NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR USE OF DIGITAL IMAGES AS AN ALTERNATIVE TO DIRECT MICROSCOPY

(First Edition 20XX)

Final draft for public consultation-2020

NPAAC Tier 4 Document

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Contents

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to medical pathology laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a potential risk to public health and patient safety.

Scope

The *Requirements for Digital Images as an Alternative to Direct Microscopy (First Edition 20XX)* is a Tier 4 NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services.* The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

In addition, the Tier 3A Document *Requirements for the Supervision of Pathology Laboratories* and Tier 3B documents *Requirements for the Retentions of Laboratory Records and Diagnostic Materials* and *Requirements for Information Communication* are also pertinent.

These Requirements set out the minimum best practice for the accreditation of laboratories using digital technology for primary morphological diagnosis and second opinions. This primarily concerns the use of whole slide imaging but also encompasses use of telepathology where digital cameras operated manually or remotely transmit images.

The Requirements cover the use of digital microscopy in anatomical pathology, cytopathology, haematology morphology and microscopy in microbiology. There are considerable similarities between all of these specimen types and the Standards are directed to all of these disciplines. Use of digital microscopy for diagnosis should be related to the nature of the individual specimen and as such this document provides a guide as to when it may be appropriate to defer to the glass slide for diagnosis.

Quality Assurance materials should comply with these accreditation requirements for digital technology as these should replicate the diagnostic setting as closely as possible.

These standards do not address areas where the original image is already in digital form such as electron microscopy and cytogenetics or the use of these technologies in education or examination environments.

The standards are not intended to apply to technologies which are used as a preliminary screening device to locate areas of interest or objects on a slide, such as those used in liquid based cytology, Cellavision in Haematology and Kiestra in microbiology. These are considered screening tools rather than providing a definitive diagnosis.

The document also does not include clinical images or macroscopic images of surgical specimens or microbiological plates where there are existing jurisdictional and Retention Requirements[1].

It is recognised that in addition to image analysis, which is already in widespread use, the emerging technologies of artificial intelligence and machine learning, which depend on

[1] Requirements for the Retention of Laboratory Records and Diagnostic Materials

digital image acquisition, will also have a significant future impact on pathology. While this is beyond the scope of this current document, these technologies and the issues they raise will need to be addressed in future document revisions.

Abbreviations

Abbreviation	Description
AS	Australian Standard
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
RCPA	Royal College of Pathologists of Australasia
QAP	Quality Assurance Program
LIS	Laboratory Information System
WSI	Whole Slide Imaging

Definitions

Term	Definition
Artificial intelligence (pathology)	means applying algorithms to data in assist in diagnosis and clinical support.
Digital imaging	means acquisition of digital facsimile slides/ whole slide images from a glass microscope slide.
Digital pathology	means the conversion of a glass microscope slide containing processed diagnostic tissue or cells into a digital image. It includes the acquisition, management, interpretation, storage and use of such images for any diagnostic assistance.
Digital microscopy	means the interpretation and use of a digital whole slide image in the same way that a glass slide is interpreted under a microscope.
Electronic device	means a device that enables access to or use of an electronic communication service, remote computing service, or location information service.
External quality assurance	means a program in which multiple specimens are periodically sent to laboratories for analysis and/or identification, in which each laboratory's results are compared with those of other laboratories in the group and/ or with an assigned value, and reported to the participating laboratory and others. Such a program may also compare an individual's results with those of their peer group.
Image analysis	means the use of computational algorithms to make a quantitative assessment of some aspect of a digital image
Method validation	means the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with that requirement.
Method verification	means procedures to test to what extent the performance data obtained by manufacturers during method validation can be reproduced in the environments of end-users.
Quality assurance	means part of quality management focussed on providing confidence that quality requirements will be fulfilled.
Quality control	means operational techniques and activities that are used to fulfil requirements for quality.

Term	Definition
Requirements for Medical Pathology Services	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.
Telepathology	means the process by which diagnostic pathology is performed on transmitted digital slide images that are viewed at a distant site in real-time on a display screen rather than by conventional light microscopy with glass slides. Telepathology can be used for histopathology and cytopathology specimens, blood films / bone marrow morphology, immunofluorence and microbiological assessments of cultures.
Whole slide imaging	means a digital image produced by scanning the content of a microscopy slide at sufficiently high resolution that it is comparable with examination by direct microscopy.

Introduction

The *Requirements for the Use of Digital Images as an Alternative to Direct Microscopy (First Edition 20xx)* is a Tier 4 NPAAC document and together with the *Requirements for Medical Pathology Services,* sets out the minimum best practice standards for the use of digital pathology, in particular relating to anatomical pathology but also other morphological disciplines such as haematology with regard to microscopic examination of peripheral blood and bone marrow specimens and microscopy in microbiology.

The purpose of the document is to provide a framework whereby these technologies, particularly whole slide imaging, can be introduced for microscopic diagnosis, not inhibiting innovation while protecting patient safety.

The digital acquisition of microscopic images, particularly whole slide imaging, (WSI) is a rapidly developing technology which offers: opportunities to enhance the capabilities of light microscopic examination of tissues and cells to better manage diagnostic work flow and ability to allow rapid transmission of microscopic images to remote sites. This has the potential to enhance the reproducibility and accuracy of quantitative assessments of microscopic features (including computer-assisted diagnosis) which is important in cancer diagnostics. The ease of remote transmission, arguably the main driver for digital pathology adoption, will enable better communication for consultation and second opinions, enhancing patient access to specialist opinions, particularly for regional centres. This should lead to better diagnosis and hence management of patients, no matter where they are located, improving equity of access to health care. There is the further potential for allowing pathology services to easily redistribute workloads across networks, to have ready access of cases for review at Multi-Disciplinary Team Meetings (MDTs) and the ability to participate in these meetings remotely. Access to cases for teaching and research is also enhanced. Additional advantages include the long term electronic storage of digital images without the deterioration/ fading suffered by glass slides, and the reduced physical space required for electronic storage compared with glass slide storage.

There are risks associated with this technological advance which need to be addressed.

1. Conversion of previously analogue data to digital form for diagnosis and storage presents additional risks to data security, including the risk of unauthorised access, the risk of data being altered or deleted and the risk of data ransom (see S2.1).
2. Production of slides for WSI requires additional quality steps in slide production and scanning (see S3.3).
3. While it has been established that diagnostic accuracy using digital pathology is generally not inferior to light microscopy, [1,2,3,4] there is a learning curve period where [,4] diagnostic discrepancy and time inefficiency may occur (see Standard 1 Personnel).
4. Very small objects such as bacteria and eosinophil and mast cell granules or material defined by a particular colour such as amyloid may be difficult to discern due limits of resolution or colour fidelity (see section 1 Personnel).
5. There appears to be additional risk of error in cases assessing dysplasia or identifying micrometastases (see Standard 1 Personnel).
6. Detection of features requiring polarised light such as oxalate crystals and birefringence in Congo red staining for amyloid is not possible (see Standard 1 Personnel).

7. While reporting of cases remote from the laboratory setting is possible using glass slides, digitisation and the ease of transmission of images greatly facilitates this. The risk of professional isolation is potentially increased, and the impact on pathology supervision and training needs to be considered (see Section 3 Practice Requirements).
8. There are also possible risks associated with the emergence of cross-border practice and how this would need to be administered (Section 3 Practice Requirements).
9. The need for long term storage of the image used in diagnosis requires ongoing access to files and risks related to technical obsolescence and for this reason, open file formats are preferred (see S2.4).
10. Proprietary formats may lead to lack of interoperability of systems inhibiting some of the benefits of WSI such as rapid external second opinions (see S2.4).

These Requirements are intended to serve as minimum Standards in the accreditation process and have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence*

ISO 12052 *Health informatics- Digital imaging and communication in medicine*

These Requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

Tier 2 and Tier 3A Documents

Tier 3B documents

- *Requirements for the Retentions of Laboratory Records and Diagnostic Materials*
- *Requirements for Information Communication and Reporting*

In addition to these Standards, Laboratories must also comply with all relevant jurisdictional legislation (including reporting requirements).

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation – Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2)**. The use of the word '**must**' in each Standard within this document indicates a mandatory requirement for pathology practice.
- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Where a Commentary contains the word '**must**' then that commentary is considered to be **normative**. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached.

Please note that any Appendices attached to this document may be either normative or informative and should be considered to be an integral part of this document.

Please note that all NPAAC documents can be accessed at - www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Personnel

(Refer to Standard 2, and Standard 4 in Requirements for Medical Pathology Services)

The use of a digital image in diagnosis in the morphological disciplines in pathology is not new. It has formed the basis of the histopathology modules of the RCPA QAP since 2008 and is used in electron microscopy and fluorescence in situ hybridisation. However, in addition to the change in the mode of examination of an image, there will be a requirement for familiarity with new workstations and software and for technical staff, more stringent requirements for sectioning and the added steps involved in managing whole slide scanning. It is thus an additive rather than alternative component of histopathological workflow.

Additional laboratory quality monitoring will need to be introduced. To ensure an effective uninterrupted scanning process there will need to be feedback from WSI back to the cut up bench to ensure that tissue blocks are small enough that there is no overhang of tissue on a slide and also in slide production that ensures sections are full face, planar and with no mis- aligned coverslips.

As discussed, apart from the circumstances mentioned previously, it has been established that diagnostic accuracy using digital pathology is not inferior to light microscopy, [1,2,3,4] however there is a definite learning curve in accuracy, time efficiency and comfort in using digital microscopy for diagnosis. Diagnostic discrepancy and time inefficiency may occur during this transient initial learning curve. [3] This requires specific training in the digital pathology system and validation procedures for each pathologist and the scientific staff in the safety of a risk-controlled period. Following the transition phase ongoing audit of performance against conventional microscopy is also recommended. [5,6,7]

The training, validation and audit processes are set out in detail within ***Appendix A***.

Training and competency

S1.1 The laboratory must have staff that have undergone manufacturer-based training in the digital system who can act as technical leads for the laboratory.

S1.2 Laboratories must document training and competency assessment for staff engaged at all levels in the process.

C1.2 All staff training records **must** be maintained for currency.

Transition

S1.3 Pathologists and technical staff must be trained in the use of the equipment.

C1.3(i) For whole slide imaging the minimum competencies **must** include the ability to troubleshoot problems with section quality and slide scanning, understanding the limitations of the digital system and when to consider also examining the glass slide directly, an understanding of the operation of the viewing system including navigation, annotation, storing information, and the ability to remove identifying metadata for teaching cases and interaction with the LIS.

C1.3(ii) Each time a change is made in this system there must also be a record of any required additional training and validation being undertaken and assessed.

S1.4 **For pathologists using whole slide imaging for routine diagnostic work, there must be a documented validation process consisting of a program of reconciliation of diagnoses made on digital images with the glass slides over the transition period (see *Appendix A*).**

S1.5 **At the conclusion of the transition phase, the validation process undertaken by the pathologist must be assessed as satisfactory by their supervisor.**

Following the transition phase

S1.6 **Internal quality control/ validation protocols must be established after the transition phase for each pathologist.**

C1.6(i) The review **must** be in accordance with Appendix A for each pathologist involved in reporting digital pathology.

C1.6(ii) An audit protocol **must** allow random review of a proportion of an individual pathologist's digital cases on a regular basis. (see Appendix A).

2. Equipment

(Refer to Standard 5 in Requirements for Medical Pathology Services)

A digital pathology system includes several hardware and software components that are used in combination to produce a digital representation of a glass slide, including its metadata. The digital pathology system provides storage, identification, display, navigation and analysis of the subsequent digital image.

Large files, the need to access data quickly and the embedding of slide metadata in whole slide images have led to the use of proprietary image formats by some scanner manufacturers and the implementation of scanner-specific image handling functionality. The use of proprietary formats can present the following risks:

- it can restrict interoperability between digital pathology systems, creating silos of proprietary whole-slide images with significantly different patient and slide metadata. This can impede or prevent the realisation of some of the benefits of whole slide imaging such as facilitating external second opinions where a different system may be in use. It can also limit standardised workflow across larger organisations where different scanning systems may be in use.
- it limits hardware selection, staged equipment replacement and access to 'best of breed' devices to ensure an organisation's digital pathology platform components remain interoperable.
- there is also a risk that vendors may alter or end support for software or image formats or go out of business. This could slow or prevent the retrieval of archival images.

To address these risks, a standard for image storage, retrieval and transmission should be used.

DICOM (Digital Imaging and Communications in Medicine) and ISO 12052:2017, this is the international standard for transmission, storage, retrieval, printing, processing, and display of medical imaging information. [8, 9] †. Finalised in 2010, DICOM Supplement 145 added the Whole Slide Microscope Imaging object definitions and attributes.‡

DICOM defines a common file format for storage of whole slide images and their metadata, including patient and specimen attributes, block and slide information, and related scan data, such as details of the optical path, and lens and colour calibration information used in image acquisition. It provides a standard way to encode image annotations and quantitative measurements that can be stored and shared without loss of fidelity. Additionally, DICOM enables interoperability by defining a common data standard and several services for transmitting that data across a network. This enables the integration of image acquisition devices, storage, analysis, and viewing platforms from different vendors, preventing vendor lock-in and image silos.

After reporting, DICOM facilitates the distribution of whole slide images in the final pathology report by providing a standard means of encoding a whole slide image into an HL7

† *https://www.dicomstandard.org/*

‡ https://www.dicomstandard.org/News/ftsup/docs/sups/sup145.pdf

CDA document to provide a link to the whole slide image, including how it should be displayed (region, magnification).

The Digital Pathology System

S2.1 The security of the digital pathology system and LIS should be reviewed to ensure that all possible protections are in place to prevent unauthorised access, hacking or sabotage.

S2.2 If the digital pathology system has TGA approval for use in the diagnostic setting, a local method verification in the laboratory is sufficient.

S2.3 If the digital pathology system is not approved for diagnostic use then a method validation study must be performed and the equipment registered as an in house in vitro diagnostic medical device.[§][1]

S2.4 If equipment is for diagnostic purposes, the laboratory must ensure that the digital pathology system in use meets the DICOM Standards (ISO 12052 - DICOM supplements 122 (specimen identification and description of specimens which are subject of an image) and 145 (whole slide images) [7.8] **or demonstrate that the laboratory has satisfactorily addressed the risks above relating to interoperability and long term system support in the event of manufacturer withdrawing this or terminating their business.**

Image Capture

S2.5 The laboratory must ensure there is a system that correctly links patient and specimen and block identification to the image.

S2.6 The clinical information, macroscopic findings, block assignment information and other available information about the patient must be linked to the LIS and linked to the digital image at the time of scanning (preferably automatically).

S2.7 The laboratory using whole slide imaging must demonstrate that the digital image is adequate for diagnosis.[**]

S2.8 The digital slide image must be retrieved on a reliable, high quality display monitor that has been colour calibrated.[††]

C2.8(i) The monitor should provide the same quality characteristics when viewing a digital slide as viewing a glass slide under a microscope.

C2.8(ii) The pathologist should have access to an ergonomic navigation control system, which must provide adequate speed, panning and zooming capabilities, with no pixilation of the image.

C2.8(iii) Common navigation control devices should be supported i.e. trackball, mouse, computer aided design mouse, and joystick.

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§ Requirements for the Development and Use of In Vitro Diagnostic Medical Devices

** Refer to Appendix A

†† RCPA Guidelines for Digital Pathology

S2.9 For optical optimisation, images of specimens must be scanned at sufficient magnification to match the size of structures being investigated.

C2.9(i) For routine cases a magnification would require a minimum of a 20x objective.

C2.9(ii) If slide imaging is being used for the identification of small objects such as microorganisms, higher magnification at 60x may be necessary and a validation study performed to demonstrate non-inferiority to light microscopic detection for this purpose.

S2.10 When detection of an object depends on colour, such as in a Ziehl-Neelsen stain, correct colour calibration must be used.

Interpreting the image

S2.11 The laboratory must have adequate IT infrastructure and support systems that are sufficient for the scope of testing and capable of supporting the streaming of images within a timely manner.

C2.11 There **must** be sufficient bandwith to allow transmission and loading of images to be able to support the laboratory workflow for diagnosis.

S2.12 Additional digital tools such as image analysis must also be clinically validated before use in the diagnostic setting.[‡‡]

C2.12 Any additional digital analysis tools **must** meet the regulatory requirements.

Telepathology

Telepathology involves remote, real-time evaluation of slides using a transmitted image from a light microscope, rather than whole slide scanning. This is mainly used in the setting of occasional remote frozen sections or rapid on site evaluation of fine needle aspiration biopsy cytology (ROSE) but can also be used in microbiology for interpretation of stained slides. In general it is not recommended as the sole method of slide reporting due to limitations of image quality and the less secure identification of slides when multiple cases are being examined.

S2.13 The laboratory must ensure that there is a secure method of maintaining the integrity of specimen identification when slides are being interpreted remotely from the microscope.

S2.14 The telepathology system in use must include the ability to record the images used for diagnosis.

S2.15 The telepathology system must undergo a process of method validation for the proposed use.

S2.16 Staff must be trained and tested for competence in the use of the equipment.

S2.17 The quality of the image and the integrity of transmission must be assessed on each occasion before use.

[‡‡] Requirements for the Development and Use of In House In Vitro Diagnostic Medical Devices

C2.17 This is particularly important if episodes of use are intermittent or infrequent.

Cytology, Morphological Haematology and Microbiological preparations using smear preparations.

There are considerable similarities between these specimen types in that the material is dispersed across a slide, the preparation may be of variable thickness and in many cases the object of interest may be small, infrequent or need examination at multiple focal planes to detect its features. This applies to most cytology samples although liquid based cytology is less variable in thickness. In haematology, blood films and marrow aspirate preparations share these features while trephine biopsies can be scanned like any histological sample. Whilst digital scanning of cytology samples is possible there are specific concerns that must be addressed that currently limit the value of digital screening for cytology.

1. Depth of Field, related to complex three dimensional cell clustering, requires high resolution "Z stack" capability, if whole slide imaging is to be used in cytology screening and diagnostic practice.
2. Confounding organic and inorganic material may compromise scan image clarity e.g. necrotic debris, old blood or lubricant gel.
3. Significant variability in stain characteristics occur from specimen to specimen and these cannot be compensated for in image capture.
4. Large volumes of potential blank spaces across large smear/slide volume make ergonomics for cytology screening difficult to resolve.
5. Variable focal plane requirements across large fields make clarity of image difficult to ensure, although this may be less for liquid based cytology.
6. Operator fatigue i.e., high power screening processes of cytology versus targeted diagnostic processes of histology diagnosis should be addressed.
7. Speed of screening the digital image may significantly impact workflow and workforce.
8. Preparations for haematology and microbiology require detection of very small objects such as bacteria, and malarial parasites for instance, and would normally be examined at least at 100x using conventional microscopy.

At this time, excluding the utilisation of image capture processes for specific situations such as cytology education, targeted diagnosis, targeted review or second opinion, digital image systems for routine cytology screening and reporting are considered still immature and the potential benefits of whole slide imaging in cytology may not outweigh the negatives at this point.

S2.18 For reporting of cytology and other smear based preparations the system used must have the capacity for scanning at different planes of focus (Z stacking) to allow complete evaluation of the characteristics of intact cells.

S2.19 For haematology and microbiology, the slides must be scanned with a system that has sufficient resolving power for the small objects of interest. A scanning system with higher numerical aperture (NA) objectives and higher

resolution camera than generally required for histopathology may be necessary.[§§]

Other devices

It is recognised that there are a variety of electronic devices, other than desk-top computer terminals, available for use to review digital images, however, these devices **must** be fit for purpose and meet the relevant requirements to ensure the delivery of quality outcomes. If users elect to use portable electronic devices, they should consider the suitability of the device for the clinical need and how to mitigate potential risks associated with patient privacy and confirmation of patient identity.

S2.20 The practitioner must determine the suitability of a device for the purpose of analysis using a digital image transmitted to that device.

C2.20 The device **must** undergo method validation comparable to onsite digital devices.

3. Practice Requirements

(Refer to Standard 5 and Standard 6B in *Requirements for Medical Pathology Services*)

The enhanced ability to access images remote from the laboratory will present challenges to current assumptions about work locations. There already exists the possibility of pathology cases being reported remotely by the transport of glass slides but this will be significantly easier for digital images.

The RCPA has a policy covering work location titled *Reporting of Pathology Specimens outside the Laboratory*. [10]

S3.1 The pathologist must conform to jurisdictional medical registration and credentialing requirements relating to the site of practice and site of origin of the specimen.

S3.2 The pathologist must hold medical indemnity insurance for the digital pathology activities being undertaken.

Internal QC/ QA

Regardless of the digital software and hardware used, the percentage of images needing to be rescanned should be kept to a minimum. There should also be a focus on reducing laboratory imaging turnaround time in order to improve patient care.

S3.3 The laboratory must have a protocol to assure the completeness of WSI where this is used.

C3.3(i) There **must** be a process quality check of the glass slide and equivalent whole slide image when scanning slides. (***see Appendix A***)

[§§] http://www.jpathinformatics.org/article.asp?issn=2153-3539;year=2013;volume=4;issue=1;spage=21;epage=21;aulast=Sellaro

C3.3(ii) Laboratories **must** monitor scanning failures, errors, downtime of instrument and rescan rates as part of the QA process (***see Appendix A).***

C3.3(iii) There **must** be good quality tissue sections produced before scanning to optimise the quality of the digital image.

C3.3(iv) The quality of the image **must** be audited as part of the internal quality assurance program.ie digital image and glass slide **must** be fit for the purpose of primary diagnosis.

C3.3(v) No matter the digital software and scanning hardware used, the percentage of rescanned images should be as low as practicable

e.g. < 2 per cent.

External QA

S3.5 The laboratory staff must be enrolled and actively participate in a relevant QA program, where available.[***]

4. Work environment, including out of laboratory

(Refer to Standard 7 in *Requirements for Medical Pathology Services*)

Images should not be reported in a situation isolated from access to clinical history, access to previous records in the LIS, other relevant information and the ability to contact clinical specialists.

See also the RCPA "*Reporting of Pathology Specimens outside the Laboratory.* [10]

S4.1 Reporting undertaken remotely from the laboratory must comply with the laboratory's management system and other accreditation requirements.

S4.2 Reporting must be undertaken in a quiet and secure environment.

C4.2(i) The pathologist **must** be able to concentrate solely on the reporting task free from distraction or interruption.

C4.2(ii) Privacy and confidentiality **must** not be compromised.

S4.3 The laboratory/ APA is responsible for ensuring that a suitable work environment, including navigation equipment is available and there must be minimum light reflection on the screen.

[***] Refer to the *Requirements for Quality Control, External Quality Assurance and Method Evaluation*

5. Storage and Retrieval

(Refer to Standard SC8.6 in Requirements for Medical Pathology Services)

Issues relating to storage and retrieval of images are important and there is a need for careful consideration of the issues outlined in this section. This section should be read in conjunction with the *Requirements for the Retention of Laboratory Records and Diagnostic Materials.*[†††] and Standard 2 of this document.

S5.1 Images must be stored such that any identifying information is securely protected.

S5.2 The laboratory must have an off-site back-up system for data.

S5.3 With reference to image compression, the laboratory must ensure that retrieved images are of the same quality as the original image upon which diagnosis was made.

S5.4 If third party or Cloud storage is used, the laboratory is ultimately responsible for storage of images, and must guarantee security of identity, back-up in the event of failure and contingency in the event that the storage provider ceases business.

S5.5 The laboratory must have a procedure for the retrieval of images and access during the period of retention.

C5.5 Software **must** support retrieval over time in accordance with the *Requirements for the Retention of Laboratory Records and Diagnostic Materials* and be backward compatible in that the images **must** be retrievable even if the associated software becomes obsolete.

S5.6 The laboratory must have secure storage and systems to retrieve images to meet clinical needs for review.

S5.7 All elements of the image on which diagnosis has been made (master copy), including metadata and annotations, must be retained and be retrievable.

C5.7 The image **must not** be able to be modified or able to be openly downloaded.

S5.8 If copies of the original WSI are produced for the purpose of education, assessment and quality assurance, all associated potentially identifying metadata and patient identification slide label must be removed.

S5.9 The laboratory must have a policy on the secure deletion of digital images.[‡‡‡]

S5.10 WSI must not be substituted for the glass slide for the purpose of archival storage.

C5.10(i) If diagnosis is based on a glass slide, the slide **must** be retained for at least the specified period.

[†††] *Requirements for the Retention of Laboratory Records and Diagnostic Materials*

[‡‡‡] *Requirements for Medical Pathology Services* & *Requirements for the Retentions of Laboratory Records and Diagnostic Material*

C5.10(ii) If the diagnosis is based on the digital image, then the image **must** be retained and retrievable for at least the specified period.

S5.11 If diagnosis was made using a digital image this must be recorded in the LIS or the pathology report.

Appendix A Pathologist validation/ competency (Normative)

Validation processes for pathologists using WSI for diagnostic use have been described by the *RCPA, College of American Pathologists and The Royal College of Pathologists (UK).* [5,6,7] These differ in approach but the UK method is preferred as reflecting performance in actual practice using the range of cases normally encountered by the pathologist.

Australian pathologists, at least those working within anatomical pathology, already have a degree of familiarity with diagnosis using WSI as this technology has been used for some years by the RCPA QAP in its AP and cytology modules and more recently in the RCPA Fellowship examination system. For that reason, a modification of the Royal College of Pathologists (UK) system has been developed.

The essential components are as follows:

1. Training and assessment on use of equipment
2. Validation of diagnostic use against conventional light microscopy. The validation cases should cover the full range of cases that the pathologist normally reports.
3. Assessment and sign off of competence for diagnosis
4. Ongoing case audit.

These processes will need to be reviewed in the future as pathologists undertake all of their pathology training entirely using digital systems.

Training in the use of the Digital System

There must be some staff members who have manufacturer-based training in the use of the equipment and computer programs associated with the digital workflow who can provide a teaching resource in-house for staff members. Competence must be assessed and signed off by one of these staff members. The initial training is specific to the digital system and must include:

1. Training in the use of the equipment
2. How to use the viewing program including case finding and worklists, navigation, annotation, storing information, the ability to remove identifying metadata for teaching cases and interaction with the LIS.
3. How to trouble shoot slide and scanned image quality
4. When it might be appropriate to refer to the glass slides and conventional microscopy.

Transition from conventional light microscopy to WSI based digital microscopy for diagnosis

After initial familiarisation and training in the use of the digital system, the pathologist should undertake a process of reporting their cases first on the digital system and then reviewing the case on a conventional microscope. The process should encompass the complete range of cases that the pathologists would normally report and should include a **minimum** volume of cases equivalent to one month's full-time work. Case details and any diagnostic discrepancies must be recorded. A sample worksheet for this appears below.

Covering the full range of cases will highlight any issues with the digital pathology system which may indicate that diagnosis of which type of case is better addressed by conventional microscopy. If cases such as those mentioned in the introduction section of this document such as biopsies for dysplasia, detection of Helicobacter, sentinel lymph nodes and cytology

are to be reported using WSI a targeted validation of these must be undertaken during this period.

Assessment and sign-off

When the individual pathologist validation process has been completed it must be reviewed with the Director or supervisor for completeness and satisfactory diagnostic performance. The record of this study and assessment must be retained. Some pathologists may take longer to achieve this level of competence on the digital system and this should be taken into account.

Ongoing case audit

The pathologist must review at least 20 cases per month on a conventional microscope to check their digital diagnosis for the first 6 months of implementation. These must be directed towards the more difficult cases or those with known issues with sensitivity. If a problem is discovered review of previous digital diagnoses in this area should be undertaken.

Following this period the digital cases should form part of the routine vertical auditing process of anatomical pathology cases within the laboratory but this should include examination of the glass slide to assess the technical aspects of sectioning and scanning as well as diagnosis.

PATHOLOGIST VALIDATION/ COMPETENCY

These tables are based on the quality control recommendations of Cross et al.

Validation Record

Date	Case ID	Digital diagnosis	Glass diagnosis	Preferred method (Digital=D, Glass=G)	Discrepancy/deferral (Yes=Y, No=N)

Validation statement and risk management

Pathologist:			**Specialty:**		**Trainer:**	**Date:**
STAGE	No of Cases	% Concord-ance	% Discord-ance	%Deferral	Discordant diagnoses (list))	Comment
Validation Stage 1: Training set						
Validation Stage 2: Live cases including deferred						
Validation Stage 2: Live cases including deferred						

(Note: Tables modified from Cross S, Furness P, Igali L, Snead D, Treanor D. 2018. Best practice recommendations for implementing digital pathology. The Royal College of Pathologists (UK).)

References

1. Snead DRJ, Tsang Y-W, Meskiri A, et al. *Validation of digital pathology imaging for primary histopathological diagnosis.* Histopathol. 2016;68(7):1063-1072.

2. Williams BJ, DaCosta P, Goacher E, Treanor D. *A systematic analysis of discordant diagnoses in digital pathology compared with light microscopy.* Arch Pathol Lab Med. 2017;141(12):1712-1718.

3. Van Es SL. *Digital pathology: semper ad meliora.* Pathology (2019); 51(1):1-10

4. Goacher E, Randell R, Williams B, Treanor D. *The diagnostic concordance of whole slide imaging and light microscopy: a systematic review.* Arch Pathol Lab Med. 2017;141:151-161

5. Cross S, Furness P, Igali L, Snead D, Treanor D. *Best practice recommendations for implementing digital pathology version 1.* United Kingdom: The Royal College of Pathologists;2018

6. Hipp J, Bauer TW, Bui MM, Cornish TC, Evans AJ, Glassy EF, Lloyd M, McGee RS, Jr, Murphy D, O'Neill DG, Pantanowitz L, Parwani AV, Rampy BA, Salama ME, Water R. *CAP Pathology Resource Guide: Digital Pathology. Version 7.0(1).* Northfield, IL: College of American Pathologists; 2017.

7. RCPA (Royal College of Pathologists of Australasia), Sydney NSW, 2002, *Guidelines for Digital Microscopy in Anatomical Pathology and Cytology* October 2015 (version 1.0)

8. DICOM (Digital Imaging and Communications in Medicine) and ISO 12052:2017, *(Reference https://www.dicomstandard.org/).* Finalised in 2010,

9. DICOM Supplement 145 added the Whole Slide Microscope Imaging object definitions and attributes.

10. RCPA (Royal College of Pathologists of Australasia), Sydney NSW, 2002, *Reporting of Pathology Specimens outside the Laboratory* viewed <*May 2020*> https://www.rcpa.edu.au/Library/College-Policies/Policies/Reporting-of-Histopathology-and-Non-Gynaecological

Bibliography

College of American Pathologists, *Validating whole slide imaging (WSI) for diagnostic purposes in pathology guideline: a summary of recommendations* https://cap.objects.frb.io/documents/validating-whole-slide-imaging-summary.pdf

Cross S, Furness P, Igali L, Snead D, Treanor D,*Best practice recommendations for implementing digital pathology version 1.* United Kingdom: The Royal College of Pathologists;2018

Royal College of Pathologists of Australasia, *Guidelines for Digital Microscopy in Anatomical Pathology and Cytology (October 2015, V1)*

Royal College of Pathologists of Australasia position statement, *Guidelines for Digital Microscopy in Anatomical Pathology and Cytology* (March 2018)

Ross J, Greaves J, Earls P, Shulruf B, Van Es SL. *Digital vs traditional: Are diagnostic accuracy rates similar for glass slides vs whole slide images in a non-gynaecological external quality assurance setting?* Cytopathology. 2018;29(4):326-334.

Treanor D and Williams B. 2018. *The Leeds guide to digital pathology,* viewed <21 November 2018 <http://www.virtualpathology.leeds.ac.uk/research/publications/pub_docs/bw/18778_Leeds%20Guide%20to%20Digital%20Pathology_Brochure_A4_final_hi.pdf>

Van Es SL, Kumar RK, Pryor WM, Salisbury EL, Velan GM. *Cytopathology whole slide images and adaptive tutorials for senior medical students: A randomized crossover trial.* Diagn Pathol. 2016;11:1.

Van Es SL, Pryor WM, Belinson Z, Salisbury EL, Velan GM. *Cytopathology whole slide images and virtual microscopy adaptive tutorials: A software pilot.* J Pathol Inform. 2015; 6: 54.

Van Es SL, Kumar RK, Pryor WP, Salisbury EL, Velan GM. *Cytopathology whole slide images and adaptive tutorials for postgraduate Pathology trainees: a randomized crossover trial.* Hum Pathol. 2015;46(9):1297-1305.

Van Es SL, Greaves J, Gay S, Ross JS, Holzhauser D, Badrick T. *Constant quest for quality: Digital cytopathology.* J Pathol Inform. 2018;9(1):13.

Vodovnik A. *Distance reporting in digital pathology: A study on 950 cases.* J Pathol Inform. 2015;6:18.

Vodovnik A. *Diagnostic time in digital pathology: A comparative study on 400 cases.* J Pathol Inform. 2016;7:4.

Acknowledgements

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Further Information

Other NPAAC documents are available from:

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