



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO 18-14-CLIA

DATE: March 16, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group (*formerly Survey & Certification Group*)

SUBJECT: Clarification Regarding Fine Needle Aspiration (FNA) Specimen Adequacy Assessment, Rapid On-site Evaluation (ROSE) and Workload Limits

Memorandum Summary

- **The Centers for Medicare & Medicaid Services (CMS) is providing clarification related to FNA and ROSE under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).**
- A slide assessment that provides only a determination of specimen adequacy is not considered to be a slide examination for purposes of determining workload limits in accordance with 42 CFR 493.1274(d).
- Thus, when establishing workload limits for qualified individuals during specimen adequacy assessment or during diagnostic slide examination, workload limits should be determined as described herein.

Background

CLIA was passed in 1988 following the identification of serious problems in laboratories, which included cytotechnologists screening such high numbers of slides that the risk of improper diagnosis was extremely high. CMS established at 42 CFR 493.1274(d) a requirement to establish a workload limit for the amount of slides each individual may screen within a 24-hour period.

During a Fine Needle Aspiration (FNA) procedure, material is aspirated from a suspicious site, and then an adequacy assessment or a Rapid On-site Evaluation (ROSE) is performed microscopically by a qualified individual to assure that diagnostic material is present. This adequacy assessment helps to ensure that the aspiration will not need to be repeated for the diagnostic slide examination. These slides are not fully screened at this time. Once specimen adequacy has been determined, laboratories, including physician office laboratories, that perform diagnostic examination of FNA or ROSE slides must comply with CLIA regulations, including, but not limited to, 42 CFR 493.20 and 493.25, as applicable.

Determination of Specimen Adequacy and Workload Limits

A slide assessment that provides only a determination of specimen adequacy, that is, verification of an adequate cellular representation of the suspicious site (hereinafter referred to as a “specimen adequacy assessment”), and not any information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, is not considered to be a slide examination for purposes of determining workload limits in accordance with 42 CFR 493.1274(d). Thus, when establishing workload limits for qualified individuals during specimen adequacy assessment or during diagnostic slide examination, workload limits should be determined as follows in accordance with 42 CFR 493.1274(d):

A. During Adequacy Assessment

Specimen adequacy assessments such as those described above are not counted toward the individual’s daily slide workload limit. However, the time spent by the individual performing such specimen adequacy assessments must be used to prorate the maximum number of slides the individual can examine in a 24 hour period. To determine how the remaining time is used to prorate the maximum number of slides that can be examined during an individual’s workday, please refer to the formula described in 42 CFR 493.1274(d)(2)(ii). This prorating formula is also listed below:

For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula—

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

B. During Diagnostic Slide Examination

1. If a pathologist or a cytologist performs the primary examination/evaluation of a slide, each slide is counted toward their daily slide workload limit.
2. If a pathologist performs a secondary examination of a cytology slide after a previous cytologist or pathologist has performed the primary examination/evaluation, the slide is NOT counted toward the secondary pathologist daily slide workload limit. As per 42 CFR 49.1274(d)(2)(iv), previously examined cytology slides are not required to be counted in the 100 slide workload limit.

Contact: For questions related to this policy memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators.

/s/

David R. Wright

cc: Survey and Certification Regional Office Management