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Report of the Subcommittee on Clinical Laboratory Standards
Clinical Laboratory Technical Advisory Committee
Department of Health Services, State of California
Dated: 2 March 2001

SUMMARY

A meeting of the subcommittee was convened at the offices of Laboratory Field Services in Oakland, CA on Thursday, November 30, 2000. Present at the meeting were the following subcommittee members: Maurice Green, PhD (Chair); Deanna Iverson; CT, Lyle Rosser, CLS; Constance Smith, CLS; Antonius Van Kessel, RCP and Jerry Hurst (LFS liaison). Absent members were Lee Hilborne, MD and Robert Footlik, CLB (ex-officio). Also in attendance were Karen Nickel, PhD (Director, LFS) and Alice Brydon (LFS examiner).

The chair opened the meeting with a review of the charge from Dr. Nickel to CLTAC (see attached) expanding the role of the subcommittee to review all of Title 17 CCR, Section 1050, "Clinical Laboratory Standards". It was noted that Section 1050 was last amended in 1978. The premise stated in the charge was that since the passage of CLIA '88 and SB113 "parts of this Section are redundant, inconsistent or more strict than state or federal law". Those sections which were redundant or inconsistent should be considered for repeal. Those sections which were stricter than current federal or state law should be re-examined to determine if they were needed to assure adequate protection of public health and safety or could be repealed without adverse effect. The previous recommendations of this subcommittee on Section 1050(h) "Clinical Laboratory Test Results", presented to CLTAC in March 1999, were reviewed (attached).

Following a detailed line-by-line review of all subsections of Section 1050, the committee voted unanimously to recommend:

1. Repeal of all subsections 1050(a) through 1050(g) inclusive, and
2. Amendment (as indicated by *italics*) of the previous recommendations for Section 1050(h) as follows:

1050 (h) Clinical Laboratory Test Results. Clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability and validity. This *critical review shall be accomplished by the following means:*

- 1) By a person authorized to perform these tests under Section 1206.5 of the California Business and Professions Code; or
- 2) By autoverification (the review and verification of results by use of a computer algorithm), when
 - a) The laboratory director or his authorized designee has established and validated explicit criteria by which the results are verified, and
 - b) *A person authorized under Section 1206.5 of the California Business and Professions Code shall be present and responsible for testing when results are being released.*

Submitted



Maurice Green, PhD

Review of Title 17 CCR, Section 1050

TITLE 17. Public Health
Division 1. State Department of Health Services
Chapter 2. Laboratories
Subchapter 1. Service Laboratories
Group 2. Clinical Laboratory Regulations
Article 5. Issuance of License

§1050. Clinical Laboratory Standards.

(a) All licensed clinical laboratories shall be conducted, maintained, and operated without injury to the public health and shall maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency program approved by the department.

Unnecessary and redundant with BPC:

1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.

1220. (b) Each clinical laboratory shall be conducted, maintained, and operated without injury to the public health.

1272. A clinical laboratory shall participate in a state-approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialties that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, cytology, and immunohematology.

and the following sections of 42CFR (10/1/94): 493.1, 493.602, 493.1804(a), 493.503.

(b) Proficiency Testing.

- (1) The laboratory must participate in a state approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialties that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, and immunohematology.
- (2) The participating laboratory must test applicable materials each time they are distributed by the approved proficiency testing service according to a schedule approved by the department.
- (3) Those procedures performed by the laboratory for which test materials are provided by the approved proficiency testing service and which have been designated by the department as a requirement for measuring test performance, must be proficiency tested by the participating laboratory each time test materials are received.
- (4) The participating laboratory must authorize the approved proficiency testing service to report proficiency test results to the department.
- (5) The participating laboratory must test applicable materials only in the laboratory to which the license and the proficiency testing requirement applies using personnel and equipment used in that facility in providing services.
- (6) A laboratory may be required to discontinue providing a service in a procedure or category of procedures if:
 - (A) For three consecutive quarters the laboratory fails to report on test materials received for procedures for which the laboratory is required to be proficiency tested, or
 - (B) For three consecutive quarters the laboratory demonstrates unsatisfactory performance in a procedure or category of procedures. A determination of satisfactory performance for a procedure shall be based upon results being within acceptable limits established by the proficiency testing service for that procedure and approved by the department. A determination of satisfactory performance for a category of procedures shall be based upon an average of performance within the category over four consecutive quarters.

Above sections 1050 (b)(1) through 1050 (b)(6) are unnecessary and redundant with BPC

1220 (2)(A) Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by HCFA, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement shall not be interpreted to prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or HCFA approved proficiency testing program.

(B) Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.

and covered by 42CFR 493.503, 493.801-493.959 (Subpart H) and 493.1445 (e)(4)

Subpart H-Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) Standard; Enrollment. The laboratory must-

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. [D2002]

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and [D2003]

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy and reliability of its testing procedures, in accordance with 493.1709. [D2004]

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify HCFA before any change in designation; and [D2005]

(4) Authorize the proficiency testing program to release to HHS all data required to- [D2006]

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) Standard; Testing of proficiency testing samples. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. [D2007] [D2008] [D2009]

(2) The laboratory must test samples the same number of times that it routinely tests patient samples. [D2010]

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. [D2011] [D2012]

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which they are certified to perform in their own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis and submits the other laboratory's results as their own will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples. [D2013]

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. [D2014] [D2015]

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly,

(e) The laboratory director must- [D6081]

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that- [D6088]

(i) The proficiency testing samples are tested as required under subpart H of this part; [D6089]

(ii) The results are returned within the timeframes established by the proficiency testing program; [D6090]

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and [D6091]

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; [D6092]

(7) A laboratory whose services have been disapproved because of unsatisfactory performance may apply to the department for reapproval to provide these services after demonstrating satisfactory performance during the two consecutive quarters or testing periods immediately prior to requesting reapproval.

Section 1050 (b)(7) is unnecessary- covered by 42CFR 493.807

493.807 Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully. [D2017]

(a) If a laboratory's certificate is suspended and/or Medicare or Medicaid approval is terminated because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The termination period for Medicare or Medicaid approval or period for suspension of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of termination or suspension.

(c) If a laboratory's certificate is suspended and/or Medicare or Medicaid approval is terminated in gynecologic cytology, the laboratory must take corrective action and reapply for certification. [D2018]

(c) Direction. The person or persons directing a licensed clinical laboratory shall assume the following responsibilities:

- (1) Determine what laboratory procedures will be performed, the techniques that will be followed, and the equipment and reagents that will be used.**
- (2) Determine the scope and nature of procedures to control the reliability of test performance and personally monitor these control programs.**
- (3) Regularly assess the activities of the laboratory by personal observation, evaluation, and review of reports of laboratory findings.**
- (4) Establish qualification criteria of laboratory personnel.**
- (5) Determine the format of laboratory report forms and decide what information is to be contained on these report forms.**
- (6) Regularly consult with supervisors and other staff members.**
- (7) Confer with those served by the laboratory on matters that relate to test performance and determine the nature and scope of technical and administrative information to be released by the laboratory staff.**

Covered in BPC as indicated:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1209 (a) As used in this chapter, "laboratory director" means any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel,

or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

1209 (b)(1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to assure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

1209(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

1209(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

- (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.
- (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
- (3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

1209(e) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

- (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.
- (B) Monitoring the recording and reporting of test results.
- (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- (D) Direct observation of performance of instrument maintenance and function checks.
- (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- (F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

1209(f) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

- (1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high quality service.
- (2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available. As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

1209(g) Subdivision (f) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

1283. It is unlawful for any person to conduct, maintain, or operate a clinical laboratory unless he is a duly licensed physician and surgeon or is duly authorized to do so under the provisions of this chapter.

1284. It is unlawful for a duly licensed physician and surgeon, or any person authorized to serve as director under this chapter, to serve only as a nominal director.

and in 42CFR 493.1407, 493.1445, 493.1701(Subpart P)

493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. [D6004]

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. [D6005]

(d) Each individual may direct no more than five laboratories. [D6006]

(e) The laboratory director must-

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; [D6007]

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards; [D6010] [D6011]

(3) Ensure that-

(i) The test methodologies selected have the capability of providing the quality of results required for patient care; [D6012]

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and [D6013]

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; [D6014]

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that- [D6015]

(i) The proficiency testing samples are tested as required under subpart H of this part; [D6016]

(ii) The results are returned within the timeframes established by the proficiency testing program; [D6017]

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and [D6018]

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; [D6019]

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; [D6020] [D6021] [D6022]

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; [D6023]

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; [D6024] [D6025]

(8) Ensure that reports of test results include pertinent information required for interpretation; [D6026]

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions; [D6027]

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; [D6028]

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; [D6029]

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; [D6030]

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and [D6031]

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. [D6032]

Subpart P-Quality Assurance for Moderate or High Complexity Testing, or Both

493.1701 Condition: Quality assurance; moderate or high complexity testing, or both. [D7000]

Each laboratory performing moderate or high complexity testing, or both, must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards of this subpart as they apply to the services offered, complexity of testing performed and reported, and the unique practices of each testing entity. All quality assurance activities must be documented. [D7001]

(8) Be available daily in any laboratory performing cytology and serve as director of no more than three (3) laboratories.

(9) Cause a licensed physician or dentist, qualified in cytopathology, to personally examine and report findings on abnormal or questionable gynecologic and all non-gynecologic specimens. CWA 1257

The committee believed that requirement for a director to be on site whenever screening is being performed is overly stringent and reduced staff availability, would negatively impact health care. The committee believed that the technical supervisor could serve in this role as provided in 42CFR 493.1257 and 493.1449. The limit of 3 laboratories for the director should be raised to 5 in accordance with 42CFR 493.1407.

493.1257 Condition: Cytology.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in 493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section. [D4312]

(a) The laboratory must assure that-

(1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method; [D4313]

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process; [D4314]

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining; [D4315] [D4316]

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and [D4317]

(5) All cytology slide preparations are evaluated on the premises. [D4318]

(b) The laboratory is responsible for ensuring that-

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissue pathology slides examined by a technical supervisor qualified under 493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under 493.1449 (b) and (k).); [D4319] [D4320]

(2) For purposes of workload calculations, each slide preparation (gynecologic or nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide. [D4321]

(3) Records are maintained of the total number of slides examined by each individual during each 24 hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the 24 hour period; [D4322]

(i) The maximum number of 100 slides described in paragraph (b)(1) of this section is examined in no less than an 8 hour workday; [D4324]

(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula- [D4325]

No. of hours examining slides X 100 to determine maximum slide volume to be examined.

(c) The individual qualified under 493.1449 (b) or (k) who provides technical supervision of cytology must ensure that-

(1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology; [D4326] [D4327]

(2) All nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor; [D4328]

(3) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases as defined in paragraph (c)(1) of this section; and [D4330]

(4) A maximum number of slides, not to exceed the maximum workload limit described in paragraph (b) of this section is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique. [D4333]

(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in paragraph (c)(3) of this section. [D4334]

(ii) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. [D4336]

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results. [D4338]

(1) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions as defined in paragraph (c)(1) of this section that are examined by each individual not qualified under 493.1449 (b) or (k). This review must be done by a technical supervisor in cytology, a cytology general supervisor qualified under 493.1469, or a cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). [D4341] [D4342]

(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information; [D4343]

(ii) Records of initial examinations and rescreening results must be available; and [D4343]

(iii) The review must be completed before reporting patient results on those cases selected. [D4343]

(2) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant (as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies. [D4347]

(3) For each patient with a current high grade or above intraepithelial lesion (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report. [D4350]

(4) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, as defined in paragraph (c)(1) of the section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section. [D4354]

(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate. [D4360]

(e) The laboratory report must-

(1) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and [D4363]

(2) Contain narrative descriptive nomenclature for all results. [D4364]

(f) Corrected reports issued by the laboratory must indicate the basis for correction. [D4365]

(g) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request. [D4366] [D4367] [D4369] [D4370]

493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. [D6004]

(d) Each individual may direct no more than five laboratories. [D6006]

493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. [D6109] [D6110]

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and [D6111]

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-

- (1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
- (2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements-

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

(2) An individual qualified under 493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under 493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(d) Facilities. The laboratory must provide for and assure that:

- (1) There is adequate space including working surface to conduct and control the performance of all test procedures performed in the laboratory.**
- (2) There is adequate area for safe storage and use of equipment and supplies.**
- (3) All areas are well lighted and properly ventilated.**
- (4) Fume hoods and biological safety cabinets, properly installed and regulated, are used if required for safe performance of tests or for safe preparation of materials.**
- (5) Instructions to be followed in case of fire and other emergencies are posted in a conspicuous place.**

Unnecessary - all of section 1050 (d) is covered in BPC 1220 (a)(1)

1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.

and in 42CFR 493.1204, 493.1407 (e)(2) and 493.1445 (e)(2)

493.1204 Standard; Facilities.

The laboratory must provide the space and environmental conditions necessary for conducting the services offered. [D4012]

(a) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate. [D4016] [D4017]

(b) Safety precautions must be established, posted, and observed to ensure protection from physical hazards and biohazardous materials. [D4018]

493.1407 (and 493.1445) Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. [D6079]

(e) The laboratory director must- [D6081]

- (3) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards; [D6083] [D6084]

(e) Equipment and Test Materials.

(1) The laboratory must provide for and assure that equipment, instruments, glassware, and reagents are maintained in proper working order by periodic inspection, testing, or calibration in a manner acceptable to the department.

(2) All reagents and stains shall be dated at the time of preparation and initialed by the person making the reagents or stains, or the date received and date opened if commercially prepared reagents or stains are used. All reagents and stains shall be labeled to indicate identity, and titer, strength, or concentration. Recommended storage temperature and expiration date, and other pertinent information necessary for quality control must be on the label.

Unnecessary – all of section 1050 (e) is covered by BPC 1220 (d)(2)(B) with reference to 42CFR Subpart K:

1220 (d)(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:

(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1201) of Title 42 of the Code of Federal Regulations.

and by 42CFR 493.1205 (d), 493.1215, 493.1407 (e)(1):

493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.

The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports. [D4022]

(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate-

- (1) Identity and, when significant, titer, strength or concentration; [D4030]
- (2) Recommended storage requirements; [D4032]
- (3) Preparation and expiration date; and [D4033]
- (4) Other pertinent information required for proper use. [D4034]

493.1215 Standard; Equipment maintenance and function checks.

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports. [D4084]

(a) Maintenance of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must-

- (i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer, and
- (ii) Document all maintenance performed.

(2) For equipment, instruments, or test systems not cleared by the FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must-

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting; [D4088]

- (ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and [D4089]

(iii) Document all maintenance performed. [D4090]

(b) Function checks of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must-

- (i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer, and
- (ii) Document all function checks performed.

(2) For equipment, instruments, or test systems not cleared by FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must-

- (i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting; [D4094]
- (ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and [D4095] [D4096]
- (iii) Document all function checks performed. [D4097]

493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. [D6004]

(e) The laboratory director must-

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; [D6007]

(f) Records.

(1) Retention of Records: The laboratory must maintain for a period of at least two years documentation of the following:

(A) Records of specimens received and tested, including identification of the patient, name of the submitter, dates of receipt and report, type of test performed, and test results.

Adequately covered in BPC 1220 (a) and 1220 (d)(2)(A)

1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.

(d)(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:

(A) A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1101) of Title 42 of the Code of Federal Regulations.

and under 42CFR 493.1103 and 493.1107.

493.1103 Standard; Procedures for specimen submission and handling.

(a) The laboratory must have available and follow written policies and procedures for each of the following, if applicable: Methods used for the preparation of patients; specimen collection; specimen labeling; specimen preservation; and conditions for specimen transportation. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported. [D3001] [D3004] [D3007] [D3010] [D3013]

(b) If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) of this section. [D3016]

(c) Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions where applicable.

493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. The record system must provide documentation of information specified in 493.1105 (a) through (f) and include- [D3032] [D3034] [D3036]

(a) The patient identification number, accession number, or other unique identification of the specimen; [D3037]

(b) The date and time of specimen receipt into the laboratory; [D3038] [D3039]

(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability, and [D3040]

(d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results. [D3041] [D3042]

(B) Records of inspection, validation, calibration, repair, and replacement to insure proper maintenance and operation of equipment and proper reactivity of test materials.

Unnecessary – covered in BPC 1220(a) and 42CFR 493.1213, 493.1215 and Subpart J

493.1213 Standard; Establishment and verification of method performance specifications.

Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.

(b) (1) After September 1, 1992, a laboratory that introduces a new procedure for patient testing using a moderate or high complexity method (instrument, kit, or test system) cleared by the FDA as meeting the CLIA requirements for general quality control, must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision, and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

(2) After September 1, 1992, a laboratory that introduces a new procedure for patient testing using: a method developed in-house; a modification of the manufacturer's test procedure; or a method (instrument, kit, or test system) that has not been cleared by the FDA as meeting the CLIA requirements for general quality control, must, prior to reporting patient test results-

(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable: [D4074]

- (A) Accuracy;
- (B) Precision;
- (C) Analytical sensitivity;
- (D) Analytical specificity to include interfering substances;
- (E) Reportable range of patient test results;
- (F) Reference range(s); and
- (G) Any other performance characteristic required for test performance.

(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish calibration and control procedures for patient testing as required under §§493.1217 and 493.1218. [D4081]

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications. [D4083]

493.1215 Standard; Equipment maintenance and function checks.

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports. [D4084]

(a) Maintenance of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must-

- (i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and
- (ii) Document all maintenance performed.

(2) For equipment, instruments, or test systems not cleared by the FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must-

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting; [D4088]

(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and [D4089]

(iii) Document all maintenance performed. [D4090]

(b) Function checks of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must-

- (i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and
- (ii) Document all function checks performed.

(2) For equipment, instruments, or test systems not cleared by FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must-

(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting; [D4094]

(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and [D4095] [D4096]

(iii) Document all function checks performed. [D4097]

(C) Manuals, card files, or flow charts for each procedure performed in the laboratory which include:

1. Name of procedure.
2. Source or reference for the test method.
3. Date the procedure was last reviewed or modified by the director or supervisor.
4. Current specific instructions for test performance.
5. The standards and controls required.
6. Instructions for collecting and handling specimens to insure test reliability.

Unnecessary – covered by 42CFR 493.1202(c) and 493.1211

493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1994.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must-

- (1) Follow the manufacturer's instructions for instrument or test system operation and test performance; [D4001]
- (2) Have a procedure manual describing the processes for testing and reporting patient test results; [D4002]
- (3) Perform and document calibration procedures at least once every six months; [D4003]
- (4) Perform and document control procedures using at least two levels of control materials each day of testing; [D4006]
- (5) Perform and document applicable specialty and subspecialty control procedures as specified under 493.1223; and
- (6) Perform and document that remedial action has been taken when problems or errors are identified as specified in 493.1219.

493.1211 Standard; Procedure manual.

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens. [D4043]

(b) The procedure manual must include, when applicable to the test procedure:

- (1) Requirements for specimen collection and processing, and criteria for specimen rejection; [D4046] [D4048]
- (2) Procedures for microscopic examinations, including the detection of inadequately prepared slides; [D4049]
- (3) Step-by-step performance of the procedure, including test calculations and interpretation of results; [D4050]
- (4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing; [D4051]
- (5) Calibration and calibration verification procedures; [D4052]
- (6) The reportable range for patient test results as established or verified in 493.1213; [D4054]
- (7) Control procedures; [D4055]
- (8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability; [D4056]
- (9) Limitations in methodologies, including interfering substances; [D4057]
- (10) Reference range (normal values); [D4058]
- (11) Imminent life-threatening laboratory results or "panic values"; [D4059]
- (12) Pertinent literature references; [D4060]
- (13) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed; [D4061]
- (14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values; [D4062]
- (15) Description of the course of action to be taken in the event that a test system becomes inoperable; and [D4063]
- (16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in 493.1103. [D4064]

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be approved, signed, and dated by the director. [D4065]

(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes. [D4066]

(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory. [D4067]

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued. [D4068] [D4069]

(D) Records of quality control procedures in use in the various technical areas of the laboratory, including results on standards and reference materials and action limits when appropriate.

Unnecessary – covered by 42CFR 493.1221

493.1221 Standard; Quality control records.

The laboratory must document and maintain records of all quality control activities specified in 493.1202 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of no less than five years. In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). [D4182] [D4184] [D4185]

(E) Additional requirements for cytology. The laboratory shall retain all cytology slides and cell blocks for a minimum of five (5) years and all cytology reports for a minimum of ten (10) years.

Unnecessary – covered by BPC 1271(g)

1271 (g) Each clinical laboratory shall retain all cytology slides and cell blocks examined for a minimum of five years and all cytology reports for a minimum of 10 years.

(2) Cytology Specimen Documents. The laboratory shall maintain cytology records indicating the daily accession of specimens, each of which is numbered, and an appropriate cross-filing system according to patient's name.

(A) Requests shall contain at least the following information:

1. The laboratory accession number when assigned by the laboratory.
2. The name of the person from whom the specimen was taken.
3. The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.
4. Minimum information provided shall include: source of specimen (anatomic site), age of patient, previous therapy (endocrine, surgical, radiation, birth control, etc.), gynecologic history on cervical-vaginal specimens, including date and normalcy of patient's last menstrual period, duration of patient's current pregnancy, if any, and patient's menopausal status or essential history on non-gynecologic specimen.
5. The date the specimen was collected.

(B) Reports shall contain at least the following information:

1. The dates the specimen was collected, received in the laboratory and reported by the laboratory; and the accession number.
2. The result of the laboratory examination.

Unnecessary – covered in BPC 1271(e) and 42CFR 493.1105

1271(e) Each clinical laboratory shall maintain records of the number of cases and slides for gynecological and nongynecological samples examined on a monthly and annual basis.

493.1105 Standard; Test requisition.

The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days. Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and must be available to the laboratory at the time of testing and available to HHS upon request. The laboratory must assure that the requisition or test authorization includes- [D3017] [D3018] [D3019] [D3020]

- (a) The patient's name or other unique identifier; [D3022]
- (b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values; [D3023]
- (c) The test(s) to be performed; [D3024]
- (d) The date of specimen collection; [D3025]

(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and [D3026]

(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results. [D3029]

(3) Cytology Laboratory Records.

(A) The laboratory director shall be responsible for the final laboratory report and shall sign all abnormal and all non-gynecological reports. Each report, or a laboratory copy, shall be signed or initialed by the cytopathologist and/or cytotechnologist who examined the preparation and evaluated the final report. The names of all persons who examined the specimen and their evaluation, if inconsistent with the final report, shall be indicated on the laboratory work sheet or report copy.

(B) Duplicate copies of laboratory reports are filed in a manner which permits ready identification and accessibility.

(C) Laboratories shall utilize reporting systems that are as explicit as is cytologically feasible and must include acceptable morphologic terminology.

(D) If a specimen is judged by the laboratory director or cytotechnologist to be suboptimal, an accompanying statement shall indicate the reason, e.g., samples of sparse cellularity, poor preservation, or exhibiting other factors interfering with the laboratory evaluation, such as, excessive blood, inflammatory cells, etc.

Unnecessary – adequately covered in BPC 1209(a) (allowing delegation to the Technical Supervisor)

1209. (a) As used in this chapter, "laboratory director" means any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

and in 42CFR 493.1257(c)(1) , 493.1445(e)(1), 493.1449(k) and 493.1451.

493.1257(c) The individual qualified under 493.1449 (b) or (k) who provides technical supervision of cytology must ensure that-

(1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology; [D4326] [D4327]

493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. [D6079]

(e) The laboratory director must- [D6081]

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; [D6082]

493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. [D6109] [D6110]

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements-

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

(2) An individual qualified under 493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under 493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. [D6112]

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and [D6113]

(b) The technical supervisor is responsible for-

(1) Selection of the test methodology that is appropriate for the clinical use of the test results; [D6114]

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system; [D6115]

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; [D6116]

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameter for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; [D6117]

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; [D6118]

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; [D6119]

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; [D6120]

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; [D6121]

(ii) Monitoring the recording and reporting of test results; [D6122]

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; [D6123]

(iv) Direct observation of performance of instrument maintenance and function checks; [D6124]

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and [D6125]

(vi) Assessment of problem solving skills; and [D6126]

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. [D6127] [D6128] [D6129]

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in 493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides; [D6130]

(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary; [D6131]

(4) Must perform the functions specified in 493.1257(c);

(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in 493.945 and achieves a passing score, as specified in 493.855; and [D6132]

(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24 - hour period to screening cytology slides. [D6133]

(g) Quality Control.

(1) The laboratory must conduct, maintain, and operate programs for controlling the quality of test performance in a manner acceptable to the department.

(2) Additional Cytology.

(A) Specimen Identification. All smears and other specimens shall be labelled for patient identification and appropriately prepared by the submitter.

(B) Specimen Preparation.

1. The laboratory shall use the Papanicolaou staining technique or its equivalent as determined by the laboratory director.

2. Staining quality of cytologic specimens shall be checked at least once daily, with suboptimal results corrected immediately.

3. Gynecologic specimens shall be processed totally separately from non-gynecologic specimens.

(C) Microscopy.

1. Each specimen shall be evaluated to determine whether the material is satisfactory and consistent with the patient source. For satisfactory specimens, a cytologic evaluation shall be rendered according to the reporting system, as outlined in Section 1050(f)(3)(C).

2. The laboratory shall have a sufficient number of certified cytotechnologists to handle, under general supervision, the volume and diversity of tests performed requiring the exercise of independent judgment. No cytotechnologist shall be required to examine more than 75 one-slide gynecologic cases or 50 two-slide gynecologic cases per day; not including aspiration cytology specimens, cell block specimens, and other not normally examined by a cytotechnologist. Work load ratios for cytotechnologists who also prepare and stain slides shall be based on time spent in examining cytologic preparations.

3. The director or a supervising cytotechnologist shall examine (to verify proper staining and correct interpretation) at least ten (10) percent of all gynecologic smears previously examined and classified as not abnormal or questionable, including smears initially examined by a supervising cytotechnologist.

(3) Clinical Correlation. The laboratory shall maintain records for a minimum of 10 years of histologic or clinical confirmation of cytologic findings on abnormal cases and false negative and false positive results for each category of specimens, when such results are made available to them.

Unnecessary - All of section 1050(g) is adequately covered by BPC 1220(d)(2)(B)

1220(d)(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:

(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1201) of Title 42 of the Code of Federal Regulations.

and in 42CFR 493.1201 – 493.1269 (Subpart K), 493.1407(e)(5) and 493.1445(e)(5):

Subpart K-Quality Control for Tests of Moderate or High Complexity, or Both

493.1201 Condition: General quality control; Moderate or high complexity testing, or both.

The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. In addition, the laboratory must meet the applicable standards in 493.1202 through 493.1221 of this subpart, unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting the CLIA requirements for general quality control, and the device/test quality control instructions contain the following statement: "Unless this device is modified by a laboratory, compliance with these quality control instructions satisfies 42 CFR 493.1201 through 493.1221 implementing the Clinical Laboratory Improvement Amendments of 1988," or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487-4630. [D4000]...

493.1407 (and 493.1445) Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. [D6004]

(e) The laboratory director must-

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur, [D6020] [D6021] [D6022].

(h) Clinical Laboratory Test Results. Clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability, and validity by a licensed physician and surgeon or a person, other than a trainee, duly licensed under Chapter 3, Division 2, Business and Professions Code (commencing with Section 1200).

To be replaced by new 1050(h) as amended:

1050 (h) Clinical Laboratory Test Results. Clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability and validity. This *critical review shall be accomplished by the following means:*

- 1) By a person authorized to perform these tests under Section 1206.5 of the California Business and Professions Code; or
- 2) By autoverification (the review and verification of results by use of a computer algorithm), when
 - c) The laboratory director or his authorized designee has established and validated explicit criteria by which the results are verified, and
 - d) *A person authorized under Section 1206.5 of the California Business and Professions Code shall be present and responsible for testing when results are being released.*

NOTE

Authority cited: Sections 1224 and 1245, Business and Professions Code. Reference: Sections 1220, 1224 and 1245, Business and Professions Code.

HISTORY

1. New subsection (h) filed 2-17-77; effective thirtieth day thereafter (Register 77, No. 8). For prior history, see Register 76, No. 51.
2. Amendment of subsections (c), (f)(2)(A) and (B), (f)(3)(A), (g)(2)(A) and (B)3, (g)(2)(C)2, (g)(3) filed 10-13-78; effective thirtieth day thereafter (Register 78, No. 41).