Australian Institute of Medical and Clinical Scientists

Competency-based Standards

for

Medical Scientists

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APPROVED BY THE AIMS BOARD

Foreword

This document was prepared by a Workforce Steering Subcommittee of the Pathology Associations Council in 2009. This document is a review of the 1993 Competency Based Standards prepared in consultation with of the following pathology industry associations:

- Australian Society of Microbiology (ASM)
- Australian Institute of Medical and Clinical Scientists (AIMS)
- Australasian Association of Clinical Biochemistry and Laboratory Medicine (AACB)
- Human Genetics Society of Australasia (HGSA)
- Australian and New Zealand Society of Blood Transfusion (ANZSBT)
- Australian Society of Cytology (ASC).

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References

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Competency Standards for Medical Scientists

Introduction

This document specifies Competency Standards for Australian Medical Scientists working in a diagnostic pathology setting. These standards have been developed to reflect the contribution normally expected from a person with a degree in a relevant area of science or applied science from an Australian (or equivalent) university, together with two years relevant professional experience in an accredited laboratory. This is the entry level of a scientist to this profession and reflects a combination of qualifications, skills and the assumption of personal responsibilities and accountability.

The first six units are required for all medical scientists as a minimum, whereas the last four represent more advanced competencies which would be required over additional time and are expected of scientists performing the roles of supervisor/manager. Given the wide range of professional groups encompassed by "Medical Science", it is intended that a scientist may be measured against these competencies in relation to a specific discipline or across several disciplines.

This document concentrates on the general competencies for Medical Scientists. In contrast, task-specific competencies refer to individual disciplines (e.g., haematology, microbiology), and are described in Range Statements and Evidence Guides.

Although the competencies described are for Medical Scientists, they are not all exclusive to this group; some (e.g., technical procedures, interpretation, clerical work) may be common to several groups, but practised in different contexts. Thus, these same competencies may be applied to all staff in the Medical Laboratory Workforce based on the appropriateness to their role.

What is Competency?

Competency has been defined as "the ability to perform the activities within an occupation or function to the standard expected in employment" (National Competency Standards Policy and Guidelines, National Training Board 1991).

Thus, the term "competency" embodies attributes such as knowledge, skills, abilities, attributes and attitudes required in professional practice.

Competency may be core, general or task-specific. Examples of core competencies are literacy, numeracy, reliability, communication skills and ability to work in teams. These are assumed to be present and are not further described in these standards.

Initial and Ongoing Competence

Competence assessment is required to determine the following:

- Effectiveness of initial training and readiness to function in work environment after initial training period.
- Ongoing continued demonstration of appropriate and necessary skills, knowledge, abilities, attributes and attitudes. This includes ongoing correct performance of work processes and procedures.
- Effectiveness of training and readiness to function after introduction of new or changed work process or procedure. This is applicable to all staff prior to release and/or reporting of new test results when change is made to testing process or procedure.

This may be done by a variety of means, which include, but are not limited to:

- Direct observation. For example, observation of work processes and/or procedures involving instrumentation such as maintenance or troubleshooting, review of records e.g., worksheets, review of results obtained, approach to problem solving and subsequent assessment of skills.
- Assessment of knowledge and understanding by written or verbal questioning.
- Assessment by case study or scenario.
- Performance of task using previously prepared materials and/or a known outcome.

For effective assessment of competence, it is essential that guidelines be set to allow determination of progress and course of action should criteria not be met. These guidelines need to be documented and communicated to staff prior to assessment occurring. Criteria may include determination of the following:

- Critical aspects of the process or procedure.
- What is allowable in the assessment process e.g., in the case of written or oral questioning, what is the 'pass mark'? What are the expected responses?
- If reassessment is required, what assessment will be performed?
- Learning styles of the staff member and what is acceptable for the procedure or method being assessed e.g., Staff member demonstrates understanding and ability in the practical assessment but not written – is this acceptable?

Assessment records need to be retained in each staff member's file as a record of initial and ongoing training and competence assessment. The records retained will be dependent on the evidence required to determine competence.

Understanding the Standards

The standards do not describe the knowledge required to demonstrate adequate evidence of personal competence. Rather, it is assumed that in the testing of competence a range of appropriate evidence guides would be utilised to confirm the required standard.

The actual standards comprise:

Units	An aspect of work activity which describes a broad area of professional performance, can be undertaken by one individual, has real meaning as a "marketable component" of work based activity, can be grouped with other units to form a credible qualification.
Elements	Each unit is further divided into elements which describe what is done in the workplace to ensure that the units can be fulfilled.
Performance Criteria	Specify the type of performance in the workplace that would constitute adequate evidence of personal competence. They seek to specify competent performance in "output" terms. Performance criteria describe the overall evidence from which competent performance in an element would be inferred.
Range Statements	Describe more precisely the circumstances and context in which the performance criteria would be applied. They are provided for informative purposes only and do not form part of the mandatory aspects of this standards document.
Evidence Guides	Are practical examples of activities to illustrate the performance criteria. These cues are provided to assist an assessor to determine whether a competency has been achieved. They are provided for informative purposes only and do not form part of the mandatory aspects of this standards document.

Unit 1: Collection, preparation and analysis of clinical material

Element

1.1 Ensure the appropriateness of sample collection procedures

If responsible for collection of specimen, staff member ensures that:

1.1.1 Correct request form is received as set out in established protocol.

1.1.2 Identification of patient and demographic information is established.

Criteria for assessment and performance:
Request form is checked for patient name, date of birth, gender, unit record number, ward, location, photographic identification, third party identification (e.g., relation, nurse, etc.).

1.1.3 Appropriate action is taken when request appears inconsistent with patient information data.

Criteria for assessment and performance:
The requestor is contacted to clarify apparent inconsistency and senior staff consulted as required. Incidents are documented.

1.1.4 Patient preparation and specimen collection is consistent with test(s) requested.

1.1.5 Patient is informed of procedure, advised of possible associated risks, and agreement to proceed is obtained.

Criteria for assessment and performance:
If patient refuses to have sample collected, refer to requestor, refer to senior laboratory staff. Patient anxieties are considered, discussed and referred to senior staff.

1.1.6 Collection is performed, consistent with established protocols and safe working practices.

Criteria for assessment and performance:
Patient's condition is monitored before, during and following specimen collection and action taken is consistent with the observations.

1.1.7 Specimen is collected into an appropriate container, then immediately and correctly labelled according to established protocols and regulations including minimum labelling requirements.

Criteria for assessment and performance:
Labelling could include nature of specimen (e.g., urine, CSF), name, date of birth, ward, unit record numbers, date/time, collector identified on specimen and request form.

1.1.8 Specimen is transported in a safe and timely manner under appropriate conditions according to established protocols and regulations.

Criteria for assessment and performance:
Ensure use of biosafety bag, appropriate packaging and conditions for transport (temperature, lid secured).

1.2 Ensure the appropriateness of specimen reception procedures

If responsible for receipt of specimens in the laboratory, staff member ensures that:

1.2.1 Documentation is checked to ensure it matches specimen and complies with current regulations.

1.2.2 Collection errors are identified and corrective action taken.

1.2.3 Specimen suitability for further processing is established.

Criteria for assessment and performance:
Subject information data is checked against request; specimen is collected in a suitable container, in appropriate timeframe and under correct conditions.

1.2.4 Decision is made whether to process sub-optimal specimen, taking into account all relevant circumstances and available resources.

Criteria for assessment and performance:
Sub-optimal specimens are flagged: consideration given to urgency of situation, difficulty of obtaining new specimen (e.g., patient access, nature of sample). Incidents are documented.

1.3 Evaluate specimen suitability prior to analysis

Staff member ensures that:

1.3.1 Correct and satisfactory labelling and matching of subject details is established.

Criteria for assessment and performance:
Request form and specimen are crosschecked for name, unique laboratory number, unit record number, date of birth, etc.

1.3.2 Confirmation is made that the nature of the specimen is consistent with requested analysis.

1.3.3 Specimen is received in correct container (i.e., containing correct anticoagulant or fixative if appropriate) and in accordance with collection and delivery protocols.

1.3.4 Quality of specimen meets defined acceptability criteria.

Criteria for assessment and performance:
Specimen is checked for haemolysis, clots, lipaemia, volume, age of specimen, normal flora, epithelial cells, etc.

1.3.5 Appropriate action, as per defined criteria, is taken upon receipt of an unsuitable specimen.

Criteria for assessment and performance:
Specimen rejection criteria, process for requesting new specimen, notifying requestor, processing specimen and consultation with senior staff, incident and outcome documented etc.

1.3.6 Satisfactory specimens are appropriately registered into the laboratory information system.

1.3.7 Specimens are prepared for analysis.

Criteria for assessment and performance:
Specimen rejection criteria, process for requesting new specimen, notifying requestor, processing specimen and consultation with senior staff, incident and outcome documented etc.

1.4 Determine the priority of laboratory requests (triage) to effectively manage service requirements

Staff member ensures that:

1.4.1 Priority of analysis is modified based on clinical necessity, as indicated by medical officer(s) and laboratory guidelines, then by staff and equipment availability.

1.4.2 Workload is organised to ensure optimal patient care and most efficient use of resources.

1.4.3 Workload is continually monitored and reorganised as required to accommodate changes in priority.

1.5 Process specimen utilising appropriate techniques

Staff member ensures that:

1.5.1 Appropriate test procedure is selected for the analysis required, the nature of available specimen(s) and the urgency of the request.

1.5.2 Appropriate standards and controls are selected and prepared and testing is organised in accordance with the analytical procedures/protocol to be undertaken, the urgency, and the clinical condition being investigated.

1.5.3 Appropriate reagents are selected and prepared to ensure maintenance of quality and suitability for use.

1.5.4 Processes are performed in accordance with prescribed methods, quality procedures and accepted safe working practices.

1.5.5 Appropriate means are used to ensure outstanding specimens are followed up.

Criteria for assessment and performance:
Actions take into account factors including time, personnel, reagents, equipment, procedures, quality control and urgency of request.

1.6 Read and validate results

Equipment based testing

Staff member ensures that:

1.6.1 Laboratory instrumentation is operated within established procedures (including quality control, troubleshooting instrument problems and performing preventative and corrective maintenance).

1.6.2 Validity of test results is confirmed in terms of protocols (including standards, quality control data and performance of analytical systems) and problems are identified and remedied or notified to the appropriate staff member.

1.6.3 Results are calculated from data outputs according to documented procedures.

1.6.4 Test data, calculations, results and acceptance/rejection of analytical procedure outcome are documented.

Criteria for assessment and performance:
Problem solving for laboratory instrumentation and analytical methods, quality control, acceptance/rejection criteria.

1.6.5 Storage/disposal of reagents, standards, controls and specimens is in accordance with regulations and guidelines where applicable.

Observation based testing

Staff member ensures that:

1.6.6 Available clinical information is reviewed.

1.6.7 Critical observations are made and recorded.

1.6.8 Observations and evaluations are summarised, using the appropriate knowledge base, and summary is recorded according to regulatory protocols.

Unit 2: Correlation and validation of results of investigations using knowledge of method(s) including analytical principles and clinical information

Element

2.1 Assess validity of data/results against possible range of outcomes

Staff member ensures that:

2.1.1 Initial observation and limited interpretation for significance of the raw data/results is undertaken.

2.1.2 Implausible results, results inconsistent with clinical information or expected outcomes based on other test results or those outside defined criteria are investigated further using defined troubleshooting strategies.

Criteria for assessment and performance:
Acceptance/rejection criteria are adhered to; controls and other specimens, knowledge of limitations of procedure, interfering substances and possible collection/specimen or analytical artefact are assessed. Other test results from internal or external sources are reviewed.

2.2 Validation of results

Staff member ensures that:

2.2.1 Possible causes for implausible or inconsistent results or outcomes are determined.

Criteria for assessment and performance:
Consideration of factors in relation to test including; patient status (e.g., immunocompromised patient), timing of collection, specimen, patient medication type and regimen, protocols.

2.3 Make decisions about reporting results, repeating procedures, consulting senior staff and carrying out further tests within established guidelines

Staff member ensures that:

2.3.1 Appropriate decisions about repeating procedures, carrying out further tests within established guidelines, rejection or reporting of results are made. Senior staff are appropriately consulted.

Criteria for assessment and performance:
Repeating the procedure (with or without change in variables of test), referring problem to senior staff, requesting further sample and discussing with requestor.

2.3.2 Rejected results are dealt with appropriately.

Criteria for assessment and performance:
Reporting the result routinely, referring the result to senior staff, communicating result urgently, conducting additional or substitute tests, checking previous results, obtaining further samples, obtaining further clinical information.

Unit 3: Interpretation, reporting and issuing of laboratory results

Element

3.1 Verify report(s) with sample identification

Staff member ensures that:

3.1.1 Sample identification is traceable from patient identification to reporting.

Criteria for assessment and performance:
Identification code of result matches with sample number; identification code of sample number matches with patient identification.

3.2 Use the administrative systems in place to communicate the results

Staff member ensures that:

3.2.1 Results are communicated in a timely manner and according to laboratory protocols.

Criteria for assessment and performance:
Significant / urgent results are communicated verbally; paper or electronic reports are also generated.

3.2.2 Confidentiality of results is assured at all times.

3.2.3 Results are only given to authorised and identified persons using verification and documentation procedures according to laboratory protocols, regardless of mode of delivery (e.g., telephone, email, fax or other electronic means).

Criteria for assessment and performance:
Confirmation of identity of caller is established for telephone enquiries.

3.2.4 Communication of results is recorded by appropriate means.

3.2.5 Overdue results are identified and investigated.

Criteria for assessment and performance:
Results communicated appropriately (correctly, logically, coherently, succinctly) according to laboratory protocols.

3.2.6 Advice or comment pertaining to the test procedure or outcome is reported in a clear and unambiguous manner.

3.2.7 Relevant reference intervals and, if appropriate, clinical decision limits are included in reports as per established protocols.

Criteria for assessment and performance:
Consideration may be given to age and sex of patient, dose of medication, disease condition.

3.3 Ensure that results with important diagnostic or treatment implications are communicated as per established protocols

Staff member ensures that:

3.3.1 Significant results, as defined by the laboratory, are identified.

3.3.2 Results are interpreted in the light of clinical information provided and knowledge of the test(s) and limitations.

Criteria for assessment and performance:
Consideration may be given to whether condition is life threatening, urgency, therapeutic ranges, clinical notes, test procedure, artefactual causes of spurious values.

3.3.3 Urgent or significant results are communicated to appropriate personnel so they understand the significance, purpose of the communication and action required. This action is documented.

Criteria for assessment and performance:
Relevant person e.g., doctor, nurse, subject is notified. Action is documented.

3.4 Ensure appropriate storage and disposal of data and reports

Staff member ensures that:

3.4.1 All results are recorded and retained according to current regulations and guidelines.

3.4.2 Reports are disposed of according to regulations and guidelines.

Unit 4: Maintenance of documentation, equipment, resources and stock

Element

4.1 Coordinate supplies of stocks and reagents

Staff member ensures that:

4.1.1 Conditions of receipt and storage of laboratory supplies are according to manufacturers' specifications and current safety and quarantine regulations.

> **Criteria for assessment and performance:**
> *Ensure on receipt that reagents have been kept at correct temperature and are not expired. Reagents are stored under correct conditions depending on requirements (temperature, security, safety).*

4.1.2 Stock supplies are maintained.

4.1.3 Expired or dangerous materials are disposed of according to regulations.

4.1.4 Inadequate stocks (e.g., expired reagents, contaminated reagents) are notified to the responsible staff member/unit and are appropriately quarantined to prevent inadvertent use.

4.2 Participate in maintenance of the laboratory and equipment

Staff member ensures that:

4.2.1 Preventive maintenance protocols are enacted and actions recorded.

> **Criteria for assessment and performance:**
> *Maintenance records are up to date. Work area is tidy / clean / organised. Solvents are returned to fireproof cabinets. Waste is placed in correct containers.*

4.2.2 Equipment maintenance by supplier is checked against laboratory requirements.

4.2.3 Equipment is calibrated against specified standards on a regular basis.

4.2.4 The status of the laboratory environment is monitored and any deficiencies detected are rectified and/or reported.

4.2.5 Safety protocols for equipment are maintained e.g., electrical checks, safety guards in place.

4.2.6 Risk assessments are performed for any deviation to recommended instrument safety protocols.

4.3 Participate in preparation and revision of manuals and protocols

Staff member ensures that:

4.3.1 Methods are regularly monitored for necessary update/modification.

4.3.2 Existing documentation is assembled and checked for appropriate references.

4.3.3 Relevant guidelines for content of manuals and regulatory requirements are followed.

4.3.4 Consultation with peers and senior staff is undertaken to discuss applicability, relevance and need for changes to any existing documentation.

4.3.5 Proposed changes to any existing documentation are discussed with, and approved by, senior staff.

4.3.6 Changes to documentation are effectively communicated to all relevant staff.

4.4 Ensure appropriate resources are available to the laboratory

Staff member ensures that:

4.4.1 Adequate and up-to-date information is utilised at time and point of need to assist in interpretation of test results and provision of advice, commensurate with experience.

Criteria for assessment and performance:
Resources for additional information relating to tests and conditions can include reference materials e.g., texts, journals, internet, access to appropriate clinical information and/or personnel to assist in interpretation of test results and provision of advice.

4.4.2 Requirements for staffing resources are communicated to appropriate authorities.

4.4.3 Requirements for equipment are communicated to appropriate authorities.

Unit 5: Maintenance and promotion of safe working practices

Element

5.1 Prepare and store reagents and solutions

Staff member ensures that:

5.1.1 Reagents and solutions are prepared using established protocols.

5.1.2 Reagents are labelled according to legislative guidelines.

5.1.3 An up-to-date inventory of hazardous reagents, Material Safety Data Sheets and supplies is maintained.

5.1.4 Reagents are stored in the correct facilities and under the correct conditions.

5.1.5 Reagents are handled as required by regulatory guidelines.

5.1.6 Expired reagents and solutions are disposed of according to safety precautions.

5.1.7 Reagent inventory is periodically reviewed and hazardous reagents no longer in use are disposed of in a timely manner.

Criteria for assessment and performance:
Reagent preparation procedures are followed with reference to Material Safety Data Sheets, safety requirements for handling, storage and disposal.

5.2 Identify and respond to unsafe work practices and breaches of regulations

Staff member ensures that:

5.2.1 All safe work practices (as laid down by legislative guidelines) are understood and promoted.

5.2.2 Methods/protocols do not incorporate unsafe work practice.

5.2.3 Upon identification or suspicion, unsafe or improper practices are notified to senior staff with suggestions for improvement where appropriate.

Criteria for assessment and performance:
Safety guidelines, risk assessments and/or audits, notification of issues to appropriate senior personnel.

5.3 Ensure correct procedures are followed for acquisition, collection, storage, transportation and disposal of biological, chemical, toxic and radioactive wastes

Staff member ensures that:

5.3.1 The condition of biological, toxic and radioactive material is monitored on receipt and when in storage by the laboratory to ensure compliance with current legislation and guidelines.

5.3.2 The despatch from the laboratory of biological, chemical, toxic and radioactive material is performed in accordance with current regulation/guidelines.

5.3.3 The disposal of biological, chemical, toxic and radioactive material is performed as per current legislation and guidelines.

5.3.4 Protocols for incidents such as spills of biological, chemical, toxic and radioactive substances are followed in accordance with current regulations and guidelines.

5.3.5 Monitoring of the workplace and staff in areas using radioactivity is performed in accordance with current regulations and guidelines.

5.3.6 Staff handling radioactive substances are appropriately trained.

5.3.7 Staff handling cytotoxic chemicals are appropriately trained.

5.3.8 Staff generating or handling genetically modified organisms are appropriately trained.

5.3.9 Laboratory workplace safety requirements are met when handling biological, chemical, toxic or radioactive substances.

Criteria for assessment and performance:
Use of biohazard cabinets, requirements for TB cultures, safety procedures, appropriate storage and disposal of biological, chemical, toxic and radioactive waste.

5.4 Respond appropriately to emergency situations

Staff member ensures that:

5.4.1 Appropriate safety equipment and personal protective equipment (PPE) is available and used according to documented protocols.

5.4.2 Possible interactions of the various chemicals, reagents and biological material and potential hazards are known.

5.4.3 Knowledge and skill in using safety equipment to respond appropriately to emergencies is developed, maintained and documented.

5.4.4 Appropriate actions are taken as described in safety manuals.

5.4.5 Any emergency or safety related incidents are recorded and appropriately notified.

Criteria for assessment and performance:
Compliance with Workplace Health and Safety documentation, Material Safety Data Sheets, instrumentation manuals, safety audits.

Range Statements:
Safety manuals including; fire, chemical spills, electrical faults, basic first aid, radiation spill, biological hazards, thermal injury/damage.

Unit 6: Professional accountability and participation in continuing professional development

Element

6.1 Establish and communicate personal goals in professional development

Staff member ensures that:

6.1.1 Realistic personal professional development goals are identified.

6.1.2 Goals are discussed and modified in consultation with relevant personnel.

Criteria for assessment and performance:
Career goals are documented and a mentor is identified.

6.1.3 A program for professional development is established.

6.2 Maintain and update scientific/technical knowledge and skills

Staff member ensures that:

6.2.1 There is participation in formal CPD program (such as APACE) if available.

6.2.2 Relevant scientific meetings are attended.

6.2.3 Relevant scientific literature is monitored.

6.2.4 Opportunities to enhance learning from investigation of unusual clinical cases and/or results are pursued.

6.2.5 Information from instrument/reagent manufacturers and suppliers is critically assessed.

Criteria for assessment and performance:
Documented attendance at internal and external meetings, workshops, presentations and regular review of scientific literature (e.g., in APACE diary and by APACE certification).

6.3 Develop skills relevant to the enhancement of professional growth

Staff member ensures that:

6.3.1 An understanding of all aspects of laboratory operation and the place of laboratories in health care systems is demonstrated.

6.3.2 Initiative is shown in suggesting or volunteering for additional tasks.

Criteria for assessment and performance:
Engagement in quality improvement activities, method development, reagent evaluations.

6.3.3 Additional skills are developed through activities in professional organisations and/or by attending courses.

6.4 Recognises own abilities and level of professional competence

Staff member ensures that:

6.4.1 Work is only undertaken within the limits of one's abilities, qualifications and training.

6.4.2 Consultation with senior staff is undertaken when a situation requires expertise beyond one's own abilities and qualifications.

6.4.3 Appropriate advice and guidance is given to other staff, commensurate with experience.

6.4.4 An appropriate example is set for other staff in the workplace.

6.5 Complies with profession's code of ethics

Staff member ensures that:

6.5.1 Decisions are made in a transparent, ethical, accountable and professional manner and conduct is demonstrated in a non-discriminatory manner.

6.5.2 Professional judgement, skill and care are exercised to optimal standard and in such a way as to bring credit to the profession.

6.5.3 Practices detrimental to patients and others are avoided.

6.5.4 Confidential information gained in a professional capacity is not disclosed to unauthorised persons.

6.5.5 Professional competence is maintained throughout career.

6.5.6 Appropriate safety regulations are always followed.

6.5.7 A responsible approach to the community and the environment with respect to the handling and disposal of hazardous materials is maintained.

Criteria for assessment and performance:
Compliance with Equal Employment Opportunity policy, Anti-Discrimination policy, Anti-sexual harassment policy, Confidentiality agreement, Workplace Health and Safety documentation, ISO14000 or appropriate environmental policies, APACE or other appropriate certification of continuing professional development.

Unit 7: Responsibility for professional practice including test selection, development and use of laboratory investigations

Element

7.1 Accepts responsibility for own actions/omissions

Staff member ensures that:

7.1.1 Tasks are delegated to other medical scientists and technical staff commensurate with their abilities and scope of practice.

7.1.2 Tasks are checked to ensure they are completed.

7.2 Makes independent, professional judgements

Staff member ensures that:

7.2.1 Problems are solved using sound judgement based upon knowledge and practical experience.

7.2.2 Implications associated with various outcomes of decision-making are recognised and understood.

Criteria for assessment and performance:
Appreciation of the risk and possible repercussions, outcomes and consequences of decisions taken; senior staff undertake assessment of decision-making.

7.3 Demonstrates knowledge of contemporary ethical issues impinging on Medical Science

Staff member ensures that:

7.3.1 Data and events are critically analysed from an ethical perspective.

7.3.2 Rights of individuals/groups are recognised and protected.

7.3.3 Ethical problems and/or dilemmas in the workplace are identified and resolved appropriately or referred to a higher authority.

7.3.4 Unprofessional conduct is identified and dealt with or notified accordingly.

7.3.5 Serious misconduct is reported to appropriate authorities.

7.4 Knowledge of new tests and their potential in the laboratory

Staff member ensures that:

7.4.1 Ongoing review of current literature for information on new or improved tests or procedures is performed.

7.4.2 Recommendations regarding suitability of test(s) as replacement is made based on review of methodology, literature and/or other laboratories' procedures.

7.4.3 New tests are developed and implemented into laboratory environment.

Criteria for assessment and performance:
May include correlation and validation of test method(s), establishment of reference intervals, instrument interfacing, test and result codes in laboratory information system, notification of appropriate staff and communication of new test requirements.

Unit 8: Liaison with health workers and others to continuously improve the service

Element

8.1. Participate in quality improvement activities

Staff member ensures that:

8.1.1 Interactions of pathology with other components of the health service are identified and developed.

8.1.2 Quality issues are documented and brought to the attention of senior staff.

8.1.3 Suggestions for the better performance of the laboratory are made and different options are evaluated.

8.2 Continually review laboratory processes and testing to streamline, minimise waste and increase efficiency

Staff member ensures that:

8.2.1 Cost effective improvements to laboratory procedures or protocols are suggested.

8.2.2 Changes in response to technology improvements that improve processes, enhance outcomes, efficiencies and economies, minimise waste and are environmentally responsible are implemented.

Criteria for assessment and performance:
Understanding performance improvement processes such as principles of lean engineering (e.g., Six Sigma).

8.3 Establish and maintain relationships with suppliers

Staff member ensures that:

8.3.1 In-house and external suppliers of goods and services to the laboratory are identified and an up to date list of contacts of suppliers of goods and services is maintained.

8.3.2 Effective communication channels with suppliers are developed and maintained.

8.3.3 Confidential information is not disclosed to suppliers.

8.3.4 Critical aspects of supplier performance are agreed between the laboratory and the supplier and performance is reviewed in line with these.

8.4 Establish and maintain relationships with service users

Staff member ensures that:

8.4.1 Effective communication channels with service users are developed and maintained.

8.4.2 Confidentiality is maintained during service delivery.

8.4.3 Key performance indicators (identified by discussion with the users of the laboratory service) are agreed and monitored by the laboratory to ensure that the laboratory service meets the needs of its clients.

8.4.4 There is participation in relevant activities that foster a broad perspective on service delivery.

Unit 9: Participation in education and training of health workers and others

Element

9.1 Research, prepare and deliver appropriate presentations

Staff member ensures that:

9.1.1 Educational topics are researched, prepared and presented to health workers and others.

9.2 Participate in interdepartmental and other meetings

Staff member ensures that:

9.2.1 Regular participation in inter or intra departmental meetings and/or intra laboratory meetings is performed.

9.3 Where appropriate, provide instruction on collection, testing of specimens, interpretation and significance of results and service delivery

Staff member ensures that:

9.3.1 Knowledge of pathology testing including collection, testing, result interpretation and clinical significance is demonstrated.

9.3.2 There is participation in relevant activities and education to foster a broad perspective on pathology.

9.3.3 Adequate and current information is available to staff for interpretation of test results and provision of advice.

9.4 Train personnel in the operation of instruments and equipment, the performance of methods and quality control procedures, patient confidentiality, and the observation of safety measures

Staff member ensures that:

9.4.1 Training complies with the requirements of ISO15189 or equivalent standard.

9.4.2 Feedback systems are established to assess effectiveness of presentation/training.

Unit 10: Contribution to advancement of knowledge and improvement of laboratory practice

Element

10.1 Contribute to planning and design of research and development projects

Staff member ensures that:

10.1.1 Initiative in identifying problems and questions, which require investigation is demonstrated.
10.1.2 The need for research or development activities is communicated to colleagues.
10.1.3 There is contribution to the experimental design and research protocol.
10.1.4 Participation in funding proposal is undertaken if appropriate.
10.1.5 Relevant information is accessed online, from libraries and other sources.
10.1.6 Principles of ethical research are understood and practiced.
10.1.7 Relevant protocols are referred to institutional ethics or biosafety committees.

10.2 Follow research/development protocol

Staff member ensures that:

10.2.1 Resources are assembled to commence project.
10.2.2 Relevant ethics approvals are sought and complied with.
10.2.3 Laboratory procedures are followed.
10.2.4 Outcomes of experimental procedures are continually monitored.
10.2.5 All experimental steps and observations, including updating of protocols, are fully documented.

10.3 Evaluate results and the need for further experimental work

Staff member ensures that:

10.3.1 Data is collected and prepared for analysis.
10.3.2 Contributions are made to the interpretation of results and conclusions.
10.3.3 Requirements are determined for further experimental work in consultation with collaborators.

10.4 Prepare and deliver report

Staff member ensures that:

10.4.1 Contributions are made regarding the format and presentation of outcomes.
10.4.2 Preparation of verbal and/or written reports or article (including for publication) is undertaken.
10.4.3 Report is presented for peer review.