# COLLEGE of AMERICAN PATHOLOGISTS

**Subject:** Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology: Guideline Update

**Date:** May 18, 2021

## If/Then Statements

| Scenario | Appropriate Action(s) |
|---|---|
| **Scanner** | |
| If using a previously validated scanner for a new, materially different use case… | Then a full validation for the new use case with documentation is needed* |
| If replacing a scanner of the same make/model for previously validated applications… | Then calibration of images for same slides scanned with each scanner with documentation is acceptable. (Also known as a function check.) |
| If deploying scanners of the same make/model as previously validated at multiple sites across a hospital network… | Then assess applications, network and histology issues at each site to determine if full validation is required for each new scanner with documentation |
| If replacing a scanner with different make/model… | Then full validation with documentation is needed* |
| If introducing scanners of different make/model to multiple sites across a hospital network… | Then full validation with documentation for at least one site with assessment of applications, network and histology issues at additional sites to determine if full validation is required for each new scanner. |
| **Software** | |
| If introducing completely different viewing software including software from same vendor where legacy software has been sunset… | Then start with calibration of images between old and new software to determine if full validation is required with documentation |
| If employing an upgrade of software from same vendor… | Then calibration of images between old and upgraded software with documentation potential function check or partial validation dependent upon the criticality and extent of the upgrade |
| **Display** | |
| If replacing/upgrading displays at pathologist workstations… | Then calibrate image quality between old and new displays with or without documentation |
| **Remote Locations/Change in Network** | |
| If allowing primary diagnosis to be remotely performed outside the hospital network (e.g., pathologist's home)… | Then a full validation with documentation is needed* |
| If there is a change in pathology or hospital network… | Then calibrate archived images immediately before and after the network changes are made either with or without documentation |

*Refer to COM.30550 in the CAP Accreditation Checklist

### References

Evans A, Brown RW, Bui MM, et al. Validating whole slide imaging systems for diagnostic purposes in pathology: guideline update from the College of American Pathologists in Collaboration with the American Society for Clinical Pathology and the Association for Pathology Informatics. *Arch Pathol Lab Med.* 2021;146(4):440-450. doi: 10.5858/arpa.2020-0723-CP

College of American Pathologists. CAP Laboratory Accreditation Checklists. Accessed May 13, 2021. https://www.cap.org/laboratory-improvement/accreditation/accreditation-checklists