that include:
  - a) a job title
  - b) the location within the organisation
  - c) accountability
  - d) the main purpose of the job
  - e) the main duties and responsibilities
  - f) a requirement for participation in staff annual joint review.
- All staff shall have contracts of employment which are in compliance
## Position Description

**CIDM-PH**

**Technical Officer**

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<thead>
<tr>
<th>Designation:</th>
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<td>Classification:</td>
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<td>Award:</td>
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<tr>
<td>Location:</td>
<td>Centre for Infectious Diseases &amp; Microbiology – Public Health (CIDM-PH)</td>
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<td>Position Number:</td>
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<td>Grading Reference:</td>
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### PRIMARY OBJECTIVES

This position is funded by several grants and commissions to CIDM-PH to provide laboratory services for various projects.

### ORGANISATIONAL CONTEXT

Sydney West Area Health Service is responsible for the provision of health services to the local government area comprised of Auburn, Baulkham Hills, Blacktown, Holroyd, Parramatta, Penrith and Blue Mountains and tertiary care to the entire western region for an estimated population of 2 million people. These services are provided through a number of hospital and community-based facilities located strategically across the Area Health Service.

Sydney West Area Health Service is committed to achieving continuous quality improvement in client services within a Quality Management framework, with a supporting Strategic Plan aimed at the continuous improvement of all facilities. The Area Health Service has individual facilities located at Westmead, Cumberland, Blacktown and Mt. Druitt, Auburn Penrith, Springwood, Lithgow/Portland and third schedule hospitals being St Josephs, Lottie Stewart and Hawkesbury Hospitals. All hospitals provide a range of both in-patient and outpatient services to clients both from within the boundaries of the AHS and cross border flows.

In addition to this, there are a number of facilities strategically located across the AHS that provide primary health care services to the community.

The primary goal of SWAHS is:

*To improve the health of, and ensure comprehensive health care services for, our community.*
### JOB DESCRIPTION FORM

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Work Team Leader?</th>
<th>Division/Department</th>
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<td>Yes</td>
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<td>Location</td>
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<th>Shift</th>
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**Purpose**

**Essential Duties**

**General Description**

**Minimum Requirements**

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### SELECTION CRITERIA

Refer to Procedure 2.2 of the Dandenong Casey General Practice Association Policy & Procedure Manual

Customise this form by adding requirements from the job description for the position being advertised. (You can cut and paste each section). Remove all comments in italics, including this one.

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### SELECTED CRITERIA FORM

#### CANDIDATE’S NAME:

#### JOB TITLE:

**RESPONSIBILITIES - SKILLS & EXPERIENCE**

List responsibilities from job description here, with a box to tick indicating the candidate has experience in each area.

- [ ] Responsibility

**PERSONAL ATTRIBUTES**

List behaviours and personal attributes from job description here, with a box to tick, indicating the candidate has demonstrated ability in each area. Note: Some attributes may not be obvious from a resume. Other attributes, such as a stable employment history, do not appear on the job description but may be added to the selection criteria if relevant.

- [ ] Personal attribute

**EDUCATION & QUALIFICATIONS**

List essential and desirable qualifications from job description here, with a box to tick, indicating the candidate complies.

- [ ] Essential

**OTHER**

List other selection criteria as applicable:

- [ ] Ability to use own vehicle

When completed, attach this form to the candidate’s resume as a record of the selection process used.

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**Sample Words 2010**

Available for free download at www.sampleswords.com

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General Practice Support Program
Reviewed March 2008
Staff records

- Maintenance of accurate staff records is an essential part of personnel management.

- Laboratory management shall ensure confidentiality of staff records in accordance with local guidelines and national legislation.
Staff Training

- There shall be the resources for training and education, that includes:
  - a) access to reference material and information services
  - b) access to a conveniently situated quiet room for private study
  - c) staff attendance at meetings and conferences
  - d) financial support.
- Records shall be kept of all training and education.
- Laboratory management shall appoint a training officer
- Records shall be kept of all training and education.
- Laboratory management shall appoint a training officer.
Document Control

One of the most overlooked areas in a laboratory is documentation. The management must define the documentation procedure and maintain it regularly.

- All information pertaining to the quality system, or that is generated from the quality system must be controlled.
- The procedures laid down should ensure that the document is valid, current, accessible, easily identified and reviewed periodically.
- A process should be in place to handle obsolete documents.
- Procedures should also ensure the integrity of documents that are maintained on the computer.
Control of Clinical Material

- Laboratory management shall establish a procedure(s) for controlling clinical material that includes:
  - a) identification and indexing
  - b) security
  - c) retention
  - d) storage and retrieval
  - e) disposal.
- Notice shall be taken of current legislation, regulations and guidelines.
Premises and Environment

- Management will be responsible for providing space ensuring client comfort and safety of clients and employees, without compromising on the quality of the service provided.
- Privacy of the patient during blood collection should be provided and the needs of patients with disability should be considered.
- Storage and disposal of dangerous materials shall be those specified by relevant regulations.
Premises and Environment

- The premises shall have staff facilities that are readily accessible and include:
  - a) sufficient toilet accommodation
  - b) shower facilities where required
  - c) a rest area
  - d) basic catering facilities and access to a supply of drinking water
  - e) a changing area and secure storage for personal effects
  - f) storage for protective clothing
  - g) safe and secure working arrangements.
Health and Safety

- A health and safety statement, and procedures to implement it, are required to ensure a safe environment in the laboratory for staff, patients and visitors.

Laboratory management shall be responsible for:
- a) defining and implementing health and safety procedures
- b) ensuring that there is a safe working environment in accordance with current safety guidelines and legislation
- c) providing personal protective equipment
- d) delegating day to day management of health and safety to the appointed health and safety officer
Equipment

- The proper procurement and management of equipment ensures that the laboratory can fulfill the needs and requirements of users.
- Laboratory management shall ensure that the equipment is sufficient and appropriate to provide the service.
- Laboratory management shall establish a procedure(s) for the procurement and management of equipment, that includes:
Policy on Equipment

- a) assessment and justification of need
- b) selection and acceptance
- c) training
- d) preventive maintenance, service and repair
- e) calibration and monitoring of the instruments, reagents and analytical systems
- g) decontamination
- h) record of instrument failure and subsequent corrective action
- i) planned replacement and disposal
- j) adverse incident and vigilance reporting.
Equipment – Criteria for selection

- Needs Analysis
- Performance characteristics of instrument
- Size and space availability
- Costs
- Service back up
Equipment – criteria for selection

- Training
- Complexity of equipment – how easy is it to operate
- Special operational requirements eg de-ionised water
- Emergency power and waste disposal
- Will reagents be provided free of charge for a limited time?
Equipment Management Program

- Helps maintain high level of laboratory performance
- Reduces variation in test results
- Improves technologists’ confidence in results
- Lowers repair costs
- Lengthens instrument life
- Reduces interruption of service due to breakdowns and failures
- Increases safety for workers
- Produces greater customer satisfaction
Equipment Management Program

- Selection and purchasing
- Installation
- Calibration and performance evaluation
- Maintenance
- Troubleshooting
- Service and repair
- Retiring and disposing of equipment
EQUIPMENT MAINTENANCE MANAGEMENT PROGRAM
CONTRACT NO. 406092
EFFECTIVE: 06/30/08 – 06/30/10
T-NUMBER 92303

WHAT ARE THE CONTRACT REQUIREMENTS?
What is the scope and objective of this contract?
What services are included in this contract?
What is excluded from the contract?
What equipment categories are included in this contract?
How are invoices or payments processed?

WHAT ARE THE CONTRACT DISCOUNTS?
What is the discount offered on Line Item 00001?
What commodity number should I use?

HOW DO I GET STARTED?
What is required from the agency?
What is required from the vendor?
How do I add equipment to the program?
How do I delete or change equipment in the program?
What if my equipment is coming off of warranty?
What if my equipment is now being handled on a time and material basis?
Can I have input in the selection of maintenance repair service providers?
What if my equipment maintenance is provided by a sole source provider?
What if my equipment requires a certified technician?

WHO DO WE CONTACT?
To get started?
To report service calls to vendor?
What are the service hours?
Technical assistance?
At Office of State Purchasing?
To request detailed reporting on agency equipment?

HOW ARE ORDERS ISSUED AGAINST THIS CONTRACT?
What commodity numbers should be used on this contract?
How do I figure the new discounted price for equipment on Contract No. 404894?
Are instructions available?
Will AGPS calculate the discounts?
How are invoices and payments paid?
Who do I call if I need order assistance?
Equipment

- Unique Laboratory identifying number
- Manufacturer’s equipment identification
- Manufacturer’s contact person
- Date of receiving and putting into service
- Manufacturer’s instructions
- Instrument performance records
- Maintenance records
- Damage to, malfunction of, modifications to, and repair of equipment
Laboratory Design and Layout

- Plan for 20 years
- Make sure that occupants of future space are involved in its design
- Use an open design allowing for proper relationships
- Have a flexible layout with movable furniture
- Use lean principles
- Application of ergonomics
Laboratory Design and Layout

Design should be done bearing in mind the flow of specimens and information:

- From Patient to Processing Area to Testing Area to Post-testing Area
- Probable implementation of changes in technology should be considered
Laboratory Design and layout

- Patients and testing activities should be separated as much as possible
- Phlebotomy area should be near entrance
- Laboratory space, as much as possible, should be off-limits to everyone except technical and maintenance staff
- Specimen preparation area should be between collection and testing areas
- Clean and dirty areas should be separated
Laboratory Design

- Benchtops must be made of impermeable material that is easily cleaned and disinfected.
- Must be enough space for equipment, specimen holding and writing or computer area to hold Operating Procedure Manual.
- Floors need to made of material that is easily cleaned.
- Separate color-coded containers for hazardous and other waste.
Laboratory Design

- Ventilation including that of hoods
- Temperature control
- Stable electrical power
- Adequate space including that for circulation and storage of supplies
- Easily cleaned on a daily basis
- Availability of deionized/distilled water
- Availability of emergency power
Laboratory Design

- Avoidance of risk of cross-contamination of specimens
- Service activities, such as sterilization and glassware washing should be located close to where they are needed
- Molecular Pathology requires separate rooms for DNA extraction and testing
- Fluorescent microscopy requires a dark room
- DNA gel photography requires a dark room
Layout

- Like activities should be grouped together
- Service activities, as much as possible, should be consolidated and located near where their products are used
- Distilled water and emergency power available where needed
Work Flow

- Optimize work flow
- Minimize handling
- Minimize costs
- Reduce walking
- Reduce work in progress
- Improve management visibility
- Improve work environment
- Improve inventory management
Implementation

- Success of planning is in its implementation. Much planning stays at the documentation stage and never sees the light of day.
- Implementation process needs to be defined and made simple and plain in achievable steps.
- Management also has the responsibility to sustain the implementation process and,
- Management has the responsibility to direct sufficient resources to enable completion of the plan.
Monitoring

Any process needs to be monitored and measured to see if

- Plans have been accomplished as outlined
- Benchmarks and standards are met
- Outcome should be a system that is continuously evolving and improving, thereby remaining dynamic and sensitive to the clients’ needs
Conclusion

- Any organisation must have strong leadership, which should breed a culture of quality and trust.

The key requirements of leadership are:
- Commitment of laboratory leaders
- Vision
- Team building
- Resources - How to use what you have well
Acknowledgement

- Professor D Young for access to his slides
Useful Education Resources

- Publications of Clinical Laboratory Standards Institute (CLSI). See 2013 Catalogue
- Laboratory Quality Management System Training Toolkit (WHO/CLSI/CDC)