

Comment: Many cytology organizations disagreed with requiring review of all normal or negative slides from the previous 5 years for any patient having a current high grade intraepithelial lesion or above. The commenters felt that the 5-year review was unreasonable and unnecessarily burdensome and suggested that the review include only the two most recent smears, if available in the laboratory. A number of commenters noted the error at § 493.1257(d)(3) in referring to patients with “a current high grade or above intraepithelial lesion . . .” and suggested rewording the requirement for retrospective review of negative cases from patients having a “current high grade intraepithelial lesion or cancer.”

Response: We are not reducing the requirement for review of negative cases from the previous 5 years for patients having a current high grade intraepithelial lesion or cancer because the law requires “. . . for each abnormal cytological result, rescreening of *all* (emphasis added) prior cytological specimens for the patient, if available.” However, we appreciate and agree with the commenters’ suggestion about rewording the requirement, formerly at § 493.1257(d)(3) (now at § 493.1274(c)(3)) to reflect current terminology.

Comment: One organization asked for clarification on the time frame for completion of the retrospective review of cases with a current high grade lesion or above and the histology and cytology correlation.

Response: The retrospective review and the histology and cytology correlation are part of the control procedures and must be completed in a timely manner. Since there is a possibility that this QC activity could result in the issuance of a corrected report that may affect patient treatment, the laboratory must have procedures in place that include time frames for these activities.

Comment: Several commenters and cytology organizations disagreed with requiring laboratories to compare the case reviews of each individual with the laboratory’s overall statistical values. The commenters stated that the case mix (specimens from various clinics with different patient populations) varies and these statistics should not be used to assess individual performance. In smaller laboratories the statistical comparison may not be valid due to the small numbers. It was suggested that laboratories be given flexibility to determine the best approach for implementing the control procedure requirements and evaluating individual performance.

Response: We established these requirements as a result of comments provided in response to the proposed rule that was published on May 21, 1990 in the **Federal Register** (55 FR 20896). The commenters stated that reviewing the laboratory’s data provided useful information on overall laboratory practice as well as individual performance. We believe these requirements have provided valuable information for assessment of laboratory and individual performance; therefore, we are not making any revisions. However, laboratories may document situations that affect the laboratory’s statistics and individual case reviews.

Comment: One cytology organization was opposed to requiring laboratories to document cases for which histologic reports were unavailable for comparison with abnormal gynecologic results, stating that it was time consuming and burdensome and provided no benefit to the patient.

Response: In an attempt to minimize the burden, (now at § 493.1274(c)(5)(iv)), we are requiring documentation of only the number of cases that have histology correlation. We believe this information is necessary to determine the laboratory’s success in obtaining histology reports for the histology and cytology correlation.

Section 493.1259 Condition: Histopathology

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

Comment: Two medical professional organizations disagreed with the requirements at § 493.1259(c) that precluded neurologists from examining nerve and muscle biopsies. Also, in May 1993, CLIAC recommended that neurologists with specialized training and board certification qualify as technical supervisors, general supervisors, and testing personnel of neuromuscular histology. Without recognition of this training, neurologists would be required to refer neuromuscular tissue specimens to an anatomic pathologists for examination.

Response: We are amending the histopathology QC requirements formerly at § 493.1259(c) (now at § 493.1273(c)) to allow individuals who have successfully completed a training program approved by HHS to examine and provide reports for neuromuscular pathology. In Appendix C of the State Operations Manual (CMS Pub. 7), subpart K, we will specify that the training program developed by the American Academy of Neurology Committee for Neuromuscular Pathology is approved by HHS. We are

making the change to § 493.1273 rather than the personnel requirements in subpart M, because in this final rule, we are limiting the personnel revisions to the phase-in provisions addressed in the December 28, 2001 proposed rule. HHS received numerous personnel comments in response to the February 28, 1992 final rule with comment period which we intend to address in a future regulation.

Section 493.1265 Condition: Histocompatibility

Specific comments received and response to comments regarding § 493.1265 are set forth below.

Comment: Several commenters were pleased with the final CLIA rule for histocompatibility testing and felt the majority of the concerns raised over the proposed rule had been addressed. They noted the requirements now generally reflect the state of the art laboratory practices in this specialty area of testing that is continuing to evolve.

Response: We appreciate this acknowledgment of the efforts made in developing the histocompatibility QC requirements specified in the final rule with comment period that was published on February 28, 1992 in the **Federal Register** (57 FR 7170). In our continuing endeavor to represent current technology and practice, we are updating some of the terminology and references used in this section. We are also deleting several requirements that are duplicative of requirements found elsewhere in the CLIA regulation. In addition, we are adding clarifying language and reorganizing the requirements in this section that apply to HLA typing, disease associated studies, antibody screening, crossmatching, transplantation, and general requirements that apply to every histocompatibility laboratory regardless of the testing and services offered by the laboratory.

Comment: One commenter requested the requirements for histocompatibility testing be separated into three groups: solid organ transplantation, including renal; bone marrow transplantation; and histocompatibility testing for transfusion services.

Response: We acknowledge that the organization of the histocompatibility requirements found in the final rule with comment period may have caused some confusion to the reader trying to determine what testing requirements apply to each type of organ or tissue transplant. While there are various ways to group the requirements in this specialty, we are reorganizing this section by first delineating the general requirements for histocompatibility