

NOTE: This checklist requirement applies only to laboratories subject to US regulations. The section director (technical supervisor) must establish the maximum workload limit (based on capability/recorded performance evaluation) for each individual who screens slides (including pathologists who screen slides); this maximum workload limit must conform to applicable federal and state regulations.

Performance must be reassessed using the following:

- *Re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists*
- *Comparing the cytotechnologist's interpretation in gynecologic specimens with the final cytologic diagnosis*
- *Comparing, in a manner determined by the laboratory, the cytotechnologist's interpretation in non-gynecologic specimens with the final cytologic diagnosis.*

These are minimal requirements and the laboratory may use additional methods of evaluating performance such as retrospective reviews, comparison of individual statistic with overall lab statistics, and competency assessment.

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): [42CFR493.1274(d)(1)].

CYP.08900 Screening Facility

Phase II



All cytopathology screening is performed within the laboratory facility or an approved referral laboratory.

NOTE: Cytopathology screening must be performed within the laboratory facility or an approved referral laboratory to provide proper access to technical and professional supervision, pathologist consultation and a controlled working environment. For laboratories subject to US regulations, all cytopathology screening must be performed within a CLIA certified facility or equivalent.

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): [42CFR493.1274(a)].

PHYSICAL FACILITIES

Inspector Instructions:

OBSERVE



- Space and utilities are sufficient

CYP.09000 Adequate Space and Utilities

Phase I

Space and utilities (water, electrical) are sufficient for processing cytologic material and for microscopic screening of slides.