5) Powsner SM, *et al*. Clinicians are from Mars and pathologists are from Venus. Clinician interpretation of pathology reports. *Arch Pathol Lab Med.* 2000;124:104-1046
6) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1273(e)].

ANP.12170 Report Review — Phase II

All reports are reviewed and signed by the pathologist or other qualified physician as defined in ANP.11660.

NOTE: The review of the report by the pathologist must include review of the gross examination, microscopic descriptions (if provided), and pathologic diagnosis.

A single signature on the final pathology report indicates that the responsible pathologist has reviewed all sections of that report. Signatures for each section of the report are not necessary.

The inspector must review a broad sampling of surgical pathology reports issued since the previous on-site inspection, representing at least the most common types of specimens seen in the laboratory. When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the pathologist may not appear on the report. It is nevertheless essential that the laboratory have a procedure that ensures and records that the responsible pathologist has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1273(c)(d)].

ANP.12173 Mohs Report — Phase I

A written report is generated for each Mohs surgical procedure.

NOTE: A written note, report, or diagram must be included in the patient's medical record or operative report. The report must include required elements such as gross description, accession number, designation of relationship of blocks to the slides, and clear diagnosis on each specimen.

ANP.12175 Significant and Unexpected Findings — Phase II

Significant and unexpected surgical pathology findings are communicated to the responsible clinician and records of those communications are retained.

NOTE: Certain surgical pathology diagnoses may be considered significant and unexpected warranting special communication to the responsible clinician(s). The pathology department determines diagnoses to be defined as "significant and unexpected," in cooperation with local clinical medical staff. Examples include: malignancy in an uncommon location or specimen type (eg, hernia sac, intervertebral disk material, tonsil, etc.), change of a frozen section diagnosis after review of permanent sections, amendments to reports that may significantly affect patient care, neoplasms causing paralysis, or fat in an endometrial curettage.

There must be a reasonable effort to ensure that clinicians receive the communications. The records must include the following:

- *Date of communication*
- *Time of communication (if required by laboratory policy)*
- *Responsible individual communicating the result*
- *Person notified using identifiers traceable to that person (a first name alone is inadequate)*

- *Findings communicated.*

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (secure email or fax) with confirmation of receipt by the responsible individual.

The record of the communication may be included directly on the patient report or in a separate location. It is not necessary to separately summarize the findings communicated if the record of the communication is on the patient report. For communications recorded in a separate location, the findings communicated may be summarized or reference the case number.

This requirement takes the place of critical result notification in the All Common Checklist (COM.30000 and COM.30100) for surgical pathology findings.

Evidence of Compliance:

✓ Records of communication of significant/unexpected findings

REFERENCES

1) Zarbo RJ, Nakhleh RE, Walsh M; Quality Practices Committee, College of American Pathologists. Customer satisfaction in anatomic pathology. A College of American Pathologists Q-Probes study of 3065 physician surveys from 94 laboratories. *Arch Pathol Lab Med.* 2003 Jan;127(1):23-9
2) Silverman JF, Pereira TC. Critical values in anatomic pathology. Arch Pathol Lab Med. 2006;130:638-640
3) LiVolsi VA. Critical values in anatomic pathology; how do we communicate? Am J Clin Pathol 204;122:171-172
4) Allen TC. Critical Values in anatomic pathology? Arch Pathol Lab Med 2007;131:684-68
5) Pereira TC, Liu Y, Silverman JF. Critical Values in surgical pathology. Am J Clin Pathol 2004;122:201-205
6) Association of Directors of Anatomic and Surgical Pathology. Critical diagnosis (critical values) in anatomic pathology. Am J Surg Pathol 2006;30:897-899
7) Nakhleh RE, Souers R, Brown RW. Significant and Unexpected Diagnoses in Surgical Pathology: A College of American Pathologists Survey of 1130 Laboratories. *Arch Pathol Lab Med.* 2009; 133;1375-1378.
8) Sarewitz SJ, Williams RB. Significant and Unexpected versus Critical Results in Surgical Pathology. Editorial. *Arch Pathol Lab Med.* 2009; 133:1366.

ANP.12185 Amended Reports — Phase II

The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that affect current patient care.

NOTE: The amended report must state the reason for the amendment. The format of amended reports is at the discretion of the laboratory. For extensive interpretive or textual data, replicating the entire original and amended pathology reports may be cumbersome and render the report difficult to interpret. In such cases, a comment in the amended report summarizing the previous information and the reason for the amendment may be provided.

Records of the notification must include date, responsible laboratory individual, and person notified.

Evidence of Compliance:

✓ Patient reports containing the reason for the amendment **AND**
✓ Records of notifications

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):3713 [42CFR493.1291(k)].

*****REVISED** 08/24/2023***

ANP.12350 Cancer Protocols — Phase II

All required data elements in applicable CAP Cancer Protocols are included with appropriate responses using a synoptic format in surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast (DCIS) and biopsies of pediatric tumor types listed in the CAP Cancer Protocols.

NOTE:

1. *This checklist requirement is not applicable to:*
   - *Cancer for which no CAP Cancer Protocol is available*