

subpart K, were in response to the cytology requirements. The comments were primarily from professional organizations, cytotechnologists, pathologists, and other physicians. The major issues that commenters addressed include—

(1) Workload limits; (2) review of reactive reparative cases by a technical supervisor; (3) the 10 percent rescreen of negative cases screened by a cytotechnologist; and (4) the 5-year retrospective review of negative smears from patients with a current high grade lesion.

Specific comments and response to comments regarding §§ 493.1257 and 493.1259 are set forth below.

Comment: Several commenters stated the language “non automated microscopic technique” used to describe the slides that are counted in the workload limit is inappropriate and might be confused with slides that are screened using a motorized mechanical stage or with slides that are read by an automated instrument.

Response: We agree with the commenters and are removing the wording “non automated microscopic technique.” We also want to emphasize that slides that are read with a human component must be included in the 100 slide limit; slides that are read by an automated instrument that do not require human review are not included in the workload limit.

Comment: A number of commenters and one cytology organization were opposed to establishing the workload limit at 100 slides examined in a 24 hour period. A few commenters felt the workload limit was too restrictive, while other commenters and the cytology organization indicated the limit was too high.

Response: The CLIA statute at section 353(f)(4)(B)(i) specifically states that the standards must establish “the maximum number of cytology slides that any individual may screen in a 24 hour period.” Limiting the number of slides that may be examined in 24 hours to no more than 100 is the absolute maximum workload limit for an individual. However, we agree with the commenters that this may not be an appropriate workload for all individuals. To clarify our position, formerly at § 493.1257(b)(1) (now at § 493.1274(d)(2)), we specify that the Federal workload limit was not to be used as a performance target for cytology personnel. In addition, we specified formerly at § 493.1257(c)(4) (now at § 493.1274(d)(1)) that the cytology technical supervisor must establish a workload limit (not to exceed 100 slides examined per 24 hours) for

each person examining slides and that at least every 6 months, the technical supervisor must re-evaluate and adjust, if necessary, each individual’s workload limit. In addition, we are emphasizing that the workload limit applies only to individuals and does not apply to automated slide examination systems that may be used to screen slides and identify those smears requiring no human microscopic examination.

Comment: One organization asked whether the workload requirements are applicable to technical supervisors or only to cytotechnologists. Several commenters suggested the workload requirement only applies to cytotechnologists.

Response: The workload requirements apply to any individual who performs primary screening of cytology slides. This may be a technical supervisor or a cytotechnologist. We are also clarifying that while tissue pathology slides and previously examined gynecologic and nongynecologic slides are not included in the 100-slide workload limit for technical supervisors, the technical supervisor must subtract the time spent evaluating these slides and the time spent on any nonscreening duties from the time spent screening slides to appropriately adjust the workload.

Comment: Many commenters and the cytology professional organizations opposed the workload provision to count as one-half slide those smears made using automated, semiautomated, or other liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the slide. Some commenters indicated that this workload limit should apply only to nongynecologic preparations, while others thought it premature to use this calculation for any cytologic preparations until sufficient scientific studies have been completed to document the establishment of a workload limit appropriate for these preparatory techniques.

Response: In order to address concerns of the commenters, we are making several clarifications. First, the 200-slide workload limit was initially established in the February 28, 1992 final rule with comment period published in the **Federal Register** (57 FR 7002) in response to innovations in cytology preparatory techniques and acknowledgment that slide preparations that only occupy a portion of the slide will not count as a whole slide. Slide preparations (gynecologic and nongynecologic) made using automated, semi-automated, or other liquid-based preparatory techniques that result in a specimen that only occupies a small portion of the slide, are counted as one-

half slide. Second, on January 19, 1993, we published a final rule with comment period in the **Federal Register** (57 FR 5212) removing gynecologic preparations. On July 22, 1993, we published a technical correction notice in the **Federal Register** (58 FR 39154) that inadvertently reinserted gynecologic preparations. In addition, Cytoc, manufacturer of ThinPrep™, agrees that a 200-slide workload limit is too high for gynecologic preparations and has requested that the 200 slide workload limit not be applicable to gynecologic slides. We agree with the commenters and Cytoc corporation, and we are eliminating gynecologic slides from the 200-slide workload limit (now at § 493.1274(d)(2)(iii)). The 200-slide workload limit will only apply to nongynecologic slides.

Comment: Many Commenters and the Cytology organizations agreed that a workload limit was appropriate for gynecologic preparations. However, they were opposed to establishing a workload limit for nongynecologic smears because these preparations vary greatly in specimen type or source, preparatory techniques, and cellularity requiring various time frames for evaluation. The commenters acknowledged the difficulty in establishing a workload limit for individuals who examine nongynecologic preparations exclusively or a combination of gynecologic and nongynecologic smears. For fine needle aspirations, several organizations suggested using the methodology employed by New York State to prorate nongynecologic preparations, that is, for cases involving one to three slides, each slide is counted as one and for cases having four or more slides, a maximum of three slides are counted for workload purposes.

Response: We agree with the commenters that it is easier to establish a workload limit for gynecologic smears than for nongynecologic preparations because of the variability in nongynecologic preparations; however, the statute requires us to determine the maximum number of cytology slides that an individual can screen in a 24-hour period. Therefore, the workload limit is applicable to all cytology slides, including gynecologic and nongynecologic preparations. Concerning the New York State proration of nongynecologic slides, this practice is no longer in use in New York.

Comment: Several individuals asked for clarification on the specific guidelines that a technical supervisor should use to determine the maximum workload for an individual. Some