783–3238 or by faxing to (202) 275–6802. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Rosemary Bakes-Martin, (404) 488–7655, for questions regarding the addition of the three PPM tests; Rhonda S. Whalen, (404) 488–7655, for questions regarding personnel; and Judy Yost, (410) 597–5907, for certificate, fee, and inspection issues.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings must meet certain requirements to perform the examination. Many of the requirements are based on the complexity of the tests performed. There are currently three test categories: Waived, moderate complexity, including the subcategory of physician-performed microscopy, and high complexity.

Following the publication on February 28, 1992 (57 FR 7002) of the initial regulations implementing CLIA, HHS established a Clinical Laboratory Improvement Advisory Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAC is composed of individuals involved in the provision of laboratory services, use of laboratory services, development of laboratory testing devices or methodologies, and others as approved by HHS. In addition, HHS has designated the following four CLIAC subcommittees: cytology; personnel; proficiency testing, quality control and quality assurance; and test categorization.

The CLIAC meets as needed, but not less than once a year. So far, the CLIAC has met in October, 1992, February, May, August, and December, 1993, and March and September, 1994. The subcommittee on test categorization has met in January and June, 1993; the subcommittee on cytology has met in December, 1993; and the subcommittee on proficiency testing, quality control, and quality assurance has met in March and September, 1994.

Following publication of the February 28, 1992 regulations, we received approximately 16,000 letters from professional organizations and individuals that provided around 71,000 comments. In response to public comments received concerning certain physician performed microscopy procedures, we requested the CLIAC to evaluate the categorization of these tests. As a result, we developed a new subcategory of moderate complexity testing, called physician-performed microscopy (PPM) procedures, and published the requirements concerning the subcategory in a rule on January 19, 1993 (58 FR 5215).

In this rule, we address the comments we received concerning the application of certain personnel requirements and comments concerning categorization of PPM tests. One area of commenter concern was that currently employed supervisors and high complexity testing personnel continue to be qualified. Another area of concern was that our requirements would diminish access to services, particularly in rural and underserved areas, leading to recommendations that we expand the PPM procedures subcategory to include dentists and midlevel practitioners.

II. Responses to Comments

A. Categorization: Physician-Performed Microscopy Procedures

As stated earlier, we established a new subcategory of moderate complexity testing called ''physician-performed microscopy (PPM) procedures'' in revisions to the CLIA regulations, published in the **Federal Register** on January 19, 1993. In response to the regulation establishing PPM, we received approximately 2,200 comments from professional organizations and individuals. A significant number of these comments addressed the tests categorized as PPM procedures, including requests that some of these tests be waived, or that additional tests be added to the list of PPM procedures. Some commenters asked that PPM be expanded to include specific tests related to a particular medical specialty or practice. Conversely, other commenters were opposed to adding additional tests or criteria to PPM, and felt that this subcategory should remain very limited.

Comments and Responses

Comment: A number of commenters stated that PPM is too restrictive, and that all of the PPM procedures should be categorized as waived tests. Some commenters specifically stated that wet mounts and urine sediment examinations should not be in PPM but should be waived tests.

Response: Tests included in PPM are moderate complexity microscopic examinations that do not meet the criteria for waiver because they are not simple procedures; they require training and specific skills for test performance. Personnel performing these tests must be proficient in the use of a microscope and must be able to detect and identify cellular elements present in a specimen, both of which require substantial training, experience, and specific knowledge to be accurately performed. To differentiate significant elements in a specimen from debris or artifacts requires a high level of interpretive skills. In fact, personnel requirements for this subcategory of moderate complexity testing are more stringent than for other moderate complexity testing due to the nature of testing in PPM. Examinations of wet mount preparations and urine sediment were included in PPM because they meet the PPM criteria. These microscopic examinations are performed during a patient's physical examination on specimens that are labile or not appropriate to send to another laboratory for analysis. In addition, controls are generally not available to monitor the complete testing process for these procedures. Therefore, only limited activities are suitable for inspection.

Comment: Several commenters expressed confusion as to which examinations are considered ''wet mount examinations''.

Response: We are revising the description of ''wet mount examinations'' at § 493.19(c)(1) (formerly § 493.16(c)(1)), to clarify what we mean by wet mount preparations. Although we provided the examples of vaginal, cervical or skin specimens as part of the wet mount definition, we never intended to limit wet mount examinations to only these specimens. By revising the definition of this test, we are not making any changes in what was originally intended for this group of examinations. They are moderate complexity microscopic examinations performed on any direct specimen that may be suspended in a drop of water or saline. They are performed using a microscope, which is limited to bright-field or phase-contrast, in order to recognize the presence or absence of bacteria, fungi, parasites, and human cellular elements (including red and white blood cells, epithelial cells, etc.) and to differentiate these from artifacts. They are not procedures in which definitive identification or enumeration is made or any staining is performed.