Australasian Health Facility Guidelines

Part B - Health Facility Briefing and Planning

0550 – Pathology Unit

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Australasian Health Facility Guidelines

Website: http://www.healthfacilityguidelines.com.au
Email: HI-AusHFGteam@health.nsw.gov.au

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01 INTRODUCTION

1.1 PREAMABLE

Purpose of Guideline

This Health Planning Unit (HPU) has been developed by the Australasian Health Infrastructure Alliance (AHIA). This revision has been informed by an extensive consultation process that was completed in 2021.

Acronyms

Acronyms used extensively throughout this HPU include:

- ANZSBT: Australian and New Zealand Society of Blood Transfusion
- NATA: National Association of Testing Authorities
- NPAAC: National Pathology Accreditation Advisory Council
- PoCT: Point of Care Testing
- RCPA: Royal College of Pathologists Australasia
- TAT: Turnaround time
- TGA: Therapeutic Goods Administration

1.2 INTRODUCTION

This HPU outlines the specific requirements for the planning and design of hospital Pathology Units.

Pathology is the branch of medicine involved in understanding the cause and processes of disease by observing changes in the tissues of the body, and in blood and other body fluids. Some of these changes may show the potential to develop a disease, while others show its presence, cause or severity, or monitor its progress or the effects of treatment.

The scale and complexity of Pathology Units varies depending on a range of factors including the role / level of service, networking arrangements, operational practices and location. These services may range from small health services with point-of-care testing to large tertiary hospitals or networks with sub-specialty services.

The main focus of this HPU is provision of an integrated on-site hospital Pathology Unit with basic core services. In addition, the document provides some guidance relating to specialised needs. The HPU does not address the following (that would only be found in major tertiary hospital sites, reference / research laboratories or other specialised units):

- laboratories utilising radioactive materials;
- teaching and research laboratories; and
- IVF laboratories.

This document should be read in conjunction with the Australasian Health Facility Guidelines (AusHFG) generic requirements and Standard Components described in:

- Part A: Introduction and Instructions for Use;
- Part B: Section 80 - General Requirements;
- Part B: Section 90 - Standard Components, Room Data and Room Layout Sheets;
- Part C: Design for Access, Mobility, Safety and Security; and
- Part D: Infection Prevention and Control.

1.3 POLICY FRAMEWORK

The following organisations provide a wide range of information on Pathology Services:

- The Royal College of Pathologists of Australasia (RCPA) advises the Commonwealth, State and Territory Health Ministers on matters relating to the accreditation of pathology laboratories.
- The National Pathology Accreditation Advisory Council (NPAAC) plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is made up of representatives from all States and Territories, nominees from peak professional bodies and the Department of Health and Ageing. It is responsible for the development and maintenance of standards and guidelines for pathology laboratories.
- The Australian and New Zealand Society of Blood Transfusion (ANZSBT) defines and promotes best practice in clinical and laboratory transfusion medicine including support for education and research.
- Audits against these standards and guidelines are conducted by the National Association of Testing Authorities, Australia (NATA), Australia's government-endorsed provider of accreditation for laboratories and similar testing facilities.
- International Accreditation New Zealand (IANZ), New Zealand's national authority for the accreditation of testing laboratories, radiology services and inspection services.

Key reference documents that will assist in the planning and design of pathology services, and have informed this updated HPU, include:

- Australian and New Zealand Society of Blood Transfusion, Guidelines for the Transfusion and Immunohaematology Laboratory Practice (2020), ANZSBT.
- NPAAC, Requirements for Medical Pathology Services (2018), Australian Government Department of Health.
- NPAAC, Guidelines for Approved Pathology Collection Centres – Requirements for Medical Pathology Specimen Collection (2013), Australian Government Department of Health.
- NPAAC, Requirements for Transfusion Laboratory Practice (2019), Australian Government Department of Health.
- NPAAC, Requirements for the Retention of Laboratory Records and Diagnostic Material (2021), Australian Government Department of Health.
- Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.
- Therapeutic Goods Administration, in relation to the regulation of blood and blood products.

There are a significant number of other standards that apply when planning, designing and operating laboratories. These are listed throughout this HPU.

1.4 DESCRIPTION

1.4.1 Definition of Health Planning Unit (HPU)

The Pathology Unit is a discrete unit of the hospital designed to cater for the examination of body tissue and fluids. This HPU is designed to provide the "building blocks" for a Pathology Unit of any size.

Key activities undertaken by a Pathology Unit include:

- specimen collection services through fixed locations (e.g. outpatient clinic), mobile services (e.g. phlebotomy service to Inpatient Units) and outreach services (e.g. home-based collection service);
- specimen reception, registration, sorting, labelling and distribution to the appropriate laboratory areas;
- referrals to reference laboratories and receivals for reference laboratories;
- specific analytical tests;
- preparation of reagents and instruments;
- calibration and quality control activities;
- calculations, reporting and interpretation of results;
- preparation of back-up facilities to cover instrument breakdown;
- preparation for specialised procedures;
- consultation services;
- multidisciplinary team meetings and training;
- clinical trials and research;
- equipment maintenance;
- ordering supplies, receipt, distribution and storage; and
- logistics and transport management of samples.

1.4.2 Range of Services

Pathology is divided into a number of 'specialist' disciplines (or areas of activity) relating to the methods used or the types of diseases being investigated. The description of pathology disciplines below is an edited extract taken from the Royal College of Pathologists of Australia (RCPA) website.

- **Anatomical Pathology / Cytopathology:** diagnosis of disease using tissue or small specimens of separated cells (including fluids and tissue smears) taken from a living patient or at post-mortem;
- **Chemical Pathology:** detecting changes in a range of substances such as electrolytes, enzymes and proteins, in blood and body fluids, and detecting and measuring tumour markers, hormones, poisons and therapeutic and illicit drugs. This specialty is also known as Clinical Chemistry or Biochemistry;
- **Genetic Pathology:** incorporates biochemical genetics which involves diagnosing and treating metabolic diseases, and medical genomics which involves the use of DNA information to inform patient diagnosis and care
- **Haematology:** concerned with diseases that affect the blood, such as anaemia, leukemia, lymphoma, and clotting or bleeding disorders:

- **Transfusion Services**: encompasses blood banking (the collection, preparation, testing and storage of blood and blood products) and the provision of blood and blood products for the treatment or prevention of disease:
- **Immunopathology:** involves both laboratory medicine and clinical practice including tests of the immune system, such as testing for 'allergy antibodies' and the measurement of different classes of antibody proteins to determine the state of the immune system's defence mechanism;
- **Microbiology:** concerned with diseases caused by organisms such as bacteria, viruses, fungi and parasites. Clinical aspects involve control of outbreaks of infectious disease and dealing with the problems of infections caused by antibiotic-resistant bacteria; and
- **Forensic Pathology:** a subspecialty of pathology focused on the medico-legal investigation of sudden and unexpected death.

Pathology services relating to mortuary and autopsy units, are addressed within the separate AusHFG HPU 490 Hospital Mortuary / Autopsy Unit.

The NATA/RCPA accreditation scheme currently registers laboratories in five main categories that parallel the categories defined by the NPAAC. Categories are determined by the range of pathology tests performed and the level of supervision provided by the designated person in charge of the laboratory.

For further details relating to the existing categories, refer to NPAAC Department of Health, 2021, Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories.

1.4.3 Level / Role of Service

Descriptions of role delineation and levels of service vary between jurisdictions.

The broad roles include:

- no on-site pathology service. A specimen collection service is available on-site and samples are transferred via courier to an approved laboratory;
- an on-site service for urgent testing with some testing performed by trained health workers using point-of-care testing devices. Blood storage may or may not be on-site;
- an on-site pathology service. A NATA/RCPA accredited laboratory undertaking a range of tests. The complexity of this service will depend on the range of clinical services provided by the health service; and
- a tertiary hospital / health service that provides a range of clinical, laboratory and business support services. This service will have a significant teaching and research role and may be a "hub" of a pathology network, providing specialised services for smaller laboratories.

1.4.4 Physical Containment Laboratories

The Physical Containment (PC) level of a laboratory describes the work practices and design requirements when working with microorganisms, based on the level of risk posed by the microorganisms. AS/NZS 2243.3: 2010 'Safety in laboratories Part 3: Microbiological Safety and Containment' describes the infrastructure requirements to meet each of the four PC levels.

For the purpose of this HPU document, the following will apply:

- microbiology laboratories will be classified PC2 at a minimum, with some major Pathology Units requiring a PC3 laboratory; and
- virology / serology laboratories, where provided, may be classified PC2 or higher.

PC4 laboratories, for microorganisms that require the maximum level of containment, are not common with only a small number provided across Australia.

For further details of containment levels, refer to Section 5.5 and AS/NZS 2243.3.

02 PLANNING

2.1 OPERATIONAL MODELS

2.1.1 Future Trends

Design teams should be aware of the rapidly changing patterns of pathology practice and evolving technology. These changes may have major implications for spatial requirements for some functions and it is essential that Pathology Units are designed to optimise flexibility to readily respond to these future changes.

Some of the changes that may impact on design are detailed below.

Changes in service activity due to demographic changes including:

- an ageing population with co-morbidities;
- prolonged survival of patients with previously untreatable diseases, with an ongoing requirement for monitoring disease status and response to treatment;
- patients of different ethnicity with diverse genetic disorders and cultural needs; and
- consumer demand for easy access to pathology services.

Developments in medicine including:

- genetic testing and personalised medicine e.g. pharmacogenetics; and
- increasing complexity and numbers of biopsies (in part due to the clinical emphasis on early diagnosis).

New developments in pathology including:

- increasing use of point-of-care testing (PoCT) with increased consolidation of high cost and/or specialised services;
- increasing convergence of disciplines and shared use of staff and equipment;
- increasing specialisation of sub-specialties with unique equipment;
- increasing automation of services and transition to digital pathology; and
- increasing size and weight of contemporary analysers impacting on spatial and engineering services requirements.

In addition, there is a need for Pathology Units to have sufficient capacity to cope with surges in activity which impact on workforce requirements, the need for additional analysers and increased demand on associated support areas.

2.1.2 Models of Service Delivery

In most jurisdictions across Australia and New Zealand, public pathology services are organised as networks, delivered across geographic regions. In many cases, operational accountability is devolved to an area or region with an overarching strategic responsibility for system development residing with jurisdictional health departments.

The future service delivery model for a Pathology Unit will be guided by the role delineation / level of service to be provided as part of the broader pathology network, and the range of pathology services to be provided onsite. At a minimum, most small hospital-based Pathology Units will provide basic haematology (e.g. full blood count and basic coagulation), transfusion services (e.g. cross matching and blood grouping) and chemical pathology (e.g. liver and renal function tests, electrolytes). Some small units may also provide critical microbiology (e.g. urine microscopy, Gram staining). This will usually be driven by the location of the service relative to hub pathology units and the need to ensure appropriate turnaround times. More specialised pathology services will be provided in higher level Pathology Units in line with broader network arrangements.

Other key project considerations relating to the pathology service delivery model that require early confirmation in the planning process, are described below.

2.1.3 Automation of Pathology Services

The use of automated equipment and information technology in pathology services is significantly reducing the amount of time spent on repetitive tasks, such as specimen transport, processing and aliquoting, as well as reducing handling and transcription errors. The level of automation being provided is increasing rapidly in response to higher volumes of testing, the need for faster turnaround times as well as workforce challenges and cost pressures.

Automated pathology systems are able to transfer specimens between devices and electronically transfer, analyse and process information related to the testing of specimens. This is particularly useful in the 'core laboratory' area of a Pathology Unit, which is focused on high volume and time critical services. In the pre-analytical areas of medium to high volume pathology services, automated track systems are becoming increasingly common. These systems are able to receive, centrifuge, sort and aliquot specimens. Specimens can then be loaded into instrument specific racks or directly onto analytical instruments.

It is important to confirm the use of automated systems early in the planning process as this will underpin the overall configuration of the Unit. The provision of a flexible, modular design as described in Section 2.3.2, is essential to support future advancements in automation and changing service profiles.

2.1.4 Digital Pathology Systems

Digital pathology involves the acquisition, management, sharing and interpretation of pathology information within a digital environment. For example, glass slides can be captured with a scanning device to provide a high-resolution digital image that can be viewed on a computer screen and shared over networks, rather than requiring individual analysis via a microscope. This supports improved efficiency and accuracy of testing and is having an impact on traditional workflows within a range of pathology disciplines including anatomical pathology, microbiology, immunology and haematology.

The transition to digital pathology will reduce the time currently taken to transport tissue specimens and enable the provision of virtual pathology services at remote services. Slide digitisation has also enabled development of Artificial Intelligence (AI) to provide pathologists with decision-support and quality control tools to improve the speed and accuracy of diagnosis.

Key planning considerations relating to digital pathology include scanning machines, access to PCs and monitors, and high network speed and data storage capacity, including consideration of cloud based systems.

2.1.5 Point of Care Testing (PoCT)

PoCT is defined as pathology testing performed in close proximity to a patient by a healthcare worker, with testing performed outside the precinct of a traditional Pathology Unit. PoCT may be carried out in a variety of settings such as Intensive Care Units (ICU), Emergency Departments (ED) and Inpatient Units.

The management of PoCT will:

- be supervised by the local pathology service to ensure that clinical supervision is provided along with maintenance to improve the reliability of this equipment; and
- ensure that all units are NATA accredited.

Given the significant growth in the use of PoCT, larger pathology services will require consideration of space to support the regular testing and routine maintenance of PoCT analysers. Close proximity between pathology and relevant clinical departments, in particular the Emergency Departments (ED), will support maintenance requirements as well as clinical staff training and trouble shooting.

The regular testing and troubleshooting requires all PoCT equipment to be interfaced with hospital Information Communication Technology (ICT) systems.

2.1.6 Specimen Collection / Phlebotomy

Inpatient specimens are routinely collected by the pathology phlebotomy service with other samples collected by medical and nursing staff.

Outpatient specimen collection services are typically located in an ambulatory care zone for ease of patient access, although for some smaller services it may be collocated with the Pathology Unit.

A range of services will be provided in specimen collection bays / rooms. Selected procedures (e.g. fine needle aspirations) are typically undertaken in procedure rooms in clinical areas.

Key planning and design considerations are outlined in Section 2.4.2.

Project teams should refer to:

- NPAAC, Guidelines for Approved Pathology Collection Centres – Requirements for Medical Pathology Specimen Collection (2013), Australian Government Department of Health.

2.2 OPERATIONAL POLICIES

2.2.1 General

Operational policies have a major impact on design requirements as well as on capital and recurrent costs for health care facilities. Operational policies should be established at the earliest stages in planning with consideration given to local jurisdictional policies.

Unit-specific operational policies are detailed below. A list of general operational policies is available from AusHFG Part B: Section 80 - General Requirements.

2.2.2 Hours of Operation

The Pathology Unit will usually provide services on a 24-hour, seven day (24/7) a week basis, particularly where the hospital has emergency and critical care units.

As a rule, the laboratory will be fully staffed between 8.00am and 5.30pm Monday to Friday. Commonly, there will be reduced staffing or call back services on weekends, public holidays and evenings. After-hours services have implications for access and staff security, not only for pathology staff but also for other hospital staff attending the Unit after hours e.g. to collect blood products.

2.2.3 Autopsies

The Autopsy Suite, where provided, will be collocated with the Mortuary Unit. These facilities are not generally collocated with the Pathology Unit (including the Anatomical Pathology service) as mortuaries have special requirements relating to access. These requirements are addressed in AusHFG: HPU 490 Hospital Mortuary / Autopsy Unit.

2.2.4 Frozen Sections

Frozen sections involve the microscopic examination of small portions of rapidly frozen fresh tissue removed surgically, and the subsequent provision of a diagnosis, often while the patient is still anaesthetised.

Although the need for a frozen section may be pre-arranged between the surgeon and pathologist, the actual procedure is considered “urgent”. Unless the volume is very high (such as supporting a neurosurgery service) or biopsies are done on a sessional basis, the process should be undertaken in the Pathology Unit. This has implications for the very necessary rapid transport and the distance between the laboratory and operating suite as specimens are hand delivered, given they are not appropriate for transport via pneumatic tube systems.

Refer to AusHFG HPU 520 Operating Unit for further information.

2.2.5 Laboratory Cleaning, Disinfection and Sterilization

The need for sterilising of reusable equipment in Pathology Units has reduced significantly with the use of commercially provided media and increasing use of disposable items.

This has resulted in a reduced need for clean-up areas but increased volumes of waste storage. Systems for waste streaming require certain categories of waste (e.g. clinical waste) be contained in bins prior to removal by waste management staff.

2.2.6 Linen

Provision will be made for the delivery, storage and retrieval of linen used by staff (e.g. gowns and lab coats). Linen may be used for patient care in specimen collection areas, however many services are transitioning to disposable options.

2.2.7 Media Production

Media, such as agar plates, is usually provided by commercial suppliers.

Although it is uncommon, media may be prepared in-house. Where this is justified, based on a cost benefit analysis, a dedicated production suite will be required.

2.2.8 Pathology Requests

All pathology requests, test information and reporting of results will be computerised with authorised access to verified results being available at selected points throughout the health service. However, some use of paper within the work areas associated with request forms, notes etc. can still be expected.

Tests not able to be performed by the laboratory will be referred to appropriate reference laboratories.

2.2.9 Records and Specimen Retention

The NPAAC outlines the minimum requirements for retention of laboratory records and materials (NPAAC, 2021 ‘Requirements for the Retention of Laboratory Records and Diagnostic Material’).

Local jurisdictional policies and requirements should also be referred to. A table of relevant state and territory legislation is available at Appendix C of the NPAAC document. This document also contains the Medicare Australia Notice of Information Technology (IT) Standards under the Electronic Transaction Act 1999 for scanning and storage of referrals and requests (Appendix B).

Increasingly, the adoption of Public Key Infrastructure (PKI) systems will eliminate the need to provide physical storage of records. Instead, requests and results are transmitted securely using PKI and an electronic version will be retained.

2.2.10 Reporting

Planning must ensure that an appropriate number of workstations are provided to support reporting of results. Pathologists spend a significant proportion of their day in reporting work areas and require privacy and minimal distractions.

Although results are manually transcribed for some disciplines, direct interfacing of instruments is becoming common practice and will require access to data points throughout the Unit.

After validation, results may be available by:

- SMS, email or through an electronic download;
- in writing (hard copy) reported either in the laboratory or at remote sites; and
- telephone reporting of results for critical care patient management ("critical values").

Design should support an efficient and effective workflow.

2.2.11 Specimen Transport

Transport of specimens will involve both internal (to laboratories) and external (between facilities / buildings) systems. Due to the speed at which many specimens deteriorate, and the instability of some specific analytes, it is critical that the interval is minimised between specimen collection and analysis.

Planning should facilitate the appropriate traffic and delivery systems for the specimen collection process.

Transport Between Pathology and Other Clinical Units

The design must facilitate unhindered delivery of all specimens to and from the Pathology Unit. Transport systems must support specimen processing within the specified Australian Council of Healthcare Standards turnaround time requirements.

Automated transport systems, such as pneumatic tube systems (PTS) are commonly used to transport specimens between clinical services and the Pathology Units on health service sites. The benefits of these types of systems is that samples are delivered quickly, reducing the need for secondary storage within clinical units. Operational costs are also reduced. It is important to acknowledge however, that a significant proportion of specimens cannot be transported via PTS (e.g. blood products and frozen sections) and so the location the Pathology Unit in relation to ED and other critical care services must be carefully considered. Refer to Section 2.3.1.

Internal Specimen Transport

Other logistics systems, such as automated track systems, robotic tug systems and dumbwaiters, may be used within Pathology Units to internally transport specimens between the Core Laboratory and specialty areas (e.g. microbiology). The systems may utilise floor and ceiling space and should be designed to enable future changes over time.

Transport of Specimens Off Site

Where specimens are to be forwarded to an external facility, they may be dispatched in batches at set times, rather than individually as they arise. It will therefore be necessary to provide suitable storage facilities such as refrigerators and freezers for the batch specimens.

It will be essential to ensure that specimens are suitably packaged for transportation to avoid breakage, spillage or deterioration whilst in transit. Packages should be clearly identified and addressed, and any special temperature requirements noted (e.g. chilling or temperature control). The design should include functional packing space and surfaces, a range of conditions for packed specimens awaiting transfer (e.g. refrigeration) and adequate storage for packing materials.

For further information refer to:

- NPAAC, 2013, Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition): and
- International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) and Packing Instructions 602, 650 and 90. These regulations apply whether the containers are sent by air, road or sea.

2.2.12 Storage

Pathology Units require bulk store areas; storage within each laboratory area; and a range of specialised storage requirements.

Indicative area allocations for storage are included in the Schedule of Accommodation at Section 5.1, however requirements will need to be developed in consultation with the pathology service.

Consideration must be given to temperature and humidity control requirements as well as ensuring these areas are vermin proof.

Project teams are recommended to familiarise themselves with the following publications:

- Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction. This includes quantities of various potentially dangerous materials that can be stored in one place;
- Standards Australia, 1997, AS 1894:1997 The storage and handling of non-flammable cryogenic and refrigerated liquids; and
- Standards Australia, 2010, AS/NZS 2243.2:2006 Safety in Laboratories - Chemical Aspects.

Storage - Specimens

Specimens may need to be stored:

- out-of-hours (e.g. when delivered by night staff to the Unit depending on local operational practices);
- in the specimen receiving area prior to distribution to the appropriate laboratory; or
- by individual laboratories for re-testing.

Storage systems for blood, serum and plasma include refrigerators, walk-in cool rooms and freezers (i.e.-20°C and -80°C).

Equipment such as refrigerators, freezers, ice machines and a small incubator will be located in the appropriate zones. Where cool rooms are provided, electrical and mechanical redundancy should be considered to mitigate the risk of losing stock. Refrigerators, cool rooms and freezers must have continuous temperature monitoring and alarms.

As well as ice machines and refrigeration, the Unit should have the capability to produce dry ice (carbon dioxide / CO2). Note that there are specific requirements for holding and using CO2 in a laboratory area. Refer to:

- TOMCO2 Systems, 2014, Safe Handling of Dry Ice (dryiceInfo.com); and
- NPAAC, 2013, Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition).

The Anatomical Pathology services will need to keep residual tissue specimens that have been used to generate blocks. These specimens can be large and are held in storage buckets, usually for between one and three months. These specimens need to be stored in a separate room or purpose-built storage unit within the Anatomical Pathology area. This storage will be well ventilated as the samples are stored in formalin (refer to Section 3.7.2 for further information).

Storage - Blood and Blood Products

All blood products must be stored in accordance with the ANZSBT, Guidelines for the Transfusion and Immunohaematology Laboratory Practice (2020). This document outlines the storage temperature and maximum storage duration for various products in line with AS 3864.1:2012 Medical refrigeration equipment - for the storage of blood and blood products.

This includes reach-in cabinets and walk-in rooms for the storage of blood and blood products in the temperature range 2°C to 6°C, and storage of frozen blood plasma at a temperature of -25°C or lower.

Separate storage will be required for cross-matched and non-cross-matched blood.

Blood refrigerators and freezers for storing fresh frozen plasma must be connected to the emergency power supply and require continuous temperature monitoring devices and alarms. Alarms will be activated in the case of a power failure or when the temperature falls outside the specified range for the particular product and must ring into a 24-hour, seven day per week staffed area.

Blood refrigerators located outside Pathology Units in critical care areas must also be monitored and alarmed and remain the responsibility of pathology staff.

Platelet concentrates must be agitated gently and continuously in a single layer on a platelet shaker during storage and should be stored at 20°C -24°C.

Temperature controlled devices are required as room air-conditioning is not sufficient to provide constant temperatures and may fail or be switched off at night.

Frozen blood products must be thawed under the control of the Blood Bank or other trained personnel. Blood and blood products are transported in refrigerated boxes.

Storage - Slides and Tissue Blocks

Storage is required for bodily specimens, samples or materials examined in a diagnostic pathology procedure and may include slides, films, blocks, cultures and related material.

These must be retained in accordance with current NPAAC minimum standards for the retention of diagnostic material.

Space required for storage will be considerable and heavy, but it is assumed that the majority of slides would be stored in a secondary storage facility. Consultation with the pathology service will be required to understand the volume of storage required within the Unit. Given the weight of these items, floor structures must be designed accordingly.

Storage - Media

Storage requirements will be dependent on the model adopted by the Pathology Unit (refer to Section 2.2.7). For most services, commercially prepared media will be used and a “just-in-time” delivery and storage system will be used. Should media be prepared locally, bulk stock will be refrigerated within the Unit in the media preparation room, if provided.

Storage - Reagents

Reagents may require storage at room temperature or within a refrigerator / cool room or freezer.

Supplies are commonly stored in a well-controlled central cool room. Some reagents will need to be quarantined within designated areas of the cool room.

Appropriate temperature control is essential, and this may include ambient temperature monitoring.

Storage – Liquid Nitrogen

Liquid nitrogen is frequently used in tissue bank storage, transplant units and research areas. It requires purpose-designed insulated storage containers located in an area that is well ventilated. This store may require environmental monitoring depending on the volume of liquid nitrogen and location of the store. Decanting of liquid nitrogen should preferably be done in an isolated area of the laboratory on an impervious bench designated for the purpose. Adjacent storage for face masks and gloves should be included in the design of the zone.

Planning related to storage and use of liquid nitrogen and other chemicals needs to consider AS 1894:1997 and AS/NZS 2243.2:2006.

Storage – Hazardous Substances

Storage / cabinets for flammable solvents, corrosive materials (e.g. acids) and other designated materials such as paraffin blocks will be required in the Unit. Security and any venting requirements will also need to be considered.

2.2.13 Waste Management

All pathological waste should be considered as potentially hazardous and be treated as clinical waste. The means of handling general clinical waste and soiled linen from the Unit should comply with measures implemented for other areas of the hospital.

The following categories of waste require further consideration and may call for the development of special policies:

- body parts and tissue (both fresh and preserved) with consideration of cultural sensitivities;
- radioactive specimens and reagents;
- large volumes of sharps requiring special sealable containers of large capacity;
- chemical waste; and
- flammable liquids.

Suitable areas should be provided, for the safe temporary storage of solid or liquid wastes collected from laboratories until they are removed by a waste collection agency or disposed of by other approved means. This waste will be streamed and collected in waste specific bins including body parts and tissue waste, cytotoxic waste, clinical waste etc. Waste holding areas should be located on the periphery of the Unit for ease of removal by Environmental Services staff.

It is anticipated that solvent recycling facilities will be used to reduce solvent waste and its associated costs. This will be located within the tissue processing room. Consideration must be given to minimising the manual handling risks associated with handling the solvent to reduce the risk of injury while maintaining efficient work practices.

Some solvents can be disposed of via the sink with large amounts of water, however this will be dependent on local Council / water authority requirements.

2.2.14 Unit Management

Requirements for laboratory supervision and management must comply with NPAAC guidelines. Other requirements will be dependent on the size and complexity of the service.

2.2.15 Operational Staff

The range of staff working in a Pathology Unit is broad and can include:

- visiting medical officers, staff pathologists and pathology trainees;
- researchers;
- scientific officers (terminology will vary between jurisdictions);

- technical officers;
- nurses;
- technical / laboratory / clinical assistants (terminology will vary between jurisdictions);
- post mortem staff;
- phlebotomist;
- couriers; and
- clerical staff.

For smaller services, some staff will have dual roles, for example phlebotomists may also work within the laboratory.

2.3 PLANNING MODELS

2.3.1 Location

The priority service connection for Pathology Units is ED, as well as other critical care services such as ICU and operating theatres. The optimal location of the Pathology Unit in relation to these services is essential to support timely access to pathology services. Even with a pneumatic tube system (PTS) in place, close horizontal or vertical proximity (ready access) between the Pathology Unit and the ED is important to:

- optimise turnaround times (TATs) for the high volume of time critical tests received from ED, the main user of pathology services;
- support rapid specimen transport times given a significant proportion of specimens cannot be transported via PTS (eg blood products and frozen sections);
- ensure optimal TATs continue to be met during periods of PTS downtime / maintenance,
- prevent the need to duplicate costly blood fridges in clinical areas that would also have operational impacts relating to daily checking and stocking by pathology staff;
- support the maintenance of PoCT devices and associated staff training and troubleshooting;
- promote communication and enhanced working relationships between services; and
- reduce costs associated with staff travel time.

For smaller hospitals, it is recommended that direct access is provided between the ED and pathology unit. Where this is not possible, such as in larger facilities with significantly sized EDs and associated areas, a PTS should be provided and close proximity between ED and the Pathology Unit should be prioritised, with the Pathology Unit proximally located to the ‘hot lifts.

2.3.2 Key Planning Principles

Open Plan, Modular Design

The overall arrangement of the Pathology Unit is key to supporting optimal workflows. Where possible, an open plan design with a clear line of sight across the Unit, should be provided.

Access to controlled natural light is also important to provide a pleasant work space.

All laboratories should incorporate a flexible, modular design to ensure they are able to readily adapt to future changes. The modular approach should include:

- height adjustable, movable benches (i.e. not fixed to floors / walls) for easy reconfiguration as required;
- use of flexible pendant power, data and water supply from the ceiling;

- provision of multiple access points for trade waste / drainage;
- reinforced flooring for large equipment; and
- location of sinks and plumbing on the periphery of laboratories to optimise future flexibility.

The structural grid of the facility will be driven by the overall hospital design. The location of columns within the Pathology Unit will need to be considered to ensure they have minimal interference with the line of sight and functionality of the Unit.

Lean Thinking / Streamlined Workflows

Lean thinking principles can be applied to pathology services to ensure the planning of the Unit is underpinned by streamlined specimen workflows with elimination or reduction of unnecessary manual specimen transport between internal areas of the Pathology Unit. For example, high volume, time critical specimen processing such as chemical pathology and haematology specimens should be located as close as possible to the pre-analytical areas to facilitate priority specimen processing, unless an automated specimen delivery track system is provided.

Planning of Pathology Units should incorporate an analysis of workflows through the Unit to identify opportunities for improved efficiency.

For further information refer to:

- Hayes KJ, Reed N, Fitzgerald A and Watt V, 2014, Applying Lean Flows in Pathology Laboratory Modelling, Journal of Health Organization and Management, Vol. 28, No. 2 pp. 229-246.

Early Analysis of Projected Workforce and Equipment Requirements

The planning and design of Pathology Units is challenging due to the significant variation in the complexity and scope of services provided, service models, current and future activity levels, testing profile and equipment requirements. It is recommended that early planning processes incorporate detailed service modelling, including projected workforce and equipment requirements, to ensure accurate allocation of space and engineering services requirements.

Given the length of planning and design timeframes, it is often challenging to forecast the specific analysers that will be available on the market, however the following equipment requirements should be estimated to provide guidance on spatial and engineering services requirements.

- type of analyser;
- quantity required;
- location i.e. proposed pathology zone / specialised laboratory;
- approximate dimensions of unit and required clearance; and
- estimated engineering services requirements.

It is acknowledged that the actual analysers procured may vary and equipment will be replaced over time, and therefore provision of a flexible, modular design is essential.

Sufficient space should be provided to support the commissioning and/or trial of new equipment. During this time, both the existing and new analysers need to be accommodated. Large chemistry analysers can be up to 3-4m wide and 1-2m deep and will require an appropriate area with sufficient circulation to support commissioning of the analyser and associated staff training. Access to power, data and drainage is also required, with consideration of noise and heat generation.

Future Expansion

Future expansion strategies should be considered during the planning phase to meet future demand and technological advancements as outlined in Section 2.1.1 and to accommodate surges in demand.

Future expansion is particularly important for the core laboratory areas, given an increasing volume of tests are appropriate for this zone, and many analysers, particularly for chemical pathology, are increasing in size.

2.3.3 Configuration / Zones

It suggested that laboratories be organised into three flexibility zones (highly flexible, semi-flexible and least flexible) that correspond to technological requirements since the equipment is central to the function of the lab.

Analysis of the workflow suggests that organising the laboratory by technologies (e.g. automated versus manual processing, rather than by the traditional lab-specific departments) is an important consideration.

Highly Flexible Zone

The highly flexible zone, known as the core laboratory, comprises of clinical areas primarily using automated systems (e.g. chemical pathology, haematology and transfusion services) together with central receiving and processing areas. This area will process the majority of routine testing and accounts for approximately 75 per cent of the testing volume.

The instrumentation configuration will dictate the design of the core laboratory. The most frequently used automated systems should be physically located closest to centralised processing and receiving areas.

An open plan, modular design should be provided, as outlined in Section 2.3.2, to optimise future flexibility as the core laboratory is the area most susceptible to change. This is also the area where the most convergence of disciplines is occurring, in terms of equipment sharing and staffing expertise. As more automation and technology become available, more testing will move to the core laboratory. The design needs to support this change in function.

Second tier testing should be adjacent to the core laboratory (e.g. specialist coagulation or chemical pathology testing). Samples can be obtained from the core laboratory storage area when completed. This could be an automated storage unit attached to a track system.

Semi-Flexible Zone

The semi-flexible zone is focused on semi-automated and manual processing and includes those functions requiring a greater degree of enclosure such as microbiology, anatomical pathology and special laboratories.

For small to medium Pathology Units, limited microbiology services may be provided within the core laboratory. This would usually be accommodated within a bay, located in a less busy area of the core laboratory, with appropriate requirements such as a biological safety cabinet. These requirements would be based on the outcomes of a risk assessment.

The blood bank is commonly located in the semi-flexible zone, however for lower volume / lower complexity services, it may be located within the core laboratory.

The open plan core laboratory must extend into the semi- flexible zone to accommodate equipment that spans laboratory areas.

Least Flexible Zone

Staff work areas and amenities should be located on the periphery to avoid workflow disruptions and provide access by other staff and visitors. It is acknowledged that some will need to be close to laboratory areas to facilitate proper oversight and supervision of the laboratory.

Shared support areas (such as clean-up rooms) should be located adjacent to the central core to promote ready access from all laboratory areas.

2.4 FUNCTIONAL AREAS

2.4.1 Functional Zones

Functional zones are as follows:

- Outpatient specimen collection services (commonly located in an ambulatory care area)
- Pathology Unit:
    - specimen / visitor reception and pre-analytical zone;
    - laboratories;
    - support areas; and
    - staff areas.

2.4.2 Outpatient Specimen Collection Services

Outpatient specimen collection services are commonly located in ambulatory care zones for ease of patient access. However, for smaller services, specimen collection may be collocated with the Pathology Unit to support staff working across both areas.

An analysis of projected activity will inform the number of specimen collection bays / rooms required and associated support areas.

Key planning and design considerations include:

- provision of self-registration and queueing systems, depending on the size of the unit;
- staff oversight of specimen collection waiting areas. This is essential given glucose tolerance tests are commonly provided which can cause patients to faint or collapse;
- direct access to a toilet for urine and stool samples;
- comfortable waiting chairs given long waiting periods. For example, patients having glucose tolerance tests will need to wait for approximately two hours;
- consideration of additional bays in larger units for patients that may feel unwell or need to lie down between procedures;
- paediatric services will require consideration of paediatric friendly specimen collection rooms. This will include consideration of an enclosed room/s, access to a bed and chair (or combined treatment recliner), sufficient space for family to attend and an appropriate fit out that supports patient distraction.
- safety and security requirements based on the outcomes of a risk assessment and local jurisdictional policies. This will have implications for the design of the Unit, ensuring the design does not create entrapment or concealment points, as well as operational strategies such as the provision of mobile or fixed duress systems; and
- location of procedure rooms for bone marrow and fine needle aspirations, as well as venesections.

2.4.3 Specimen / Visitor Reception and Pre-Analytical Zone

A single location should be provided to accommodate the receipt of all specimens from all sources including the pneumatic tube system, couriers and other staff. The area should be easily visible / recognisable from the Unit entry and visible from within the Core Laboratory. However, access to the receiving area should not permit any unauthorised access to the Pathology Unit.

Depending on the operational arrangements in place, specimens may also be delivered after hours. This may require access to a small zone within the receiving area with appropriate refrigeration / warming storage.

The transfusion laboratory must also have an external reception to facilitate blood product dispatching which may also be located adjacent to the visitor and/or specimen reception area. The location of the transfusion external reception and dispatch area can vary depending on the layout of the Unit. 24/7 access is required for dispatch and receipt of large deliveries of products that may be required for immediate use or to be stored.

Once received, specimens will be registered and triaged at workstations prior to being transferred to the centrifuge area; held in racks ready for transfer to the appropriate laboratory area; or transferred to temporary storage awaiting transfer to a specialist laboratory.

The specimen reception area should be open to the rest of the laboratory for easy access by staff.

The pre-analytical area should provide for:

- identification and registration of specimens;
- sorting / triaging of urgent from routine specimens;
- distribution of specimens to the relevant internal laboratory;
- separate storage for specimens waiting to be forwarded to a specialist laboratory. This will require access to fridges and freezers;
- temporary storage for specimens received from external sources (for referral laboratories);
- safe storage of retained portions of specimens (aliquots);
- benches to accommodate centrifuges that are accessible to all areas of the core laboratory;
- immediate access to hand washing facilities and safety shower / eyebath; and
- ready access to staff amenities for after-hours staff.

2.4.4 Laboratories

The Core Laboratory will be continuous with the pre-analytical area to support rapid progression of specimens. The Core Laboratory will be open plan but zoned to provide functionally discrete areas for haematology, transfusion services and chemical pathology. For small to medium Pathology Units, limited microbiology services and the blood bank may also be provided within the core laboratory. Refer to Section 2.3.3 for further information. An area for morphology may be located on the periphery of the core laboratory area in a quieter or partitioned area to support the high levels of concentration required by staff.

Height adjustable, movable benches should be provided. For general laboratory work, standard laboratory computer workstations will require a 750mm deep bench. A 900mm deep bench will be required to accommodate larger high throughput bench-mounted testing equipment such as Coagulation and Full Blood Count Analysers.

The laboratories must be designed to comply with AS 2982: 2010 Laboratory Design and Construction. A typical rectangular module of three metres wide for an open plan laboratory will allow for a bench on two walls 750mm deep and a corridor space of 1400mm between facing benches. Refer to AS 2982: 2010 for further details regarding the minimum aisle widths.

The flow of work from initial specimen reception needs to be fully understood to ensure that all steps in the process are accommodated. Internal logistics and automated transport systems may be used to transport the sample within the Unit. These large open plan areas can generate significant noise and heat and both factors will need to be considered and managed during planning.

The need to physically confine a laboratory is based primarily upon the physical, chemical or biological hazards generated in laboratories including Microbiology, Anatomical Pathology and Virology / Serology laboratories. Where required, these laboratories must be physically separated by means of walls and doors, including air handling, from other laboratory work areas and may incorporate associated specialised areas for sterilisation and media preparation facilities.

The design of sub-areas that have special equipment or work processes requires consideration.

For example:

- fluorescence microscopes, where installed, need a small work area that can be completely darkened - either a dark room or inherent in the equipment itself;
- areas dealing with blood and blood products may require special construction to comply with TGA requirements (e.g. no visible joints, all timber fully sealed etc.); and
- access to a purified water source for the main chemical pathology analysers with appropriate water storage and waste amenities. Consideration will need to be given to the required water flow rates and filtration capacity.

Refer to Section 4.2 for more detailed design considerations relating to laboratory areas.

2.4.5 Support Areas

A range of support areas and equipment are required and should be centralised where possible.

These will include:

- Cool room;
- Bulk storage for consumables and may include clinical unit trolleys for phlebotomy services;
- Equipment store;
- Other store areas for blocks and slides and flammable liquids;
- Clean up area;
- Clean linen trolley/s and separate dirty linen skip/s;
- Waste holding;
- Access to a cleaner’s room

Other storage space will be decentralised within laboratory areas, including fridges, freezers and consumables storage.

2.4.6 Staff Areas

Staff work areas may be collocated in an administrative cluster with access to office supplies and equipment and readily accessible to authorised visitors. Some pathologists and senior scientists will however prefer to have workspace close to their area of clinical laboratory work. Write-up stations within the laboratories will therefore be required.

Meeting room/s, toilets and showers and the staff room / beverage bay will be collocated in a “Staff Only” zone with access by corridor and not through the laboratories. The staff room / beverage bay requires oversight of the core laboratory.

The allocation of staff work areas and amenities will be in accordance with jurisdictional policies.

Consideration must be given to ensuring that staff working after hours have ready access to necessary facilities such as toilets, beverage bays and office equipment without having to travel outside the immediate work area.

Also refer to AusHFG Part C: Design for Access, Mobility, Safety and Security.

2.5 FUNCTIONAL RELATIONSHIPS

2.5.1 External

Refer to Section 2.3.1. The priority service connection for Pathology Units is ED, as well as other critical care services such as ICU and operating theatres. This includes proximal access between operating theatres and anatomical pathology services (where provided) to support rapid analysis of frozen sections.

Direct access to a delivery / drop off zone for couriers is required, as well as ready access to the loading dock/s.

2.5.2 Internal

Transfusion services, haematology and chemical pathology areas will be collocated with specimen reception / pre analytical zone where the bulk of general work is carried out.

These services are generally arranged so that transfusion services have external access for blood product dispatching and are collocated with haematology, given staff commonly work between these two services. There is also a relationship between haematology and chemical pathology services so these areas should also be collocated.

All laboratory areas will have ready access to support and staff areas, to minimise staff travel distances.

The staff room / beverage bay should be located to provide direct oversight of the core laboratory.

Administrative work areas should be easily accessible to visitors without accessing any laboratories.

03 DESIGN

3.1 ACCESSIBILITY

3.1.1 External

The following requirements and issues need to be considered:

Access for Couriers

Access for couriers from the local pathology service, the Australian Red Cross Blood Transfusion Service and/or outside laboratories. This access includes short-term parking bays for vehicles in close proximity to facilitate the drop-off / pick-up of specimens and supplies. Access pathways and issues for out-of-hours courier deliveries direct to the Pathology Unit needs to be considered.

Movement of Materials

The movement of materials and equipment to and from the loading dock includes:

- a broad range of supplies (e.g. large boxes of consumables, flammable liquids and reagents, Dewar tanks of liquid nitrogen). Where supplies are delivered directly to the Unit, they may be placed in a central storage zone or distributed to individual laboratories. Provision should be made for container collection by suppliers e.g. gas cylinders. This may involve either a local or a central collection facility;
- waste disposal with centralised waste holding areas (Disposal Rooms) being located on the periphery of the Unit so waste can be removed without the need to pass through laboratory areas; and
- access for equipment. Some chemical analysers are extremely large, consequently installation service and equipment replacement issues need consideration early in the design phase.

Staff and Public Access

While the Pathology Unit will be a staff only area, the public will need access to specimen collection areas. These should be easily accessible to facilitate the high volumes of service.

Staff will gain access to the Unit via the main entrance or a separate staff entrance. Any additional access points will increase the Unit's security requirements. Separation of staff from public areas must ensure staff security, particularly if working out-of-hours.

3.1.2 Internal

The Pathology Unit design needs to ensure that internal paths of travel accommodate the safe movement of staff, specimens and equipment.

3.2 PARKING

The delivery of specimens should be supported by an adequate number of short-term spaces with time limits not less than the delivery time required.

For information regarding staff parking, refer to Part C: Design for Access, Mobility, Safety and Security.

3.3 DISASTER PLANNING

The Unit must have plans in place in case of disaster. For further information refer to AusHFG Part B: Health Facility Briefing and Planning and Part C: Design for Access, Mobility, Safety and Security.

3.4 INFECTION CONTROL

Pathology Units require special consideration in respect of infection control.

On a daily basis, Pathology Units deal with potential sources of infection such as:

- a broad range of body tissue / fluid specimens; and
- the growth of living pathogens which, themselves, are capable of causing infection.

It is essential that the design contributes to the prevention and control of infection and incorporates:

- a layout to minimise cross-contamination between laboratories and work areas;
- efficient work-flow design and detailing;
- suitable materials and finishes;
- adequate numbers and location of hand wash basins;
- appropriate cleaning, waste storage and disposal facilities;
- effective specimen storage facilities; and
- first aid facilities (Refer to NATA / RCPA :Requirements for registration: medical testing).

Additionally, for those areas that grow organisms and handle known infectious materials, the design must include:

- appropriate isolation of space and ventilation systems which present potential hazard (see Australian Standard AS 2982: 2010); and
- provision of effective extraction apparatus to specific equipment items such as biological and chemical safety cabinets and to specimen storage, temporary holding and disposal systems.

Refer to jurisdictional infection control policies for further details, and to:

- Part D: Infection Prevention and Control;
- National Association of Testing Authorities, Australia (NATA), National Association of Testing Authorities, Australia (NATA); and
- Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.

3.5 ENVIRONMENTAL CONSIDERATIONS

3.5.1 Heat Generation

Heat generation is a significant issue in laboratories which needs to be managed through air handling systems to ensure that accurate specimen testing results are provided. This heat is generated from staff, computers and equipment such as instruments, fridges and freezers.

3.5.2 Acoustics

Noise is a major issue in laboratories and should be a major consideration during planning and design. Core Laboratories are generally open plan and accommodate staff and equipment. This arrangement can generate significant and constant noise. The design should aim to reduce the impacts of this noise on staff and create a pleasant and productive work environment.

Some equipment items generate significant noise (e.g. refrigerators and freezers). Where possible, these items should be positioned in locations that are accessible by staff but separate, to reduce the impact of this noise.

Some areas, such as administration and office areas, may be carpeted.

3.5.3 Natural Light

Controlled natural light is desirable to provide a pleasant working environment for the staff, however, direct sunlight onto benches and equipment should be avoided not only to minimise glare to staff but also because some chemicals may become unstable, or their properties altered, if exposed for extended periods. Some equipment may also be unsuitable or intolerant to direct sunlight. Refer to Section 3.10.8 for further information.

3.6 SPACE STANDARDS AND COMPONENTS

3.6.1 Ergonomics and Human Engineering

Human engineering covers aspects of the design that permit effective, appropriate, safe and dignified use by all people, including those with disabilities. It includes occupational ergonomics, which aims to fit the work practices, fixtures, fittings and equipment (FF&E) and work environment to the physical and cognitive capabilities of all people.

In the case of office and laboratory areas, access to height adjustable benches and workstations should be considered where staff are working for prolonged periods of time.

Most bench top equipment will be located flush to the edge of the bench for easy use.

For further information refer to Part C: Design for Access, Mobility, Safety and Security.

3.6.2 Doors, Windows and Corridors

Subject to the appropriate building and fire codes, for the purpose of this HPU, it is suggested that minimal doors are provided between the laboratory areas. Doors to enclosed laboratories must be sized to accommodate the equipment to be installed. Standard doors may not always be large enough especially if lifting equipment or large trolleys are required for transport.

Day / sun light control may be achieved by means of appropriate window coverings and consideration of placement of benches and equipment depending on the location of windows and orientation of the building (refer to Section 3.10.8).

For further information refer to AusHFG Part C: Design for Access, Mobility, Safety and Security.

3.6.3 Placement of Equipment

Project staff will need to itemise the various items of equipment, particularly floor-standing equipment to ensure it can be suitably housed. This will require early input from the pathology service regarding projected equipment requirements, including engineering services requirements.

Adequate space for maintenance of any major equipment must also be considered.

Technology in pathology is constantly changing with large equipment items often replaced by bench-top units and conversely, multiple smaller equipment items being replaced with large processing instruments. Where possible, the provision of a flexible, modular design should be provided to accommodate changes in requirements over time.

Sufficient space should be provided to support the commissioning and/or trial of new equipment. Refer to Section 2.3.2.

The Unit will need to accommodate further replacement of major instrument platforms. A new instrument needs to be installed and correlated before the old instrument is removed.

3.7 SAFETY AND SECURITY

3.7.1 Safety

Corrosive, toxic, flammable, infectious, pathogenic materials are handled in the Unit and effective levels of health and safety must be maintained (NPAAC – Requirements for Pathology Laboratories).

Safety issues to be considered when designing a Pathology Unit include:

- provision of non-slip flooring materials for areas where floors are subject to water and chemical splashing and paraffin / wax spills;
- installation of effective extraction units for the removal of toxic fumes (particularly formalin);
- provision of sealed centrifuge units for protection against aerosols;
- inclusion of biological safety cabinets;
- adequacy and location of collection and holding system for sharps, contaminated waste and soiled linen;
- appropriate disposal of fluids a) into sewage system or b) by off-site high temperature incineration;
- appropriate location and number of emergency shower and eyewash facilities relevant to laboratories;
- appropriate handling and storage facilities for flammable and highly explosive substances including fire blankets, fire hoses, fire extinguishers (refer to Section 3.10.5); and
- appropriateness of equipment used in specimen collection (e.g. use of reclinable chair in anticipation of patient feeling faint during blood withdrawal and provision of resuscitation equipment).

Also refer to Section 3.7.5 for details regarding risk / hazard management, local occupational health and safety (OHS) policies and procedures and to:

- National Pathology Accreditation Advisory Council (NPAAC), 2007, Requirements for Pathology Laboratories (2007 Edition);
- Standards Australia, 2010, AS/NZS 2243.3: 2010 Safety in laboratories; and
- New Zealand, Hazardous Substances (Exempt Laboratories) Regulations 2001, under the Hazardous Substances and New Organisms (HSNO) Act.

3.7.2 Formaldehyde

Formaldehyde is classified as a known human carcinogen by the International Agency for Research on Cancer (IARC) and there are specific workplace controls required to meet the associated exposure standards.

The recommended workplace controls in relation to formaldehyde include:

- use of local exhaust ventilation at each specimen station;
- relocation of specimen vats to areas with isolated ventilation or use of local exhaust ventilation over vats;
- avoiding the need for dilution of concentrated formalin products by purchasing diluted formalin products; and
- ensuring effective ventilation, especially in areas where formaldehyde levels may be high, such as exhaust ventilation in storage areas, and down draught arrangements at dissection areas.

Workplace Exposure Standards (WES) are provided by Safe Work Australia and WorkSafe New Zealand. Current requirements relating to the permissible exposure to formaldehyde must be referred to given anticipated changes to the WES-TWA (time weighted average) exposure limits. This will impact on the facility design and engineering services required to meet these standards.

3.7.3 Flammable and Combustible Liquids

Health services will usually have a central bulk storage area for flammable and combustible liquids. Only small quantities of these materials will be held within the Pathology Unit. Storage requirements depend on quantities stored.

Refer to AS 1940:2017 - The storage and handling of flammable and combustible liquids, which provides requirements for the planning, design, construction, and safe operation of all installations in which flammable or combustible liquids are stored or handled.

3.7.4 Security

Security must encompass the physical well-being of staff and the integrity of specimens, equipment and patient information. The design for the Unit will essentially involve controlled access on a 24-hour basis. Issues requiring further consideration include:

- security of the Unit for staff working after hours;
- authorised access to emergency after-hours blood storage facility; and
- provision of a duress alarm system. This needs to consider the mobility of pathology staff to determine whether a fixed or mobile system is required.

Location of computer terminals should be such that the public cannot readily read the screen, especially at reception points.

Access control may be achieved through the provision of minimal access points and electronic door controls.

3.7.5 Risk / Hazard Management

The physical environment has a significant impact on the health and safety of staff. A risk management approach ensures risks are managed systematically utilising a process that supports the anticipation, identification and avoidance of risks that may have an impact on users and services.

Broad consultation with all stakeholders and other identified processes may be utilised to identify risks according to the availability of expertise to ensure security, health and safety risks are proactively managed. Individual jurisdictions should refer to their local legislation for further requirements for plant and buildings. Work Health and Safety (WHS) legislation requires designers to identify, assess and control risks in order to provide an optimal ergonomic design and to do this in consultation with stakeholders.

3.8 FINISHES

Refer to AusHFG Part C: Design for Access, Mobility, Safety and Security for general information relating to finishes. Considerations specific to pathology services are noted below.

3.8.1 Wall Protection

Walls must be washable, impermeable and non-porous.

3.8.2 Floor Finishes

Floor wastes, where installed, should not be graded as this impedes easy movement of equipment and mobile benches; rather grids should be located at door entries if overflow can be expected. In “wet” areas where floor hosing may occur, wastes should be located in the far corner of the room.

Slip resistant flooring will be required in Anatomical Pathology owing to the potential for paraffin and wax spills. In addition, the colour of the flooring will need to contrast with the colour of the wax so that staff can easily identify spills. This will complement the use of other strategies to control slips including footwear and safety mats.

Where a floor surface is part of a containment area for spills, as is required in flammable and corrosive store rooms, a drop-down floor may be required rather than bunding.

3.8.3 Ceiling Finishes

Ceilings must be washable, impermeable and non-porous. Consideration needs to be given to ceiling finishes in significant negative pressure areas such as PC3 laboratories.

3.9 FIXTURES, FITTINGS & EQUIPMENT

3.9.1 General

Refer to Room Data Sheets (RDS) and Room Layout Sheets (RLS) for further detailed information and to Part C: Design for Access, Mobility, Safety and Security.

3.9.2 Laboratory Furniture

Modular furniture, adjustable height tables, and mobile units are recommended so that workstations and equipment can be removed or reconfigured as technological processes change. The laboratory should have little or no fixed joinery. Refer to Section 2.3.2.

Furniture must be washable and impermeable / non-porous to avoid contamination.

Project staff are recommended to refer to Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.

3.9.3 Fume Cupboards and Safety Cabinets

Fume cupboards and safety cabinets should comply with the following standards:

- Standards Australia, 2009, AS/NZS 2243.9:2009 Safety in laboratories - Recirculating fume cabinets;
- Standards Australia, 2009, AS 2252.2: 2009 Controlled environments - Biological safety cabinets Class II - Design ;
- Standards Australia, 2010, AS 2252.4: 2010 Controlled environments - Biological safety cabinets Classes I and II - Installation and use;
- Standards Australia, 2011, AS 2252.3: 2011 – Controlled environments – Biological safety cabinets Class III – Design;
- Standards Australia, 2011, AS 2252.6 2011 Controlled environments - Clean workstations— Design, installation and use; and
- Standards Australia/Standards New Zealand, 2014, AS/NZS 2243.8 Safety in laboratories: Fume cupboards.

3.9.4 Refrigeration / Freezer Needs

The laboratory will require a range of walk-in cool rooms and/or refrigerators and freezers.

Where cool rooms are provided electrical and mechanical redundancy is recommended to mitigate the risk of losing stock. Refrigerators, cool rooms and freezers must have continuous temperature monitoring and alarms.

3.9.5 Safety Showers and Eye Washes

At least one safety shower and eye wash or eye / wash facility is required in each laboratory where hazardous substances are used.

Eyewash equipment should permit a constant flow of water without requiring one hand to hold open the tap / valve.

For details regarding safety shower and eye / face wash equipment location, refer to Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.

3.9.6 Decontamination and Sterilization

Sterilizers are not generally required in Pathology Units unless they are needed to support highly specialised laboratories or when media is produced in-house. Instead, decontamination of reusable equipment is required. Should items require sterilization, they should be processed through the Sterile Supply Unit.

It is likely that waste will rarely be sterilized prior to disposal and will instead be “streamed” into approved bins and removed by waste management staff.

3.9.7 Equipment - General

All equipment should be itemised and located during the design phase to ensure that:

- the necessary space is provided for its operation and maintenance;
- the necessary services are available with appropriately located connection points;
- doors are sized to accommodate the passage of equipment;
- heat loads are estimated and catered for;
- weight loads are estimated and checked structurally; and
- the need for special anti-vibration benches can be assessed.

3.10 BUILDING SERVICE REQUIREMENTS

3.10.1 General

High cost engineering systems requiring careful consideration by design teams include:

- the number of sanitary fittings and the potential for reducing these by strategic location;
- extent of the required emergency and uninterrupted power supply (UPS) and the necessary cabling and power outlets;
- provision of essential back-up systems (e.g. air handling system fans to maintain the required pressure regime); and
- the need for and the cost benefit / implications of a pneumatic tube system.

3.10.2 Air-Conditioning / Ventilation

As outlined in Section 2.3.2, identification of all major pathology equipment requirements at the commencement of the planning process is critical for informing engineering services, including Heating, Ventilation and Air Condition (HVAC), requirements. The design of HVAC systems for pathology will need to be tailored to the specific functions of each area, to the heat load from machines, and to minimising temperature variation. Operating hours may also influence requirements.

Air-conditioning should be provided both for human comfort and to minimise variation and fluctuation of temperature and humidity for sensitive equipment, especially in the blood storage areas.

Each type of laboratory should be evaluated in terms of the permissible amount of air recycling. For instance, anatomical tissue processing rooms and microbiology PC3 rooms require 100 per cent exhaust to the atmosphere. In addition, the required pressure regime and air movement direction must comply with AS 1668.2

Air intake filters must not be contaminated by expelled air or fumes.

Special attention to ventilation will be required in areas generating aerosols, dangerous fumes or noxious odours. The risks associated with asphyxiant gas leaks require a planned management system of ventilation.

Detail of requirements should be ascertained via discussion with the client and by reference to:

- Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction
- Standards Australia, 2012, AS 1668.2: 2012 The use of ventilation and air-conditioning in buildings - Mechanical ventilation in buildings.

3.10.3 Gases

The following gases may be required in the Unit, depending on services provided:

- special gases to fuel or calibrate instruments (e.g. special mixtures of oxygen, nitrogen and carbon dioxide for calibration of blood gas analysers, nitrogen to purge air from certain systems, carbon dioxide or nitrogen used in certain incubators);
- high purity gases such as nitrogen, argon and helium for High Performance Liquid Chromatography (HPLC) and trace metals laboratories;
- special mixtures of nitrogen / carbon dioxide / hydrogen used for anaerobic incubators in microbiology; and
- compressed air for some laboratories such as HPLC and trace metals. Compressed air may also be a requirement for the operation of sterilizers and for robotic sample handling systems.

Gases other than town gas may be provided via a reticulated system or by cylinders. A reticulated system affords significant advantages in safety, convenience and often economy. Cylinders can create a laboratory hazard due to difficulty in moving or replacing and are generally discouraged under the Laboratory Safety Codes.

If piped gas systems are considered, especially with high purity systems, a specialised gas consultant should be engaged in the design of the reticulated gas system as special pipework, soldering / braze welding and monitoring systems are required.

Issues to be considered with a reticulated gas system include:

- alarm systems to identify a gas leakage in the laboratory;
- monitoring of supplies;
- emergency cut-off;
- purity of gas required at the outlet; and
- pressures to be delivered at the outlet.

Whether piped or provided from local cylinders, the risk of gas leakage and concentration build-up must be managed by ventilation systems. The storage quantity requires confirmation to determine risk levels in line with dangerous goods (storage and handling) regulations.

3.10.4 Electrical Services

Electrical wiring and services installations serving all laboratories should comply with relevant Australian / New Zealand Standards (see below).

Ducts for power cabling should ideally be brought in vertically from the ceiling and not run horizontally above benches as they can clutter; nor from the floor as this restricts future changes. In general, all services should be contained within the floor-to-roof area to facilitate future change with minimal disruption to adjacent areas. It is essential that sufficient power and data points are provided with the flexibility to support future changes to the Unit.

The placement of safety showers and eyewash stations must be situated to comply with required travel distance. Care must be taken to ensure this does not lead to conflict with electrical fixtures. Uniform, low glare lighting is required for staff comfort.

UPS to critical items of equipment will be needed, acknowledging that many modern laboratory instruments have built-in UPS.

Electrical wiring and services installations serving all laboratories should comply with the requirements of the relevant authority and with Standards Australia, 2018, AS/NZS 3000:2018 Electrical installations (known as the Australian / New Zealand Wiring Rules).

3.10.5 Fire Safety

Pathology laboratories present particular concerns in relation to fire. Issues for consideration include:

- storage, decanting and use of highly inflammable liquids and/or gases;
- the presence of open flame equipment and hot surfaces;
- exhaust facilities to disperse flammable vapours;
- disposal of contaminated solvents;
- separation between hazardous reagents;
- travel distances in respect of fire egress (refer to the BCA);
- safety standards in respect of installation of electrical equipment;
- the need to grade each room's activities so that the most potentially dangerous are sited furthest from the exits; and
- adequate separation between laboratories and egress passages and other areas. (AS 2982: 2010 and the Australian and New Zealand Building Codes).

Fire safety equipment will include extinguishers, blankets and hoses in accordance with BCA and laboratory safety requirements.

For further information, refer to Australian and New Zealand Building Codes, and to:

- Standards Australia, 2010, AS/NZS 2243.3: 2010 Safety in laboratories; and
- Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.

3.10.6 Hydraulic Services

The quality of the water required in the area will vary according to use:

- domestic (potable water) to showers, hand basins and beverage bays; and
- purified water for laboratory use. This may be provided through reverse osmosis units, filtered water or deionised water systems. A study of the most appropriate water purification system will need to be undertaken.

Consideration should be given to locating the water services on the perimeter of the Unit thus leaving the central area free of floor penetrations. This will assist with any future design changes.

The location of the power outlets relative to water outlets must be considered to ensure that electrical standards are met.

The design of the hydraulic systems should ensure that spillage of hazardous or other waste will not flow through the floor penetrations.

Durable, non-corrosive, chemically inert piping should be selected for all the laboratory areas to avoid distortion, swelling and softening.

For large units that produce high volumes of blood waste, consideration should be given to options to flush drainage systems to avoid blood congealing. This is particularly important for high volume chemistry departments.

Safety shower / eye wash will be required (refer to Section 3.9.5).

3.10.7 Information Technology / Communications

Information and communication systems considerations include:

- wireless technology;
- radiofrequency identification (RFID) for access control and equipment management/ tracking including pneumatic tube cannisters;
- voice and data for telephones and computers;
- integrated pathology systems that will include electronic ordering and reporting and bar coding for sample identification and tracking;
- digital pathology and data storage including cloud-based systems;
- security systems such as fixed duress;
- alarm systems where necessary to monitor equipment such as refrigerators and freezers; and
- teleconferencing / telepathology facilities.

As with power, cabling ducts should ideally be brought in vertically from the ceiling and not run horizontally above or along benches.

Telepathology is the process of transmitting digital images (real time video or still) over telephone lines or a local / wide area network (LAN / WAN) and requirements need to be addressed during early planning stages.

3.10.8 Light - Glare and Heat Minimisation

Glare and solar heat is a significant issue in laboratories where the outside windows are large and where either direct sunlight or reflected sunlight can enter the laboratory. Planners and designers need to consider effective glare and heat minimisation strategies. The utilisation of large volumes of constant southern light without direct sun exposure is a useful design feature.

Consideration must be given to the changing path of the sun between winter and summer and recognise that in laboratories that operate over extended hours, staff may be operating equipment at sunrise and sunset when direct sunlight entering the building is difficult to eliminate without external louvers. Morning (eastern) sun exposure is preferable to western sun.

Tinting is not always effective and solar-type blinds that still admit light only minimise the problem. Consideration must be given the colour and transmittance of the glazing and blinds to address solar penetration.

3.10.9 Pneumatic Tube System

For smaller hospitals, direct access should be provided between the Pathology Unit and ED. Where this is not possible, such as in larger hospitals, a pneumatic tube system (PTS) should be provided, as well as providing close proximity between ED and Pathology. Refer to Section 2.3.1.

Depending on the complexity and number of stations in the PTS, delivery of a sample to the laboratory from clinical units can take several minutes. This delay needs to be factored in to the design of the PTS especially in relation to ED and ICU where short turnaround times are required.

During planning and design, it will be necessary to understand the range of samples to be transported using a PTS so that tube diameter is adequately sized. A diameter of 110mm is generally considered adequate.

Radiofrequency identification (RFID) should be considered to track cannisters through the system and redundancy requirements will need to be addressed.

3.10.10 Trade Waste

Special attention must be directed to the plumbing and drainage systems and they must be at a minimum, designed to be compliant with local government authority requirements.

Information on the quantity of chemicals to be used / discharged must be provided by the health service to the hydraulics engineer. Pre-treatment facilities may include dilution, pH adjustment and holding tanks.

04 COMPONENTS OF THE UNIT

4.1 STANDARD COMPONENTS

Rooms / spaces are defined as:

- standard components (SC) which refer to rooms / spaces for which room data sheets, room layout sheets (drawings) and textual description have been developed;
- standard components – derived rooms are rooms, based on a SC but they vary in size. In these instances, the standard component will form the broad room 'brief' and room size and contents will be scaled to meet the service requirement; and
- non-standard components which are unique rooms that are usually service-specific and not common.

The standard component types are listed in the attached Schedule of Accommodation.

The current Standard Components can be found at: www.healthfacilityguidelines.com.au/standard-components.

4.2 NON-STANDARD COMPONENTS

4.2.1 Pre-Analytical Zone

Description and Function

This space provides for the sorting, triaging, registering and temporary storage of specimens arriving for analysis.

The space will also be used for the storage of specimens awaiting transfer to other facilities and labs and the packaging of such specimens.

Functions and activities of the area include:

- receipt of specimens from collection area/s, clinical units and outside agents by delivery or pneumatic tube;
- identification and registration of specimens;
- sorting / triaging of specimens;
- distribution of specimens to the relevant internal laboratory;
- temporary storage of specimens including safe storage of retained portions of specimens (aliquots);
- separate storage for specimens waiting to be forwarded to a specialist laboratory. This will require access to fridges and freezers;
- packaging of specimens for transfer, if applicable; and
- centrifuging specimens.

Location and Relationships

This area should be located adjacent to and continuous with the Core Laboratory, and also allow for ease of access for internal and external delivery services. The space is functionally related to all laboratories.

Direct access to staff amenities must be provided for afterhours staff.

Considerations

The integrity of specimens, the confidentiality of patient information and the physical security of personnel are essential.

The use of automated systems to move samples from this zone through to the laboratory will need to be assessed as this may impact on the arrangement of space.

Sufficient space will be required for:

- workstations including computers and scanners;
- shelving / wall fixtures to support specimen baskets, trays, racks;
- storage for eskies;
- hooks for protective clothing;
- refrigerator;
- freezer;
- bench for centrifuges;
- waste;
- hand basin;
- stainless steel sink for clean-up purposes; and
- immediate access to a safety shower / eyebath.

4.2.2 Laboratory - Core

Description and Function

The Core Laboratory is an open plan area consisting of modular units of equal size that will adapt to future changes of use and technology. It comprises of pathology disciplines primarily using automated systems together with central receiving and processing areas.

The Core Laboratory will typically include:

- Transfusion and blood product management;
- Full blood counts / morphology;
- General coagulation;
- General chemistry assays;
- Serology;
- Specimen Storage;
- Rapid Nucleic Acid Amplification Test – critical microbiology (optional depending on service requirements);
- Blood cultures – critical microbiology (optional depending on service requirements); and
- Point of Care Testing support (optional depending on service requirements)

Transfusion Services

Description and Function

Key functions and activities include:

- grouping of recipients' blood;
- cross matching recipient and donor blood;
- testing patient blood by manual or automated means;
- requesting supplies of blood and blood products;
- receiving blood supplies and blood products;

- storing cross matched blood (separate from un-cross matched);
- storing un-cross matched blood; and
- reporting on results (written or verbal).

Considerations

Key facility requirements include:

- entry for blood product delivery that accommodates large trolley loads of deliveries in large facilities;
- a dedicated hatch that hospital staff will access to pick-up blood products which will include a doorbell or intercom notification system;
- flexible benches with access to workstation/s and computer/s and a range of analyser/s;
- rear access to the analysers to complete regular servicing requirement;
- discrete laboratory work space to complete more complex specimen testing;
- a bench top water bath with access to a sink and a free-standing and/or bench top platelet shaker machine as required;
- a blood product fridge / freezer (cool room) area containing sufficient room to house the multiple blood bank fridges and freezers. This area will require appropriate ventilation to accommodate the heat generated from the fridges and freezers. The fridge used to issue blood products to clinical areas will be located closest to the dispense hatch; and
- connection of all blood fridges and freezer to the Building Management System (BMS) and emergency power.

Haematology

Description and Function

The haematology service will undertake limited investigation of the blood and its disorders. These specific services include:

- core haematology (FBC and blood films);
- coagulation; and
- blood film interpretation, reading and report.

Considerations

Key facility requirements include:

- flexible benches with access to workstation/s and computer/s and a range of analyser/s;
- an integrated Full Blood Count Analysers system. Depending on the size of the Unit, this may include slide maker, stainer and digital morphology;
- other analysers including coagulation analyser/s, shall be positioned to improve specimen workflow and result turnaround times. Generally, each analyser will have a dedicated computer supporting analyser activities;
- rear access to the analysers for regular servicing requirements; and
- fridge and freezer storage, including -80°C storage (could be a shared central cool room).

Morphology

Description and Function

A discrete morphology area towards the periphery of the core laboratory area is required to support morphology activities. The size will be scalable to activity.

Requirements include height adjustable workstations with computer screen and microscopes located in a quieter area of the lab or partitioned, to support the high levels of staff concentration needed. Digital morphology requirements should also be considered and where provided, at least two monitors will be required.

Larger sites may require a larger separate space for multi-header microscopes and/or large screen/s for the reporting, teaching and multidisciplinary team meetings (MDTs). These functions may be located closer to the staff administration areas.

Chemical Pathology

Description and Function

Key functions and activities include:

- centrifuging specimens;
- blood gas analysis;
- chemical analysis of specimens;
- 24-hour laboratory service for acute emergency care and investigative medicine;
- supervision of complex and dynamic biochemical tests;
- ensure that processing and data registration of tests is completed on all samples;
- use of instruments that ranges from complex platforms to point of care devices; and
- reporting and dispatching of results from the laboratory computer system.

Considerations

Key facility requirements include:

- flexible benches with access to multiple workstations and computers and a range of analysers;
- flexible specimen triage zone for miscellaneous testing;
- modular chemical pathology analysers that may be linked by a track system at larger sites, requiring sufficient space to accommodate growth and expansion of these analysers into the future;
- access to a purified water source and appropriate water storage and waste amenities;
- rear access to the analysers to complete regular servicing requirements;
- location of less common, more manual and specialised chemical testing towards the periphery of the Chemical Pathology area;
- storage of specimens when testing is complete. This may be undertaken automatically via a track / automated robotics system or stored manually; and
- fridge and freezer storage including -80°C storage (could be a shared central cool room).

As technology evolves, personalised pathology such as proteomics and metabolomics may require dedicated laboratory spaces outside of core chemistry spaces. These new pathology services will have high pathologist involvement requiring space, bioinformatics and multidisciplinary collaborations.

Critical Microbiology (microbiology services appropriate for locating in the core lab)

Considerations

Key facility requirements include:

- locate on the periphery of the core laboratory, away from high throughput areas;

- open area with flexible benches with access to multiple workstations and computers and a range of analysers;
- biological safety cabinet;
- microbiology reagents and culture media, which are large and bulky and will require extensive dedicated cold and dry storage areas; and
- microbiology samples require prolonged storage at various temperatures and so extensive room temperature, fridge temperature, freezer temperature and -80°C temperature storage will be required.

Point of Care Testing Support

Description and Function

Larger pathology services will include a dedicated area to support the regular testing and routine maintenance of PoCT analysers.

Considerations

The PoCT support area will include benches for analysers with access to power and data, and PC access. All analysers will need to be interfaced with hospital ICT systems.

Access to refrigerated storage within the core laboratory will be required.

4.2.3 Laboratory – Microbiology (specialist enclosed laboratory)

Considerations

Key facility requirements include:

- microbiology testing will continue to require higher level of microbiological containment, and protection from environmental contamination and so should be partitioned away from the Core Laboratory as a certified PC2 laboratory at a minimum;
- larger sites will require a PC3 containment laboratory to cater to high level pathogen testing such as for Mycobacterium tuberculosis, and so that new and emerging pathogens can be dealt with in a safe environment for all pathology and clinical staff;
- dedicated cool room and incubators for culturing purposes are required;
- specialist areas within microbiology including parasitology, mycology, virology and mycology do not require direct access to the pre-analytical area and so can be located towards the back of the department;
- access to medical gases and to high pressure oil-free air is required to run various robotic instruments;
- stainless steel sinks are required;
- access to areas for decontamination (autoclaving) and disposal of infectious waste and for limited preparation of sterile laboratory reagents and equipment are required; and
- consideration should be given to automated door access.

4.2.4 Laboratory - Anatomical Pathology

Description and Function

Macroscopic and microscopic examination of tissue specimens (microscopy is normally done in the Pathologist's office).

This service does not operate on a 24/7 basis but does commonly operate extended hours. Frozen sections may be performed in an on-call capacity after hours.

Specimens are received, recorded, prepared and reported on following their examination.

For hospitals undertaking post mortem examination, tissue will be forwarded to the main Regional / Area laboratory for processing and reporting.

Considerations

Key facility requirements include:

- Anatomical Pathology testing will require a higher level of containment to control exposure to department processing fumes and needs appropriate ventilation to support tissue processing areas including specimen cut-up work areas;
- Larger Units will include the following areas: cut-up room, tissue processing room, cytology preparation area, embedding / microtomy area, staining area, cytology screening room and support areas;
- Frozen Section Services will be done within the department, assuming close proximity to theatres;
- Consideration of solvent recycling facilities should be included to reduce solvent water and its associated costs. This should be located in the tissue processing room. WHS risks associated with manual handling associated with solvents must be considered to reduce the risk of injury;
- Separate HVAC control, with the temperature maintained at 18^{o}C - 22^{o}C; and
- Slip resistant flooring with appropriate colour choice is required to mitigate the risk of falls associated with wax spills (refer to Section 3.8.2 for further information).

4.2.5 Emergency Shower / Eye Wash

Description and Function

Deluge shower and eyewash facility will be required in case of blood or chemical spillage or contamination. To ensure the best utilisation of space, consideration should be given to placing the deluge shower adjacent to a hand wash basin.

Location and Relationships

Locate in central easily accessible position or if separate laboratories, one in each laboratory. Determination and number of emergency showers and eyewash stations should be in accordance with Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.

05 APPENDICES

5.1 SCHEDULE OF ACCOMMODATION

Indicative Schedules of Accommodation (SOA) for a Pathology Unit are provided in the following tables. The recommended area allocations for specimen collection services are included separately given they are frequently provided in ambulatory care / hospital outpatient areas (separate to the Pathology Unit).

The area recommendations for the Pathology Unit are based on three scenarios as described below.

Area allocations are indicative only and will need to be adjusted, in consultation with the local pathology service, to suit the scope of services being delivered, networking arrangements and unit location, the volume of activity, level of automation being implemented, and the required staffing profile.

- Scenario 1: Pathology Unit within a Small Hospital – this scenario relates to Australian Hospital Peer Group C hospitals, and Level 3 pathology services as per the NSW Health Guide to the Role Delineation of Clinical Services (2019). It is assumed that basic haematology, transfusion services and chemical pathology services only are provided.
- Scenario 2: Pathology Unit within a Medium Hospital – this scenario relates to Australian Hospital Peer Group B hospitals, and Level 4 pathology services as per the NSW Health Guide to the Role Delineation of Clinical Services (2019). The Unit will provide core laboratory services and may provide microbiology and limited anatomical pathology (frozen sections).
- Scenario 3: Pathology Unit within a Large Hospital – this scenario relates to Group A Hospital Peer Groups and Level 5 pathology services as per the NSW Health Guide to the Role Delineation of Clinical Services (2019). The indicative area allocations align with a major regional referral hospital, as the 'hub' of a pathology network, providing specialised services for smaller laboratories across the network. It will provide a comprehensive range of pathology services and support for clinical trial and research activities. Pathology Units within major regional hospitals often provide a broader range of services than Units within major metropolitan hospitals given the distance to higher level laboratories within metropolitan areas.

Due to the complex nature and specialisation of higher level Pathology Units, e.g. within Principal Referral Hospitals, they are not included in the scenarios below. Area requirements will need to be developed on a project by project basis to reflect the range of services / specialist laboratories provided, role within the network and associated equipment and workforce requirements. For state-wide referral laboratories, it is recommended that early planning should assume a minimum area requirement of 5,000m2.

The 'Room / Space' column describes each room or space within the Unit. Some rooms are identified as 'Standard Components' (SC) or as having a corresponding room which can be derived from a SC. These rooms are described as 'Standard Components –Derived' (SC-D). The 'SD / SD-C' column identifies these rooms and relevant room codes and names are provided.

All other rooms are non-standard and will need to be briefed using relevant functional and operational information provided in this HPU.

In some cases, Room / Spaces are described as 'Optional' or 'o'. Inclusion of this Room / Space will be dependent on a range of factors such as operational policies or clinical services planning.

5.1.1 Outpatient Specimen Collection

Outpatient specimen collection services may be located within an Ambulatory Care / Outpatients Department or collocated with the Pathology Unit. For small pathology services, specimen collection is typically located with the Pathology Unit to facilitate staffing efficiencies with staff working across both areas, however for larger pathology services, specimen collection is typically located with ambulatory care for ease of patient access.

The SOA below assumes the provision of a two to three bay specimen collection unit. Optional area requirements for enclosed specimen collection rooms, e.g. to support paediatric services, are noted. A range of additional optional areas are included, however these would only be required for larger services where the activity justifies dedicated support areas rather than sharing with adjacent units.

Access to staff amenities, including lockers and toilets will be required, and is assumed to be shared with an adjacent department within the scenario below.

AusHFG Room Code	Room / Space	SC / SC-D	Qty	m2	Remarks
WAIT-10	Waiting	Yes	1	8	
RECL-10	Reception / Clerical	Yes	1	10 (o)	Optional. May be shared with adjacent service.
BMFD-3	Bay - Multifunction Device	Yes	1	3 (o)	Optional. May be shared with adjacent service.
SPECC	Specimen Collection Bay	Yes	2	9	
BHWS-B	Bay - Handwashing, Type B	Yes	1	1	
	Specimen Collection Room		1	12 (o)	Optional, depending on service requirements. Assumes an enclosed room with basin. May require dual egress depending on jurisdictional policies and risk assessment. Paediatric services will require access to bed and chair (or combined treatment recliner) and fit out / technology to support patient distraction. Includes handwash basin.
WCPT	Toilet - Patient	Yes	1	4	Specimen collection. 6m2 if accessible access required. May have pass-through hatch.
CLN-10	Clean Store	Yes	1	9	For storage of consumables. Includes underbench fridge for glucose tolerance drinks.
BMEQ-4	Bay - Mobile Equipment	Yes	1	4	Phlebotomy trolleys. May be combined with clean store to support workflow of stocking trolleys with consumables.
BPTS	Bay - Pneumatic Tube	Yes	1	1 (o)	Optional, depending on location and hospital- wide approach. Bench space for packing may be required depending on workflows.
BPATH	Bay - Pathology	Yes	1	3 (o)	Optional, depending on scope of services provided.
BLIN	Bay - Linen	Yes	1	1 (o)	Optional, depending on opportunity to share with adjacent department or use of disposable linen.
CLUP-7	Clean -Up Room	Yes	1	7 (o)	Optional, depending on opportunity to share with adjacent department. Includes area to wash and dry tourniquets and dirty linen skip.
	Discounted Circulation		32%		

5.1.2 Pathology Unit

The specimen / visitor (staff and courier) reception and pre-analytical zones are usually combined to support efficient workflows. The pre-analytical zone should also be continuous with the core laboratory.

Reception / Pre-Analytical Zone

AusHFG Room Code	Room / Space	SC / SC-D	Scenario 1		Scenario 2		Scenario 3		Remarks
			Qty	m2	Qty	m2	Qty	m2	
RECL-12	Reception - Visitor and Specimen	Yes	1	12	1	12	1	20	Includes specimens delivered via staff, couriers and pneumatic tube.
	Pre-Analytical Zone				1	20	1	35	Area must be continuous with the Core Laboratory to support optimal specimen workflows.
	Discounted Circulation		32%		32%		32%		

Laboratories

The recommended laboratory areas noted below are indicative only and provided to assist with the early stages of planning. Actual area requirements will need to be developed on a project by project basis to reflect the role of the Unit within the network, the scope of services provided, the level of automation being implemented and the projected volume of activity.

AusHFG Room Code	Room / Space	SC / SC-D	Scenario 1		Scenario 2		Scenario 3		Remarks
			Qty	m2	Qty	m2	Qty	m2	
	Laboratory - Core		1	50	1	90	1	240	At a minimum the core lab will include transfusion services, haematology and chemical pathology. Area allocations noted are indicative and will depend on the role of the unit within the network, volume of activity and analyser capacity. For Scenario 3 the recommended area is based on a major regional referral hospital of approximately 450 beds. Actual area requirements will depend on local service requirements. Includes area for new equipment commissioning, handwash basins, emergency shower/eye wash, fridges, freezers and other storage.
	Laboratory - Microbiology				1	30 (o)		100	Optional if the service cannot be provided in a timely manner by a higher level networked service. Areas are indicative only, actual requirements will depend on the volume of activity.
	Laboratory - Anatomical Pathology				1	30 (o)		200	Optional if the service cannot be provided in a timely manner by a higher level networked service. Areas are indicative only, actual requirements will depend on the volume of activity.
	Discounted Circulation		32%		32%		32%		

Support Areas

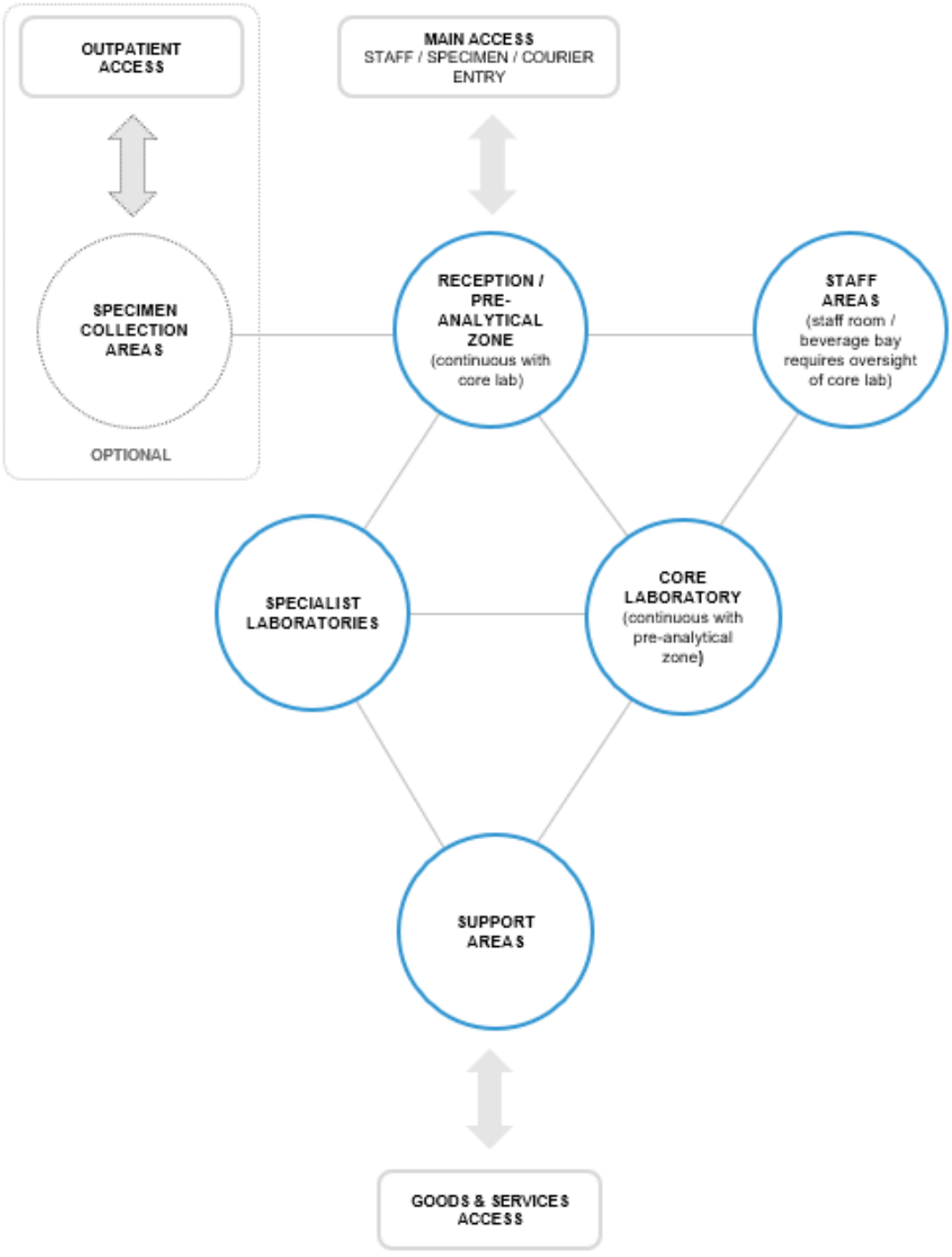
AusHFG Room Code	Room / Space	SC / SC-D	Scenario 1		Scenario 2		Scenario 3		Remarks
			Qty	m2	Qty	m2	Qty	m2	
	Store - Cool Room / Refrigerators/ Freezers		1	6	1	12	1	20	Specimens and reagants.
CLN-10	Clean Store	Yes	1	6	1	12	1	30	Consumables store. May require additional capacity to store clinical trolleys depending on operational arrangements. May be combined with general store for efficient use of storage.
STGN	Store - General	Yes			1	14	1	20	May be combined with clean store for efficient use of storage. Floor loading will need to be considered if a compactus is being provided.
	Store - Flammable Liquids		1	2	1	3	1	5	
CLUP-7	Clean-Up Room				1	7	1	10	Clean up functions included in core laboratory area allocation for small unit.
CLRM-5	Cleaner's Room	Yes			1	5	1	5	May be shared with collocated departments for small and medium sized units.
DISP-8	Disposal Room	Yes			1	8	1	8	Assume disposal room is shared with adjacent department for smaller unit. May be shared with collocated departments for medium sized units.
AHBBF	After-Hours Blood Fridge		1	8	1	10			Collocate with the blood bank.Secure but accessible after hours for emergencies. Not included in large hospital unit given 24/7 pathology access.
	Discounted Circulation		32%		32%		32%		

Staff Areas

AusHFG Room Code	Room / Space	SC / SC-D	Scenario 1		Scenario 2		Scenario 3		Remarks
			Qty	m2	Qty	m2	Qty	m2	
OFF-S9	Office - Single Person, 9m2	Yes	1	9		9		9	The number of staff work areas will depend on local requirements based on the staff profile and local jurisdictional policies. Pathology reporting will require quiet work areas. Larger sized offices may be required to support teaching and training requirements and accomodation of microscopes, depending on local policies. Include vision panel for oversight of labs.
	Office - Workstation, 5.5m2					5.5		5.5	The number of workstations will depend on local requirements based on the staff profile and local jurisdictional policies.
BMFD-3	Bay - Multifunction Device	Yes			1	3		3	
MEET-L-15	Meeting Room, 15m2	Yes			1	15	1	15	Meeting room size is indicative and will depend on local requirements.
MEET-L-30	Meeting Room, 30m2						1	30	Meeting room size is indicative and will depend on local requirements.
BBEV-OP	Bay - Beverage, Open Plan, 4m2	Yes	1	3					Supports 24/7 access for staff. Requires oversight of the laboratory. Must be external to PC2 facility where provided.
SRM-15	Staff Room				1	12	1	20	Supports 24/7 access for staff. Indicative area noted, requirements will depend on the staff profile. Requires oversight of the core laboratory. Must be external to PC2 facility where provided.
BPROP	Bay - Property, Staff	Yes			1	1	1	3	Smaller units will require shared access to staff amenities.
SHST	Shower - Staff, 3m2	Yes			1	3 (o)	1	3	Optional.
WCST	Toilet - Staff, 3m2	Yes			2	3	4	3	Indicative, number will depend on staff profile. Smaller units will required shared access to staff amenities.
	Discounted Circulation		25%		25%		25%		

5.2 FUNCTIONAL RELATIONSHIPS / DIAGRAM

A following diagram sets out the functional relationships between zones in a Pathology Unit.



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- Standards Australia, 2011, AS 2252.3: 2011 – Controlled environments – Biological safety cabinets Class III – Design, Standards Australia, Sydney NSW
- Standards Australia, 2011, AS 2252.6 2011 Controlled environments - Clean workstations
- Standards Australia, 2018, AS/NZS 3000:2018 Electrical installations (known as the Australian/ New Zealand Wiring Rules, Standards Australia, Sydney NSW
- Standards Australia, 2012, AS 1668.2: 2012 The use of ventilation and airconditioning in buildings - Mechanical ventilation in buildings, Standards Australia, Sydney NSW
- Standards Australia/Standards New Zealand, 2005, AS/NZS 2381.1:2005 Electrical equipment for explosive atmospheres - Selection, installation and maintenance, Standards Australia, Sydney NSW
- Standards Australia/Standards New Zealand, 2014, AS/NZS 2243.8 Safety in laboratories: Fume cupboards, Standards Australia, Sydney NSW

5.4 FURTHER READING

- NSW Health Guide to role delineation of clinical services, 2019
- NSW Health Policy Directive, PD2018_28 Managed Point of Care Testing (PoCT) Service, July 2018
- NSW Health Policy Directive PD2018_042 Blood Management, November 2018
- NSW Health Pathology, 2019, NSW Health Laboratory Design Guideline
- NSW Health Pathology, 2019, Design Requirements for Anatomical Pathology Departments
- Queensland Health Clinical Services Capability Framework for Public and Licensed Private Health Facilities, version 3.2, 2015 https://www.health.qld.gov.au/system-governance/licences/private-health/cscf
- Queensland Health Health, Safety and Wellbeing Policy, 2020, https://www.health.qld.gov.au/__data/assets/pdf_file/0034/395764/qh-pol-401.pdf

5.5 PHYSICAL CONTAINMENT LEVELS

5.5.1 Physical Containment Laboratories

Laboratories can be defined according to their level of risk and their subsequent physical containment. These levels are described below and are as defined in the Standard Standards Australia, 2010, AS/NZS 2243.3:2010 Safety in laboratories - Microbiological safety and containment.

5.5.2 Physical Containment Level 1 (PC1)

A Physical Containment Level 1 laboratory is suitable for work with micro-organisms where the hazard levels are low and where laboratory personnel can be adequately protected by standard laboratory practice. The organisms used are not known to cause disease in healthy adults (i.e. organisms in Risk Group 1). Work may be carried out on the open bench. Specimens that have been inactivated or fixed may be handled in a level PC1 laboratory. A PC1 laboratory may be naturally ventilated.

5.5.3 Physical Containment Level 2 (PC2)

A Physical Containment Level 2 laboratory is suitable for work with material likely to contain micro-organisms which may be present in the community, where the micro-organism may be associated with animal, plant or human disease of moderate severity (i.e. organisms in Risk Group 2). With good microbiological techniques, work with these agents may be carried out on the open bench. If there is a significant risk from the production of aerosols, a biological safety cabinet must be used. These laboratories are usually maintained at negative pressure to surrounding areas.

5.5.4 Physical Containment Level 3 (PC3)

A Physical Containment Level 3 laboratory is suitable for work with indigenous or exotic micro-organisms and where there is a risk of serious infection to humans, animals or plants (i.e. organisms in Risk Group 3). A Physical Containment Level 3 laboratory provides safeguards to minimise the risk of infection to individuals, the community and the environment. PC3 laboratories are provided with a controlled airlock entry and are usually contained within a PC2 laboratory area.

5.5.5 Physical Containment Level 4 (PC4)

A Physical Containment Level 4 laboratory is suitable for work with dangerous micro-organisms that pose a high individual risk of life-threatening disease and may be readily spread to the community (i.e. organisms in Risk Group 4). A Physical Containment Level 4 laboratory is a facility situated in a building separate from other laboratories or constructed as a fully isolated area within a building requiring a complete change of clothing, footwear etc. on entry and departure.

5.6 THE PLANNING BRIEF

During the stages of planning a laboratory, a written brief should be provided by the building owner to the building designer containing the following information:

- type and function of the laboratory;
- detailed description of the work in so far as it may affect building requirements, including its layout and containment levels;
- details of hazards associated with the work;
- any proposed operations which may give rise to air contaminants, including chemical, biological or radioactive operations and operations where flammable liquids, hazardous or infectious materials or objectionable odours can contaminate ventilation air, particularly in the event of accidental spillage;
- the types of gases and flammable vapours likely to be produced by particular laboratory processes or to arise from flammable liquid stores or cabinets and the tendency of those gases or vapours to ascend or descend;
- equipment and apparatus to be installed;
- degree of flexibility required.
- staff complement (present and projected);
- conditions that might necessitate special structural requirements (e.g. heavy loads);
- additional loading, anti-vibration or insulation requirements which may result from the location of the laboratory or from the nature of the work to be carried out in it, or other special hazards such as fire, explosion or radiation;
- types and amount of waste;
- future extension needs; and
- any other relevant matters.

Through the design, planning and implementation process, programmed risk assessments should be undertaken.

Extract from Standards Australia, 2010, AS/NZS 2982:2010 Laboratory design and construction.