qualified pathologist (either physically present in the laboratory or available by telephone or other electronic means).

- *Non-certified personnel who perform grossing must work under direct supervision of a qualified pathologist when engaging in the processing of specimens involving dissection (present in the vicinity of the clinical laboratory subspecialty area and be available for consultation and direction).*
- *Tissue processing that doesn't involve dissection may be performed under the supervision and control of a qualified pathologist.*

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(b)(7)].
2) Cibull ML. Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
3) Grzybicki DM, et al. National practice characteristics and utilization of pathologists' assistants. Arch Pathol Lab Med. 2001;125:905-912
4) California Business and Professions Code §1269.3.

*****REVISED** 12/26/2024***

ANP.11610 Gross Examination - Qualifications to Assist with Grossing **Phase II**

For laboratories subject to US regulations, individuals other than a pathologist or pathology resident (or an individual who meets the grossing subspecialty qualifications listed under ANP.11600) who assist in gross examinations meet high complexity testing personnel qualifications. For laboratories not subject to US regulations, such individuals are qualified under national, state or provincial, and local regulations, as applicable.

NOTE: Individuals assisting with grossing may perform physical examination/description of tissue specimens, including color, weight, measurement or other characteristics of the tissue, or other mechanical procedures (eg, dissection) under appropriate supervision. The laboratory director may delegate the grossing of specimens to non-pathologist individuals, but is responsible for determining whether an individual's education, training and experience meet the required qualifications.

For laboratories subject to US regulations, these individuals must be qualified as high complexity testing personnel under the CLIA regulations. The minimum training/experience required of such personnel is:

1. *An earned associate degree in a laboratory science (chemical or biological science) or medical laboratory technology, obtained from an accredited institution, OR*
2. *Education/training equivalent to the above that includes the following:*
   - *60 semester hours or equivalent from an accredited institution. This education must include 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that includes six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination, AND*
   - *Laboratory training including either completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) (note that this training may be included in the 60 semester hours listed above), OR at least three months of recorded laboratory training in each specialty in which the individual performs high complexity testing.*

If there are more stringent state or local regulations for grossing qualifications, they must be followed. Additional educational pathways for qualifying as high complexity testing personnel may be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

For US Department of Defense laboratories, effective May 29, 2014, newly hired high complexity testing personnel must have either:

- *A minimum of an associate degree in a biological or chemical science or medical laboratory technology from an accredited institution **AND** be certified by the ASCP, AMT or other*

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 subspecialities 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