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**