Cytopathology in focus: Inspection pitfalls: Common cytology lab-related deficiencies

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May 2021—As COVID-19 restrictions ease, many laboratories are ramping up for biennial CAP inspections. Some of these inspections were delayed due to COVID restrictions and others were performed virtually and now must complete the statutory requirement of an on-site inspection. To add to the mix, the CAP published its 2020 checklist edition earlier than usual because of its impending reapplication with the CMS for deeming authority as an accrediting organization under CLIA. Together, these have made the 2021 inspection process appear unusually daunting. While no laboratory is immune to inspection anxiety, it does help to arm oneself with the knowledge gathered from the collective experiences of peers and colleagues across the country. Knowing what the common inspection pitfalls are can bring us a step closer to the "utopia" of a flawless inspection.

Based on the information gathered from inspection data in 2018, 2019, and 2020 (partial), establishing the workload policy for manual screening of cytology slides (CYP.08500) remained the most frequently cited phase two deficiency in the cytopathology laboratory. This individual maximum workload and its documentation addresses the final CLIA '88 rule that requires personnel who evaluate cytologic samples by manual technique to examine no more than 100 slides (gynecologic or nongynecologic or both) in a 24-hour period.[1] In cases where there are additional state regulations for cytology workload limits, the most stringent of these regulations must be followed to establish the said workload.

To clarify the count, gynecologic slides include new routine slides, 10 percent rescreen slides, and five-year look-back negative slides. Primary screening of nongynecologic liquid-based slide preparations requires each slide to be counted as one-half slide for the purpose of workload recording, provided that cells are dispersed over one-half or less of the total available slide area. For primary screening of all other slide types (including gynecologic liquid-based preparations, FNA, and others), each slide must be counted as a single slide for the purpose of workload recording. These guidelines are designed to optimize sensitivity and accuracy rather than numeric productivity.[2,3]

In situations where employees screen less than eight hours at an individual laboratory, the workload is prorated according to the following formula: number of hours spent screening × 100/8 (maximum workload being completed in no less than an eight-hour workday). This is particularly relevant to screening personnel, who assist in or perform adequacy assessment of fine-needle aspiration smears or rapid on-site evaluation (ROSE). While ROSE is not considered primary cytology screening as such, the time spent performing adequacy assessments is used to prorate the maximum number of slides an individual can screen in a 24-hour period. To be compliant, stringent records of a tally showing the total number of slides examined by everyone during each 24 hours must be maintained along with time spent on ROSE and other cytopreparatory activities.[3]

A pitfall in this regard is the workload assessment for pathologists who screen previously unscreened gynecologic slides and previously unscreened nongynecologic slides (including FNA slides). CLIA '88 requires laboratories to adhere to and record the aforementioned workload limit similarly for pathologists. For pathologists, this limit does not include previously screened reactive/repair, atypical, premalignant, and malignant gynecologic slides, rescreened five-year look-back slides, 10 percent rescreen of negative gynecologic slides, and prior screened nongynecologic slides including FNA slides.[3]

Another inspection "flag" that consistently rises to the top is competency assessment. Competency assessment (GEN.55500), a phase two deficiency, is one of the top three commonly cited deficiencies laboratorywide, based on the inspection data in years 2018–2020. More than 20 percent of laboratories are cited annually for deficiencies in this area. Its relevance to the cytopathology laboratory cannot be overemphasized, given that it is one of the most regulated areas in the laboratory overall. Competency assessments confirm that laboratory personnel are performing their routine laboratory duties adequately. While proficiency testing can be used as one of the assessment methods, PT performance alone is not sufficient to meet all competency assessment criteria. In the cytology laboratory, the technical supervisor is responsible for performing and documenting competency assessments; however, the laboratory director is held ultimately responsible for ensuring the implementation and supervision of laboratory staff competency assessments. Personnel competency assessment is required at least semiannually during the first year a new employee tests patient specimens and must be performed at least annually thereafter.

Table 1. Significant CAP inspection citations relevant to cytology laboratory

Year	Phase	Checklist ID	Requirement	% times cited
2020 (partial)	II	CYP.08500	There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.	4%
2019	II	CYP.08500	There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.	4.1%
2018	II	CYP.08500	There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.	3.3%
2020 (partial)	II	CYP.08575	There is a policy for the establishment of an individual maximum workload for the screening of cytology slides.	3%
2019	II	CYP.08575	There is a policy for the establishment of an individual maximum workload for the screening of cytology slides.	2.8%
2018	II	CYP.08575	There is a policy for the establishment of an individual maximum workload for the screening of cytology slides.	2.7%

Although each laboratory can establish its own competency checklist, assessments need to reflect all areas of routine duties—for example, routine patient test performance; specimen handling, processing, and testing; instrument maintenance; and test reporting. Another criterion for competence is communication and problem-solving, an area of particular importance owing to cytology's unique role in clinical encounters including ROSE.[4,5]

Another phase two deficiency that finds its place in the top 10 of laboratorywide citations addresses the disparity between the performance of daily duties and the procedures laid out in the procedure manual in cytology (COM.10000 and COM.10100). Although listed under the all common checklist, it applies equally to all laboratory areas. These two checklist requirements tie into the competency assessments that are performed periodically with regular updates of the policies and procedures, such that they accurately reflect the current laboratory practices and daily routines in the lab. This also includes annual and biennial procedure manual review and signoff by the laboratory director and/or the director's designee, something that can slip from the minds of the most diligent of laboratory teams.

Table 2. Laboratorywide CAP inspection citations for inadequate competency assessments

Year	Phase	Checklist ID	Requirement	% times cited
2020 (partial)	II	GEN.55500	Competency Assessment	21.3%
2019	II	GEN.55500	Competency Assessment	20.9%
2018	II	GEN.55500	Competency Assessment	24.6%

To conclude, cytology-laboratory–specific deficiencies remain low overall, representing no more than five percent of the cited deficiencies. Laboratorywide phase two deficiencies that reflect on cytology are more frequent and typically involve personnel oversight, competency assessments, and procedure manual reviews. In these areas, clear delineation of oversight responsibilities within the laboratory and continued periodic communication with cytology personnel might help reduce the frequency of citations or deficiencies during an inspection.

1. Centers for Medicare and Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA).

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. Modified April 9, 2013.
2. Nakhleh RE, Fitzgibbons PL, eds. *Quality Improvement Manual in Anatomic Pathology.* 2nd ed. College of American Pathologists; 2005.
3. Centers for Medicare and Medicaid Services. Clarification Regarding Fine Needle Aspiration (FNA) Specimen Adequacy Assessment, Rapid On-Site Evaluation (ROSE) and Workload Limits. March 16, 2018. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-18-14-CLIA.pdf.
4. Centers for Medicare and Medicaid Services. What Do I Need to Do to Assess Personnel Competency? November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf.
5. Clinical and Laboratory Standards Institute. QMS02-A6: Quality Management System: Development and Management of Laboratory Documents; Approved Guideline, 6th ed.; 2013.

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