INTRODUCTION

This checklist is used in conjunction with the All Common (COM) and Laboratory General Checklists to inspect an anatomic pathology laboratory section or department.

Do NOT use this Checklist if the laboratory does NOT perform any on-site preparation or examination of anatomic pathology specimens, but refers all submitted material to an outside laboratory, or if the laboratory's involvement in anatomic pathology is limited to filing of reports and/or slides.

Laboratories that do not file slides on-site (eg, "read-only" laboratories) must retain a sample of cases and all associated slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all cases and associated slides accessioned over a continuous 2-week period within the previous 2 years.

*If telepathology is used by the pathologist to review slides or images for primary diagnosis, frozen section diagnosis, formal second-opinion consultations, ancillary techniques in which the pathologist participates in interpretation of images, or real-time evaluation of FNA specimens for triaging and preliminary diagnosis, refer to the Telepathology and Remote Data Assessment section of the Laboratory General Checklist for additional requirements. Telepathology occurs when a pathologist views digitalized or analog video or still image(s), or other data files (eg, flow cytometry files) at an off-site or remote location and an interpretation is rendered that is included in a formal diagnostic report or recorded in the patient record. The Telepathology and Remote Data Assessment section of the Laboratory General Checklist is not applicable if the image(s) and/or data files are generated and interpreted **within the same laboratory** using the laboratory's validated software.*

Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

***Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

GENERAL ANATOMIC PATHOLOGY

PERSONNEL

Inspector Instructions:

READ

- Policy for assessing professional competency
- Sampling of records for assessment of professional competency

ANP.10010 Professional Competency **Phase II**

The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory.

NOTE: The mechanism for competency assessment must be pertinent to the type of interpretive services provided (eg, general anatomic, neuropathology, renal pathology, forensic pathology). There must be a written policy for assessing professional competency at defined intervals, criteria for the assessment, and records of the assessment must demonstrate review by the laboratory director.

Evidence of Compliance:

- ✓ Participation in a peer educational program (eg, CAP Educational Anatomic Pathology Programs) or intra-departmental or inter-institutional peer review program **OR**
- ✓ Metrics developed from diagnostic quality management reports (ANP.10100, ANP.10150, ANP.12075, etc.) **OR**
- ✓ Quality management records (internal audits, error reports, etc.) **OR**
- ✓ Individual assessment according to defined criteria

SURGICAL PATHOLOGY

QUALITY MANAGEMENT

Many technical and procedural quality control items are covered elsewhere in this Checklist. They are integral components of a comprehensive quality management system and should be included within the defined system. This section determines if there is an active system of surveillance of the quality of surgical pathology activities, particularly the diagnostic reports. How this is accomplished depends upon the number of departmental staff, as well as the volume and type of diagnostic material. Such a system must include appropriate combinations of activities such as the use of intra- and extra-departmental consultations, circulation of diagnostic material (random or by case type), periodic review of completed surgical pathology reports, and participation in self-assessment and performance improvement programs.

Inspector Instructions:

	• Sampling of surgical specimen submission and examination policies and procedures • Instructions for handling bodies • Sampling of the following records: previous/current material review, intra-departmental consultations, extra-departmental consultations • Sampling of records of formalin monitoring
	• Does your laboratory exclude any specimen types from routine submission to the pathology department? • What is the process for histology personnel to provide feedback on quality issues identified in tissue sections submitted for processing? • What is your laboratory's course of action when a significant disparity exists between the initial intra-operative consultation and final pathology diagnosis?

ANP.10016 Surgical Pathology Exclusion **Phase I**

The institution defines specimen types that may be excluded from routine submission to the pathology department for examination, where applicable.

NOTE: This policy may be made in conjunction with the hospital administration and appropriate medical staff departments and must be in compliance with national, federal, state (or provincial), and local laws and regulations. The laboratory director should have participated in or been consulted by the medical staff in deciding which surgical specimens are to be sent to the pathology department for examination.