The California Department of Health Care Services requires all tissues and objects removed during surgery to be submitted for pathology examination, unless a specific request is submitted to the state requesting a variance.

This checklist item is not applicable if 1) all specimens are submitted to pathology, or 2) the laboratory is not part of an institution that provides surgical services.

REFERENCES
1) Netser JC, *et al*. Value-based pathology: a cost-benefit analysis of the examination of routine and non-routine tonsil and adenoid specimens. *Am J Clin Pathol.* 1997;108:158-165
2) Zarbo RJ, Nakleh RE. Surgical pathology specimens for gross examination only and exempt from submission. A College of American Pathologists Q-Probes study of current policies in 413 institutions. *Arch Pathol Lab Med.* 1999;123:133-139
3) College of American Pathologists. *Policy M. Surgical Specimens to be Submitted to Pathology for Examination.* Northfield, IL: CAP; 2022.
4) Jean Iacino. AFL 16-07, Program Flexibility Letter Recall. California Department of Public Health, State of California Health and Human Services Agency. June 13, 2016.
5) Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.

ANP.10032 Surgical Pathology Microscopic Exemptions — Phase I

The institution defines which types of surgical specimens (if any) may be exempt from microscopic examination.

NOTE: Irrespective of any exemptions, microscopic examination may be performed whenever there is a request by the submitting or attending physician, or at the discretion of the pathologist when indicated by the clinical history or gross findings. Policies that exempt certain types of specimens from microscopic examination may be approved by the medical staff or appropriate committee. Typical exempt specimens include foreskins in children, prosthetic cardiac valves without attached tissue, torn meniscus, varicose veins, tonsils in children below a certain age, etc.

REFERENCES
1) Weibel E. Pathological findings of clinical value in tonsils and adenoids. *Acta Otolaryngol.* 1965;60:331-338
2) Wolkomir AF, *et al*. Selective microscopic examination of gallbladders, hernia sacs and appendices. *Am Surg.* 1991:57:289-292
3) Boutin P, Hogshead H. Surgical pathology of the intervertebral disc: is routine examination necessary? *Spine.* 1992;17:1236-1238
4) Cornell WB, Levin HS. The inguinal hernia sac: trash or treasure? Anatomic pathology II check sample, APII-9. Chicago, IL: American Society of Clinical Pathology, 1993:17(4)
5) Delong WH, Grignon DJ. Pathologic findings in ribs removed at the time of radical nephrectomy for renal cell carcinoma. *Int J Surg Pathol.* 1994;1:177-180
6) Raab SS. The cost-effectiveness of routine histologic examination. *Am J Clin Pathol.* 1998;110:391-396
7) Zarbo RJ, Nakleh RE. Surgical pathology specimens for gross examination only and exempt from submission. A College of American Pathologists Q-Probes study of current policies in 413 institutions. *Arch Pathol Lab Med.* 1999;123:133-139
8) College of American Pathologists. *Policy M. Surgical Specimens to be Submitted to Pathology for Examination.* Northfield, IL: CAP; 2022.

ANP.10038 Tissue Sample Quality — Phase II

Trained histology personnel responsible for tissue processing provide feedback on the quality of the tissue sections received for tissue processing.

NOTE: Inadequate fixation, overly thick tissue sections, non-decalcified bone, the presence of staples, etc., can lead to poor quality histologic sections and/or poor quality special stains/special studies.

The feedback on quality issues must be provided to a pathologist. When non-pathologist personnel assist in grossing, feedback must be provided to a pathologist with responsibility for supervising non-pathologist personnel. In case of other pathology subspecialities that gross tissue specimens (eg, dermatology), the feedback is provided to the individual responsible for the gross processing of those specimens.

This requirement applies to both laboratories that gross tissue and perform all processing onsite, as well as laboratories that gross tissue and send it to another laboratory for processing, embedding, and sectioning (regardless of the outside laboratory's accrediting organization).

Records of such feedback and corrective action taken when problems are identified may be incorporated into the laboratory's quality management program.

Evidence of Compliance:

- ✓ Records of feedback and corrective action for problems identified with tissue quality

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

ANP.10041 Quality of Formalin **Phase I**

The laboratory monitors the quality of formalin provided for fixation of specimens to be submitted for pathology and for use as a fixative in the laboratory (eg, spot check or other processes).

NOTE: Laboratories that mix their own formalin need to check and record the pH to ensure that it was mixed correctly. The standard for tissue fixation is 10% neutral buffered formalin with a pH of 7.0.

Laboratories that purchase formalin ready for use or prefilled containers that are distributed to areas that collect specimens are also responsible for ensuring the quality of the formalin.

This requirement does not apply to situations where specimens are received from outside sources using containers not provided by the laboratory.

Evidence of Compliance:

- ✓ Records of pH checks for new batches of formalin prepared by the laboratory **OR**
- ✓ Records of manufacturer's quality control of pH **OR**
- ✓ Records of spot checks performed by the laboratory for purchased formalin ready for use

REFERENCES

1) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.

ANP.10042 Histologic Preparation Quality **Phase I**

Pathologists or their designees provide feedback to the histology laboratory on the quality of histologic preparations. This process includes the daily recording of the histologic preparation quality for each day of tissue processing and slide preparation.

NOTE: Histologic preparations refer to H & E sections, histochemical stains, immunohistochemistry preparations, and in situ hybridization preparations.

This requirement applies to laboratories that process and interpret histologic preparations at the same location, as well as laboratories that interpret histologic preparations processed at another laboratory (regardless of that outside laboratory's accrediting organization).

When histologic preparations are inadequate or cross-contamination between specimens or cases is identified, feedback and corrective action must be recorded. These records may also be incorporated into the laboratory's quality management system.

Specific quality control requirements for special stains, immunohistochemistry, and other special studies are found elsewhere in this checklist.

Evidence of Compliance:

- ✓ Records of feedback and corrective action for problems identified with histologic prep quality

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(a)].

ANP.10050 Previous/Current Material Review **Phase II**