

- board or registry deemed comparable by OASD(HD) or their designee Center for Laboratory Medicine Services (CLMS) as an MLT or MT/MLS; OR
- Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and currently hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).

Evidence of Compliance:

- ✓ Records of qualifications including degree or transcript and work history in related field

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):[42CFR493.1489].
- 2) California Business and Professions Code §1269.3.

ANP.11640 Competency Assessment of Individuals Assisting with Grossing Phase II



The competency of individuals assisting with grossing is assessed at least annually by a qualified pathologist (or by another qualified individual for specific subspecialties as defined in ANP.11600).

NOTE: Please refer to GEN.55500 and GEN.55505 on competency assessment in the Laboratory General Checklist for a list of criteria and frequency for competency assessment. Not all six elements may apply in all cases.

For dermatopathology cases, including Mohs surgery, an MD or DO dermatologist who is licensed to practice (if required) in the jurisdiction where the laboratory is located and is board certified in dermatology is qualified to perform gross examination and evaluate non-pathologists.

Evidence of Compliance:

- ✓ Records of competency assessment performed at a defined frequency

REFERENCES

- 1) Cibull ML. Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
- 2) Grzybicki DM, et al. The usefulness of pathologists' assistants. *Am J Clin Pathol*. 1999;112:619-626
- 3) Galvis CO, et al. Pathologists' assistants practice. A measurement of performance. *Am J Clin Pathol*. 2001;116:816-822

ANP.11660 Surgical Tissue Diagnosis Phase II

All surgical tissue diagnoses are made by a qualified pathologist. Exceptions for other qualified individuals for specific subspecialties are described in the NOTE.

NOTE: The following are exceptions for specific types of tissue diagnosis for non-pathologist individuals:

- Neuromuscular pathology specimens may be interpreted by an MD or DO who is licensed to practice (if required) in the jurisdiction where the laboratory is located and has completed a training program in neuromuscular pathology approved by HHS (ie, the American Academy of Neurology Committee for Neuromuscular Pathology Training Program).
- Other exceptions for dermatopathology, ophthalmic pathology and oral pathology as defined in the CLIA regulation 42CFR493.1449(f) and (g).

Evidence of Compliance:

- ✓ Pathology reports signed by diagnosing pathologist or other qualified individual based on subspecialty

REFERENCES

- 1) Cibull ML. Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
- 2) 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(b)(c)(d)].
- 3) 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): [42CFR493.1449(b)(f)(g)].

ANP.11670 Specimen - Gross Examination Phase I