

commenters noted the technical supervisor may have to justify a workload that is lower than 100 slides to hospital and laboratory administrators.

Response: Formerly at § 493.1257(c)(4)(i), individual workload is based on the performance evaluation described formerly at § 493.1257(c)(3). Therefore, we are revising the requirement, now at § 493.1274(d)(1)(i), to make it more understandable. Performance must be evaluated using the following: (1) Re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists; and (2) comparing the cytotechnologist's interpretation with the final diagnosis on cases of atypical squamous cells of undetermined significance (ASC-US), low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), glandular epithelial cell abnormalities, or other malignant neoplasms. However, the evaluations listed in the former CLIA regulations must be viewed as minimal requirements and the laboratory may have additional mechanisms or criteria to evaluate individual performance. For example, the following provisions in the CLIA regulations may be used: (1) Number of discrepant findings on the retrospective review of previous negative cases from patients with a current HSIL, adenocarcinoma or other malignant neoplasm; (2) individual statistics evaluated against the laboratory's overall statistics; and (3) competency assessment activities.

Comment: Many of the commenters and the cytology organizations suggested that the requirement for confirmation of cases by the technical supervisor be limited to those having atypical squamous or glandular cells, or any premalignant or malignant cell changes. The commenters suggested deleting the reference requiring confirmation of "reactive or reparative changes," stating that the requirement was excessive. Other commenters recommended changes to allow technical supervisors the discretion to determine the level of supervisions, that is, review of cases with benign cellular changes, needed by each employee. In addition, several commenters suggested we revise the language to include the Bethesda terminology.

Response: We have not removed all reference to reactive and reparative changes because many laboratories still use this classification. The regulation, however, incorporates the Bethesda terminology, which provides for a uniform categorization of the cellular changes seen in gynecologic cytology. Most of the slides formerly classified as

having "reactive and reparative" changes that would have exhibited marked or extensive cellular changes on technical review will, therefore, be classified as ASC-US or as having a squamous cell abnormality under the Bethesda terminology. As specified at § 493.1274(e), all of these slides are required to be reviewed by the technical supervisor. However, we have retained the classification reactive and "reparative changes," and similar cellular changes under the Bethesda category "Negative for Intraepithelial Lesion or Malignancy" that would formerly have been categorized as reactive or reparative to encompass those slides needing review by the technical supervisor. Technical supervisors continue to have the discretion to review more cases as necessary to train and manage cytotechnologists under their supervision. Although we are not requiring the use of the Bethesda terminology, the majority of the laboratories have adopted it, and we encourage other to do the same.

Comment: One organization stated that the technical supervisor's signature on the worksheet is acceptable documentation for the review of abnormal gynecologic cases. For nongynecologic cases, the organization suggested that laboratories allow the technical personnel to verify the final computer generated report that would include the name of the technical supervisor who reviewed the case. Another commenter asked for clarification on electronic signatures and whether CLIA regulations allow electronic requisitions.

Response: We do not believe that any change in the CLIA regulations is appropriate. The final report must be verified by the technical supervisor who reviewed the case and signs the report, and electronic signatures must be authorized and verified by the technical supervisor who signs the report. As specified at § 493.1241, electronic requisitions are acceptable, as long as the requisition contains the required information.

Comment: Several commenters, including one cytology organization, disagreed with requiring laboratories to rescreen 10 percent of the cases interpreted to be normal or negative by cytotechnologists. One organization stated the 10 percent rescreen is a statistically invalid mechanism for reducing the false negative rate and suggested the requirement be replaced by a goal-oriented statistically valid system for promoting laboratory QC. One organization was opposed to requiring laboratories to complete the 10

percent rescreen before reporting patient results.

Response: The CLIA statute requires " * * * random rescreening of cytology specimens determined to be in the benign category * * *" Accordingly, random rescreening of negative cases is required in CLIA rules. We view the 10 percent rescreen as a minimum requirement and only one component of the laboratory's control procedures and QA activities. In addition, rescreening is supported by the results of cytology surveys conducted under CMS contract that includes rescreening approximately 0.1 percent of the laboratory's caseload. In many of these surveys, diagnostic discrepancies were noted between the contractor's evaluation of patient specimens and the results reported by the laboratory, even though the sample rescreened was less than 10 percent of the laboratory's caseload. The control procedures, including the 10 percent rescreen, assess the quality of the laboratory's results, and the rescreen must be completed before issuing patient reports on the slides selected for the 10 percent rescreen as specified formerly at § 493.1257(d)(1)(iii) (now at § 493.1274(c)(1)(ii)).

Comment: One commenter asked whether the 10 percent re-evaluation of negative cases could be performed by the same individual who performed the primary review.

Response: The 10 percent rescreen of negative cases is one provision of the cytology control procedures specified formerly at § 493.1257(d) requiring laboratories to have a program designed to detect errors in cytology examinations. This provision is now at § 493.1274(c). Ten percent of the cases interpreted as negative by cytotechnologists must be reevaluated by a cytology technical supervisor qualified under §§ 493.1449(b) or 493.1449(k), a cytology general supervisor qualified under § 493.1469(b)(2), or a cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2). For laboratories with a solo pathologist (no cytotechnologists), the 10 percent rescreen need not be performed; however, the following cytology QC procedures must be performed: a laboratory comparison of clinical information and histopathology reports (as specified at § 493.1274(c)(2)), a retrospective rescreen of normal and negative cases received within the previous 5 years from a patient with a current high grade lesion (as specified at § 493.1274(c)(3)) and annual statistical evaluation (as specified at § 493.1274(c)(5)).