WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §§ 16-1-7, 16-1-10(6), 16-2E-3, 16-5B-8, 16-5C-5, 16-5H-2, 16-5I-5, 16-5J-3, 16-5J-10, 27-9-1, and 27-17-3

AMENDMENT TO AN EXISTING RULE: YES___ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 57

TITLE OF RULE BEING PROPOSED: Clinical Laboratory Technician and Technologist Licensure and Certification

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Gretchen O. Lewis

Gretchen O. Lewis, Secretary

24.10

DATE: October 5, 1995

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: Kay Howard, Director
Office of Regulatory Development
Department of Health and Human Resources

LEGISLATIVE RULE TITLE: **Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57**

1. Authorizing statute(s) citation: W. Va. Code §§ 16-1-7, 16-1-1-(6), 16-2E-3, 16-5B-8, 16-5C-5, 16-5H-2, 16-5I-5, 16-5J-3, 16-5J-10, 27-9-1, and 27-17-3.

2. a. Date filed in State Register with Notice of Hearing: June 23, 1995

   b. What other notice, including advertising, did you give of the hearing?

   Copies were sent to several professional associations, laboratories, other health care facilities, West Virginia colleges which have laboratory technician training, local health departments, and other interested persons.

   c. Date of hearing(s): Comment Period 6-23-95 to 7-24-95

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received ____

   e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

   October 5, 1995

   f. Name and phone number of agency person to contact for additional information:

   Kay Howard, 558-3223

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

      N/A

   b. Date of hearing: N/A

   c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

      N/A

   d. Attach findings and determinations and reasons:

      Attached N/A

AMENDED
FISCAL NOTE FOR PROPOSED RULES

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

Type of Rule: _X_ Legislative ___ Interpretive ___ Procedural

Agency: Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	$	$	$	$111,627	$145,384
Personal Services				37,272	55,740
Current Expense				57,755	84,744
Repairs & Alterations					
Equipment				16,600	4,900
Other					
Revenue				100,000	100,000

2. Explanation of above estimates.

See attachment.

3. Objectives of this rule:

Provide licensure and certification of Medical Laboratory Technicians and Technologists working in West Virginia as required by Clinical Laboratories Quality Assurance Act 16-5J-10.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

1. Personnel employed in medical labs would be subject to cost of licensure and certification.

2. Possible reduced income from HCFA contract with OHFLAC for CLIA-88 Inspections.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

1. All Medical Technologist and Technicians would be subject to the cost of licensure and certification.

2. All other health care workers providing laboratory tests would be subject to licensure and certification costs.

C. Economic Impact on Citizens/Public at Large.

1. Could raise health costs if facilities paid cost of licensure and certification of personnel.

2. Could reduce availability of lab services if health care facilities choose not to have licensed employees.

Date: September 15, 1995

Signature of Agency Head or Authorized Representative

Gretchen O. Lewis, Secretary
Department of Health and Human Resources

Amended Fiscal Note for Proposed Rule - Attachment

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

2. Explanation of above estimates.

Personal Services	First Year	Second Year
1.0 Secretary II	$ 16,116	$ 16,116
1.0 Administrative Services Assistant III	$ 21,156	$ 21,156
1.0 Investigator		$ 18,468

Current Expenses		
Fringe Benefits	$ 16,955	$ 25,394
Postage	2,200	2,200
Copier Lease	4,000	4,000
Telephone (800 Number)	9,600	8,000
Printing	8,000	8,000
Records Microfilm	2,000	2,000
Travel (investigations) + car lease	10,000	20,000
Telephone	5,000	5,000
Equipment Maintenance Contracts		1,700
Lease Space 650 sq. ft. @ $13.00 sq. ft.	8,450	8,450

Equipment		
2 Computers & Software	$ 12,000	
3 File Cabinets	800	
1 Typewriter	500	
1 Conference Table	800	
1 FAX Machine	2,500	
1 Computer and software		4,000

Revenue

There is no information on the total number of individuals required to be licensed; the Department has used an estimate of 4,000 to estimate revenue.

Discussion of Public Comments Received
Concerning the Proposed Rule
Clinical Laboratory Technician and Technologist
Licensure and Certification, 64 CSR 57

GENERAL COMMENTS

This proposed new legislative rule sets forth standards and procedures for the certification and licensing of laboratory technicians and laboratory technologists as clinical laboratory practitioners, and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory scientists by laboratories, health care facilities, and physicians. Establishment of this rule will bring the Department of Health and Human Resources into compliance with W. Va. Code § 16-5J-10. A public comment period was held from June 23, 1995 to July 24, 1995. The Department received numerous comments. Comment summaries, the Department's responses to comments and descriptions of proposed modifications to the rule appear below.

1. Comments: Two (2) commenters supported the rule. A number of commenters offered generally negative comments. -- The rule is too lenient. Having only one (1) level of licensure will be detrimental to quality and provides no motivation for professional advancement. The federal (CLIA) standards are inadequate, or change too frequently. The Department should have adopted the suggestions of the advisory board. The Department should not have taken the easy way out of just using the federal standards. The rule does not do enough to guarantee quality of care. The legislature intended that the rule be stronger than the federal standards. --

The State Society for Medical Technology, the group which brought suit to compel the Department to promulgate the rule, proposed a detailed set of standards which provide for three (3) levels of testing personnel, two (2) levels of supervisory personnel, two (2) levels of laboratory directors, and twenty (20) hours of continuing education every two (2) years. This group also submitted documents identified as recommendations of the West Virginia Clinical Laboratory Advisory Board. Several other commenters stated that the rule should adopt standards higher than the CLIA standards and cited these recommendations as desirable examples of the type of standards which should be adopted.

Response: The Department believes that CLIA-88[1] and related federal regulations are adequate to meet the intent of the law, and that the rule has sufficient detail. Many of the advisory board's recommendations were incorporated in the rule. The proposed rule is in some respects stronger than the CLIA-88 Standard. For example, waived laboratory personnel are included under this rule and continuing education requirements are required for licensure renewal.

2. Comment: A separate board for licensing individuals, similar to those that exist for licensing other professions in West Virginia, should be established to accomplish the licensure of these individual professional persons.

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[1] Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

Response: The Department does not disagree with this comment. However, the law does not provide for a separate board to administer the law. This is the only health care profession for which the Legislature has assigned licensure responsibility to the Department, and the Department would not oppose legislation to establish an independent licensure board.

3. Comment: A few individuals stated that their on-the-job training, workshop attendance and experience performing high complexity testing should qualify them for recognition by the State. It was also suggested that a grandfather clause could be included for all current workers, possibly with a requirement to begin to obtain necessary training.

Response: The exemptions from certification are set out in the law. No one is exempt from licensure. Paragraph 8.2.2 exempts CLIA-qualified testing personnel in moderate and high complexity laboratories from State certification. The licensure law establishes only one (1) criterion for grandfathering; it is reflected in §7.2.3 of the rule.

4. Comment: Licensure should be required for clinical laboratory supervisors. Can laboratory consultants, directors, and supervisors perform testing? Are they required to have a clinical laboratory scientist license in order to perform testing? The rule needs clarification in this area.

Response: Anyone working in a clinical laboratory who processes specimens or performs or reports laboratory tests is required to be licensed, regardless of what classification he or she may hold in the clinical laboratory; except for licensed physicians who perform laboratory tests on their own patients.

5. Comment: The rule should set standards for point-of-care testing. Such testing should not be restricted solely to medical technicians and technologists. Some commenters made specific recommendations.

Response: Point-of-care testing is included in §3.13. Requirements for personnel performing these tests are specified at §7.2. The rule does not restrict testing solely to medical technicians and medical technologist.

6. Comment: The rule should clarify that individuals involved only in specimen processing, i.e., phlebotomists, histology technicians, clerical and other support staff, would not be subject to certification requirements.

Response: The commenter has confused specimen collection and/or opening specimens with specimen processing. Specimen processing is part of the preanalytical process.

7. Comment: Disagree with "liberal" interchange of the words "licensure" and "certification." The State is to grant licenses; various bodies grant certification and are approved to do so by the feds. Why does the rule use both terms? One or the other would seem sufficient.

Response: The licensure law requires the Department both to license and certify lab technicians and technologists. Certification (or exempt status) is a requirement for licensure. The

terms are not used interchangeably in the rule.

8. Comments: A two-year license period might save money. The projected potential for increased cost of health care and reduction in lab services, while unlikely, would certainly be minimal and offset by increased accuracy of laboratory results. The estimates for the 800 number and the rent seem high.

Response: The law requires annual licensure. Although a two-year license period might save on administrative cost, it would presumably also result in less revenue to support the program. A license fee of $25 is not adequate to support an extensive licensing operation.

The Department has reconsidered the fiscal note and agrees that some adjustment is appropriate. The rent estimate has been reduced and is based on expected occupancy costs in a Bureau for Public Health facility. The 800 number is needed for the public to report problems or violations of the law and for inquiries by current or potential licensees; the cost estimate has been reduced to reflect a lower estimated volume of calls. An amended fiscal note is included with this filing.

9. Comment: One (1) commenter objected to the licensure fee.

Response: The fee is set by law.

COMMENTS RELATED TO SPECIFIC ITEMS

§2.2. Comments: Since the rule deals with the licensure of personnel, why is it necessary to include exceptions for local health departments, primary care centers and laboratories? Primary care centers should not be exempt. Research facilities should not be exempt. Research can be compromised if the scientist performing the test is not qualified. Local boards of health organized under W. Va. Code § 16-2-3 should be included.

Response: The exceptions are mandated by the licensure law, in W. Va. Code § 16-5J-7, and are for the facilities, not the individual laboratory personnel. The exemption applies to any form of local board of health organization; the commenter is probably unfamiliar with the Code citation format.

§3.3. Comment: A consultant should minimally meet the certification requirements for personnel certified to supervise high complexity lab testing.

Response: The Department believes that the CLIA-88 requirements used in the definition are adequate for the purposes of the proposed rule.

§3.4. Comment: The definition of a clinical laboratory director should be more specific and include additional qualifications, such as those required for laboratory directors under federal standards.

Response: This section of the rule defines the director as an individual who meets the CLIA-88 requirements. The definition is needed to identify individuals who are acceptable to provide a job description. The proposed rule does not set requirements for laboratory directors, nor does the law authorize the licensure of the position of laboratory director. See discussion of §6.2.

§3.5. Comments: Strike specimen processing as this is routinely a function of personnel who are also responsible for phlebotomy and other clerical duties. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement. The exclusion of supervisors seems to prohibit a supervisor from performing the tasks enumerated, thus forcing a financially prohibitive choice in smaller laboratories where the supervisor assumes dual roles. Usually a physician's employees rather than the physician perform the test carried out in the physician's office; these individuals should not be exempt. The CLIA certification sections referenced in §7.2.4.a include personnel outside of the realm of medical technologists and technicians. The definition of "clinical laboratory scientist" should include personnel meeting the requirement of the CLIA sections referenced in §7.2.4.a. Failure to license different levels of competence provides no motivation for educational advancement and will lead to low pay.

Numerous commenters expressed concern about the proposed use of the term "clinical laboratory scientist" to include both laboratory technicians and laboratory technologists. It was stated that because these two terms as commonly employed and accepted in the field of laboratory practice involve different levels of academic training, expertise, national accreditation/recognition and professional roles, that they should not be grouped together under one term for licensure purposes. In some instances, the term "clinical laboratory scientist" is used as a certification classification with a specific meaning which is not reflected in the proposed rule.

Response: The issue of specimen processing versus specimen collection and opening specimens was discussed above under item #6. The intent of using the term "for remuneration" in the definition of "clinical laboratory practitioner" was to permit individuals to perform laboratory tests in their own homes without requiring them to be licensed. In order to clarify the intent of the rule, a more specific exemption has been added in §2.2.5 of the rule and the term "for remuneration" has been deleted from §§3.5 and 5.1 of the rule. Clarifying language has also been added to the text excluding clinical laboratory directors, etc. from the definition of "laboratory practitioner." "Test performance" includes the analytical functions of patient test management.

In drafting the proposed rule, the Department followed the CLIA-88 model of incorporating the terms "laboratory technician" and "laboratory technologist" into a single category, utilizing the term "clinical laboratory scientist." Since the term "clinical laboratory scientist" appears to be of concern, it has been changed to "clinical laboratory practitioner." The use of a single term for licensure purposes does not need to reflect the various forms of national certification, nor does it need to reflect a system of remuneration and financial reward for increasing levels of skill and professional expertise.

§3.6. Comment: Define how long it will take to obtain a license, post graduation.

Response: There is no time limit for obtaining a license.

§3.12 (now §3.13). Comment: Define biophysical.

Response: Biophysical is one of the types of examinations itemized in the definition of "clinical laboratory" under the licensure law, W. Va. Code § 16-5J-2. The term is used as defined in a standard dictionary, and there is thus no need for a special definition in the rule.

§4. Comment: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of ninety (90) days.

Response: The State Administrative Procedures Act, mandates a public comment period (or hearing) on all new rules or amendments of existing rules, and that a notice and a copy of the proposal be filed in the State Register. It also specifies that the comment period end no less than thirty (30) and no more than sixty (60) days from the date of the filing of the notice of the proposed rule-making.

§5.2. Comment: Failure to specify a limit for how long an individual might function as a "trainee" is a weakness which could permit an unlicensed individual to function indefinitely as a "trainee." Process and time limits should be clarified for individuals entering a new job who have come from a state with no licensure requirements, individuals just out of school with no work experience, and employees of physician offices just beginning to do testing.

Response: The Department believes specifying process and time limits are unnecessary. Subsection 3.6 of the rule defines a trainee as a person who has applied for a license or is in a training program. Training programs are commensurate with the type of testing performed. The director of each laboratory can decide the amount of training needed for the level of his or her laboratory. The Department has deleted text that required direct supervision of trainees only when they perform moderate or high complexity tests, and has also deleted text which allowed physicians to supervise clinical laboratory practitioner trainees.

§6.1.2. Strike this completely. It is not clear. If adopted as written would this mean the laboratorians would become specialized and could not practice in a separate lab discipline?

Response: The purpose of this section is to provide the Department with a record of the applicant's job and competencies. There is no intent to limit the lab disciplines in which an applicant may have competency. This information will be used by the Department in validating the applicability of educational activities, and for reference purposes in investigations of complaints or violations of the rule.

§6.2. Subsection 6.2 is not needed if §6.1.2 is eliminated. Why should county [local] health department and primary care centers not have to supply their employees with job descriptions the same as everybody else? Subsection 6.2 contradicts §2.2.2 and is vague and confusing.

Response: The commenters are essentially correct. The law specifically exempts these facilities from licensure as a laboratory. However, CLIA-88 requires this type of laboratory to have an individual who functions as a laboratory director, and sets minimum qualifications for such

individuals. Subparagraph 3.4.2.c of the rule has been added to reflect CLIA-88 standards, and the exemption from providing a job description has been deleted from §6.1.2 of the rule. An analogous exemption has been deleted from §11.1 of the rule. CLIA-88 requires up-to-date job descriptions; the job descriptions should be available routinely. The exemptions in §§2.2.1 and 2.2.2 for laboratory directors of these facilities have been deleted. An additional cite has been added to §1.2. Finally, §6.2 has been deleted, and subsequent items have been renumbered.

§6.3.1 (now §6.2.1). Eliminate "are exempt from such certification under this rule."

Response: The Department disagrees with this comment. This section is needed to cover the applicants who are exempt from the State certification process under §8.1 of the rule.

§§6.4 & 6.5 (now §6.3). Some commenters requested that the rule specify the process for approval of continuing education programs, the necessary course content, the addition of in-service training, and a definition of the meaning of the term "hour." It was suggested that these details should be offered for public comment since they might involve considerable difficulty and expense, depending on the specific of the requirements. It was suggested that all continuing education be "accredited."

It was also suggested by local health departments that for a waived laboratory performing pregnancy tests, hemocue hemoglobins, dip-stick urinalysis and blood sugar testing with a glucose testing device, ten (10) hours of continuing education annually seems excessive, and further, that sending personnel from a waived laboratory to laboratory training sessions where the subject matter is beyond the scope of a waived laboratory would be of little value. It was noted that individuals performing the hemocue procedure for clients in the Department's WIC program should be exempt.

Response: The requirement for continuing education has been clarified as follows: 1) Text has been added to clarify that "hours" means "contact hours" and to clarify the relationship of "contact hours" to continuing education units; 2) A definition of contact hours has been added (§3.8); and 3) Examples of types of training have been added; and 4) Text has been added to clarify that the training must relate to the level and complexity of tests the individual will perform. Additionally, §6.5 has been merged into §6.4 (now §6.3); the two (2) items were nearly identical.

The Department disagrees with the suggestion to require "accredited" continuing education because it would unnecessarily restrict the type of training the laboratory director could employ in training employees under his/her supervision. The Department believes the CLIA-88 training requirements stated at 42 CFR §§493.1423, 493.1483, and 493.1489 are adequate.

§7. Comment: There should be a provision for adopting future CLIA rules.

Response: West Virginia law does not permit automatic adoption of possible future federal standards. If the Department needs to adopt new federal standards at a future date, it must allow a public comment period, submit the proposal to the Legislature for approval, and otherwise comply with the requirements of the State Administrative Procedures Act.

§7.2.2. Delete "is" and replace with "has been" certified. This would better equalize the

acceptable national registries.

Response: The Department disagrees with this comment. W. Va. Code § 16-5J-10 specifically grants certified status to individuals who are currently certified by any of the three (3) national certifying agencies listed.

§7.2.4.a. Comments: Since so much of this rule is referenced to CLIA, 493.1489 - allowance for individuals with high school degrees to continue moderately complex testing beyond those working and trained by April 24th, 1995 needs to be deleted. This is contradictory to the original intent of the law as approved by the State of West Virginia.

Response: The Department disagrees and, as stated elsewhere, believes the federal standards to be adequate.

§§8.2.1 & 8.2.2. Comments: Commenters questioned the need for and the intent of the exemptions from certification. Speculation was offered that the exemptions are meant to allow testing personnel to acquire a license until certification can be verified, but that it would be more appropriate to include under 64-59-7 another line to include provide documentation of "registry eligible." Commenters recommended not certifying those working in "waived labs" based on 42 CFR 494 with no further modifications. Registry eligible individuals need a time period of two (2) years to pass a registry. They could be awarded a two-year non-renewable temporary license. Alternatively, it was suggested that all of Section 8 might be unnecessary, since CLIA automatically supersedes less stringent requirements. It was also suggested that too many could claim exemption under this section. It was stated that this section conflicts with, or is not consistent with §2.2. Paragraph 8.2.1 appears to exempt everyone that should be licensed by exempting everyone who works in a CLIA-certified laboratory, except for laboratories holding CLIA waivers. The exemption of individuals in CLIA-certified laboratories will decrease funding needed to support the program. Also it will exempt individuals in these laboratories from the continuing education requirements.

Response: The licensure law specifically grants automatic certification to individuals certified by "any federal certification program." Although there is not a separate federal laboratory technologist and technician certification program, the Department believes that the CLIA-88 standards serve the function of a certification program. Therefore, the rule assumes that individuals who meet the federal standards are, in a sense, "federally certified," and therefore do not need to be certified by the State. Thus they are exempted from the State's certification process, but not from licensure. Individuals who are "registry eligible" should meet the qualifications stated in §7.2.4. Therefore, a two-year non-renewable temporary license is unnecessary. There is no exemption from the continuing education requirements.

11.1. Comment: Since most CLIA-waived laboratories don't have a supervisor or clinical consultant (not required under CLIA), this requirement seems redundant. If the license does not control which tests an individual can perform, it has very little power.

Response: Sections 11.1 and 6.1.2 have both been changed by deleting the alternative for a supervisor or consultant to determine job qualifications. See discussion of §6.1.2.

STATE OF WEST VIRGINIA

IN THE SUPREME COURT OF APPEALS

STATE OF WEST VIRGINIA ex rel.
STATE SOCIETY for MEDICAL TECHNOLOGY,
INC.,

Petitioner,

vs. No. 22579

GRETCHEN LEWIS, Director of the
West Virginia Department of Health
and Human Resources; WILLIAM T.
WALLACE, JR., M.D., Commissioner,
Bureau of Public Health; the
Clinical Laboratories Quality
Assurance Act Advisory Board; and
ROBERT C. BELDING, M.D., WILLIAM E.
TRIEST, M.D., WILLIAM L. HARRIS, M.D.,
KIMBERLY CHEUVRONT, M.T., and GARY
MCKINNEY, M.T. (ASCP), Members of the
CLINICAL LABORATORIES QUALITY ASSURANCE
ACT ADVISORY BOARD,

Respondents.

AGREEMENT FOR ENTRY OF ORDER ADOPTING AND APPROVING SETTLEMENT AGREEMENT

On a former day came the parties by their respective counsel and announced to the Court that they have agreed as follows:

This is an original proceeding in mandamus instituted by the relator State Society for Medical Technology, Inc. to compel the respondents to promulgate certain rules in fulfillment of the mandatory statutory duty required by W. Va. Code § 16-53-3 providing that the Director shall promulgate rules to implement the Clinical Laboratories Quality Assurance Act pursuant to the procedural requirements set out in W. Va. Code § 29A-3-1 et seq.

The relator contends that the respondents have delayed unreasonably in promulgating such rules as required by statute. The respondents have admitted that

they have the legal obligation to promulgate such rules and that they have begun the internal administrative process to promulgate the required rules. The Respondents Gretchen Lewis, as Secretary of the Department of Health and Human Resources and William T. Wallace, M.D., as Commissioner of the Bureau of Public Health have consented to the issuance of a writ of mandamus requiring and ordering them to promulgate and adopt and approve as appropriate the mandated rules within the time frames hereafter set out.

The parties agree that the Supreme Court of Appeals of West Virginia may enter an order incorporating this settlement agreement by reference and dismissing the referenced action now pending before that Court. It is further agreed that the entry and service of such an order by said Court shall have the same effect as if the Court had issued a formal writ of mandamus against the Respondent Gretchen Lewis, as Secretary of the West Virginia Department of Health and Human Resources and William T. Wallace, Jr., M.D., as Commissioner of the Bureau of Public Health requiring them on behalf of the West Virginia Department of Health and Human Resources to promulgate such necessary legislative rules as may be required to implement the provisions of W.Va. Code § 16-5J-1 et seq. Such action or procedures as may required to be taken by Respondent to achieve promulgation of said legislative rules shall proceed forthwith upon entry of an order incorporating and adopting this agreement and shall be completed by the agency on or before the date established by law for submission of proposed rules to the legislative rulemaking interim committee or by July 10, 1995, whichever is sooner, in order that notice of approval of such proposed legislative rules can be filed in the state register and with

the legislative rule making review committee in compliance with the requirements of W.Va. Code § 29A-3-9.

This the 26th day of April, 1995.

WALT AUVIL
Counsel for Petitioners

L. EUGENE DICKINSON
Counsel for Respondents

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[PROPOSED]

WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION

64 CSR 57

199_

For Filing with the Legislative
Rule-Making Review Committee

WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION
64 CSR 57

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PROPOSED RULE - TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 57
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION

§64-57-1. General.

1.1. **Scope** - This legislative rule sets forth standards and procedures for the certification and licensing of laboratory technicians and laboratory technologists as clinical laboratory practitioners and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory practitioners by health care facilities.

1.2. **Authority** - W. Va. Code §§ 16-1-7, 16-1-10(6), 16-2E-3, 16-5B-8, 16-5C-5, 16-5H-2, 16-5I-5, 16-5J-3, 16-5J-10, 27-9-1, and 27-17-3.

1.3. **Filing Date -**

1.4. **Effective Date -**

§64-57-2. Application and Enforcement

2.1. **Application** - Except as otherwise provided in this rule, this legislative rule applies to:

2.1.1. Clinical laboratory practitioners employed as such in West Virginia;

2.1.2. Health care facilities performing laboratory tests in West Virginia; and

2.1.3. Clinical laboratory directors in West Virginia.

2.2. This rule does not apply to:

2.2.1. County health departments organized under W. Va. Code § 16-2-1 et seq. or § 16-2A-1 et seq.: **Provided**, That it does apply to clinical laboratory practitioners employed as such by county health departments;

2.2.2. Primary health care centers having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law: **Provided**, That it does apply to clinical laboratory practitioners employed as such in the clinical laboratories of such centers;

2.2.3. Any laboratory operated by the federal government;

2.2.4. Any laboratory operated purely for research or teaching purposes; or

2.2.5. Any individual who performs laboratory tests only on himself or herself or members of his or her family.

2.3. **Enforcement** - This rule is enforced by the secretary of the West Virginia department of health and human resources.

§64-57-3. Definitions.

3.1. **CLIA** - Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

3.2. **Clinical Laboratory** - Any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings.

3.3. **Clinical Laboratory Consultant** - A person who:

3.3.1. Meets the qualifications for:

3.3.1.a. Moderate complexity testing technical consultant found at 42 CFR § 493.1411;

3.3.1.b. Moderate complexity testing clinical consultant found at 42 CFR § 493.1417; or

3.3.1.c. High complexity testing clinical consultant found at 42 CFR § 493.1455.

3.4. **Clinical Laboratory Director** - A person who:

3.4.1. Provides overall management and direction of a clinical laboratory; and

3.4.2. Meets the qualifications for directors of:

3.4.2.a. Moderate complexity testing laboratories found at 42 CFR § 493.1405;

3.4.2.b. High complexity testing laboratories found at 42 CFR § 493.1443; or

3.4.2.c. Waived clinical laboratories found at 42 CFR 493.35.

3.5. **Clinical Laboratory Practitioner** - A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory. The term "clinical laboratory practitioner" includes laboratory technicians and laboratory technologists, but does not include: clinical laboratory practitioner trainees; clinical laboratory directors, consultants, or supervisors whose job tasks do not include processing specimens, or

performing or reporting laboratory tests; or physicians licensed under W. Va. Code § 30-3-1 et seq. or § 30-14-1 et seq. who perform laboratory tests only on their own patients.

3.6. **Clinical Laboratory Practitioner Trainee** - A person who is in a training program designed for his or her qualification as a clinical laboratory practitioner or who has successfully completed such a training program and has applied for, but not yet received a clinical laboratory practitioner license.

3.7. **Clinical Laboratory Supervisor** - A person who meets the qualifications for:

3.7.1. A high complexity testing technical supervisor found at 42 CFR § 493.1449;

3.7.2. A high complexity testing general supervisor found at 42 CFR § 493.1461; or

3.7.3. A high complexity testing cytology general supervisor found at 42 CFR § 493.1469.

3.8. **Contact Hours** - The actual number of hours an individual participates in continuing education. Ten (10) contact hours equal one (1) continuing education unit.

3.9. **Department** - The West Virginia Department of Health and Human Resources.

3.10. **Health Care Facility** - An entity subject to licensure as a:

3.10.1. Birthing center under W. Va. Code § 16-2E-1 et seq.;

3.10.2. Hospital or extended care facility operated in connection with a hospital, or an ambulatory surgical facility, or an ambulatory health care facility, including a medical adult day care center under W. Va. Code § 16-5B-1 et seq.;

3.10.3. Nursing home or personal care home under W. Va. Code § 16-5C-1 et seq.;

3.10.4. Residential board and care home under W. Va. Code § 16-5C-1 et seq. and § 16-5H-1 et seq.;

3.10.5. Hospice under W. Va. Code § 16-5I-1 et seq.;

3.10.6. Clinical laboratory under W. Va. Code § 16-5J-1 et seq.;

3.10.7. Hospital, center or institution for the care and treatment of the mentally ill or mentally retarded, or for the prevention of such disorders under W. Va. Code § 27-9-1 et seq.; or

3.10.8. Group residential facility for the developmentally disabled or behaviorally disabled under W. Va. Code § 27-17-1 et seq.

3.11. **Laboratory Technician** - A clinical laboratory practitioner.

3.12. **Laboratory Technologist** - A clinical laboratory practitioner.

3.13. **Laboratory Test** - The biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

§64-57-4. Incorporation by Reference.

The provisions of the October 1, 1994, edition of **42 CFR Part 493, Laboratory Requirements**, as amended in the April 24, 1995, edition of the **Federal Register (60 FR 20035)**, are hereby incorporated by reference.

§64-57-5. Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees.

5.1. No person shall perform any clinical laboratory practitioner tasks in West Virginia, except as specified in this rule, unless the person is licensed by the secretary as a clinical laboratory practitioner.

5.2. A clinical laboratory practitioner trainee may perform tasks related to laboratory tests only under the personal and direct supervision of: a licensed clinical laboratory practitioner; or a clinical laboratory director, consultant or supervisor.

§64-57-6. Licensure Requirements, Duration, Renewal.

6.1. Applicants for a clinical laboratory practitioner license shall submit to the secretary:

6.1.1. A completed application form supplied by the secretary with the documentation of qualifications required by this rule;

6.1.2. If employed in a clinical laboratory, a current job description and a statement identifying the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform, except as specified in this rule. The required job description and statement of competency shall be signed and provided to the applicant by the applicant's clinical laboratory director. The attestation shall be partially based on the applicant's performance, if any, in proficiency testing programs; and

6.1.3. The licensure fee shown on the application as may be set by W. Va. Code or rule.

6.2. The secretary shall grant a clinical laboratory practitioner license to applicants who:

6.2.1. Are certified as a clinical laboratory practitioner under section 7 of this rule or are exempt from certification under section 8 of this rule; and

6.2.2. Comply with the requirements of subsection 6.1 of this rule.

6.3. An applicant for renewal of either a current or an expired license shall submit the application, information and licensure fee required by subsection 6.1 of this rule and evidence that the applicant has completed at least ten (10) contact hours (one (1) continuing education unit) of educational activities commensurate with the level of complexity of testing the individual performs from a program or programs approved by the secretary, since the issuance of his or her current or expired license, as applicable. Acceptable continuing educational activities include, but are not limited to, activities such as: lectures, seminars, workshops, formal classes, in-service programs or correspondence courses.

6.4. The secretary shall renew a license if the applicant complies with the requirements of subsection 6.3 of this rule.

6.5. A clinical laboratory practitioner license expires the earlier of:

6.5.1. One (1) year after issuance; or

6.5.2. The expiration of the individual's certification or exemption from certification as a clinical laboratory practitioner.

§64-57-7. Certification Requirements.

7.1. A person seeking certification as a clinical laboratory practitioner shall, at the time of application for initial licensure as a clinical laboratory practitioner, also apply for certification on the form provided by the secretary and submit documentation sufficient to establish that he or she meets one (1) of the qualifications for certification established by this rule.

7.2. An individual qualifies for certification as a clinical laboratory practitioner if the individual:

7.2.1. Is certified as a medical laboratory technician or technologist by the American Medical Technologists or the American Society of Clinical Pathologists;

7.2.2. Is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel;

7.2.3. Was performing clinical laboratory practitioner tasks in a clinical laboratory in West Virginia on July 7, 1989; or

7.2.4. Meets the qualifications, except for State licensure, for:

7.2.4.a. Testing personnel found at: 42 CFR §493.1423, or §493.1489; or

7.2.4.b. Cytotechnologists found at 42 CFR § 493.1483; or

7.2.5. Is certified under any other applicable federal program.

§64-57-8. Exemption from Certification.

8.1. A person seeking an exemption from certification as a clinical laboratory practitioner shall submit a request for exemption from certification on a form provided by the secretary. The request shall include a statement signed by the director of the clinical laboratory in which the applicant is employed of: the type and number of the laboratory's CLIA certificate, and which of the qualifications for exemption established by this rule the applicant meets.

8.2. The secretary shall exempt a person from certification as a clinical laboratory practitioner if:

8.2.1. He or she is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

8.2.2. His or her laboratory director states that the person applying for exemption from certification meets the qualifications, except for State licensure, for:

8.2.2.a. Testing personnel found at: 42 CFR § 493.1423, or § 493.1489; or

8.2.2.b. Cytotechnologists found at 42 CFR § 493.1483.

§64-57-9. Expiration of Certification and Exemption.

An individual's certification or exemption from certification as a clinical laboratory practitioner expires when the person holding the certification or the exemption no longer meets the qualifications stated in this rule for certification or for exemption from certification.

§64-57-10. Reciprocity.

The secretary may issue a clinical laboratory practitioner license or certification to a person who holds a license or certification from another jurisdiction which has licensure or certification requirements at least comparable to the requirements of this rule. Applicants for reciprocity shall submit the license application fee and a statement from their licensing or certifying jurisdiction that they are in good standing with their application.

§64-57-11. Limitations on Certification, License and Use of Titles by Health Care Facilities.

11.1. Licensure or certification as a clinical laboratory practitioner does not authorize the person to perform laboratory tests unless his or her clinical laboratory director has determined that the person is qualified by education, training or experience to perform such tests.

11.2. Health care facilities shall not use the terms clinical laboratory practitioner, laboratory or medical technician or laboratory or medical technologist, or abbreviations thereof, to refer to a

person who is not licensed as a clinical laboratory practitioner.

§64-57-12. Revocation and Non-issuance of Clinical Laboratory Practitioner Certifications and Licenses and Health Care Facility Licenses.

12.1. A clinical laboratory practitioner license, certification, or exemption from certification, shall not be issued or shall be revoked if the applicant for or holder thereof:

12.1.1. Has misrepresented material facts in an application or has assisted another person in doing so;

12.1.2. Does not meet requirements for licensure, certification, or exemption from certification; or

12.1.3. Has been convicted of a felony involving laboratory practices.

12.2. No license shall be issued to a health care facility as long as it uses in West Virginia an unlicensed clinical laboratory practitioner.

§64-57-13. Criminal Penalties.

A violator of the provisions of this rule is subject to fine or imprisonment as found at W. Va. Code §§ 16-1-18 and 16-5J-8.

§64-57-14. Hearings.

14.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner certification or license, by a holder thereof or by a health care facility. The request shall specify the grounds relied upon as a basis for the relief requested.

14.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code § 29A-5-1 et seq., and **Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, 64 CSR 1**.

§64-57-15. Severability.

The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions remain in effect.

biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements.* (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993]

§491.10 Patient health records.

(a) *Records system.* (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

(b) *Protection of record information.* (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[57 FR 24984, June 12, 1992]

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AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by HCFA in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by HCFA.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received HCFA's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received HCFA approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.630, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for physician-performed microscopy procedures* means a certificate issued or reissued, pending an appeal, in accordance with §493.630, to a laboratory in which a physician performs only the microscopy tests listed in §493.16(b), or issued or reissued to a laboratory in which a physician performs microscopy tests and waived tests as listed in §493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA, (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.632, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued, pending an appeal, in accordance with §493.626, to an entity that is not qualified to receive a certificate of waiver or certificate for physician-performed microscopy procedures, that enables the entity to conduct moderate or high complexity laboratory testing until the entity is determined to be in compliance through a survey by HCFA, its agent, or the State; is accredited by an approved accreditation organization; or becomes exempt from CLIA by virtue of it being licensed by a State with a HCFA-approved laboratory licensure program.

(5) *Certificate of waiver* means a certificate issued or reissued, pending an appeal, in accordance with §493.631, to a laboratory to perform only the waived tests listed at §493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or ap-

proved by a State where HCFA has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by HCFA in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as "conditions" in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

HCFA agent means an entity with which HCFA arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component HCFA approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the HCFA agent.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by HCFA or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is licensed by the State to practice medicine or podiatry.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where HCFA, the State survey agency or other HCFA agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

EXAMPLE: Assume the State survey agency, HCFA or other HCFA agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. HCFA reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program

as meeting standards for licensing or approval established under State law.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by HCFA to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at §493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993]

§493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, a certificate, or a certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§493.10 Categories of tests by complexity.

(a) Laboratory tests are categorized as either—

(1) Waived tests;

(2) Tests of moderate complexity; or

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only tests of high complexity or any combination.

(c) Each laboratory must be either CLIA-exempt or possess one of the following, as defined in this part:

(1) Registration certificate;

(2) Certificate of waiver;

(3) Certificate; or

(4) Certificate of accreditation.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non- automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—nonautomated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§493.16 Physician-performed microscopy procedures.

(a) *Requirement.* Procedures to be categorized as physician-performed microscopy procedures must meet the cri-

teria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by a physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member;

(2) The procedure must be categorized as moderately complex;

(3) The primary instrument for performing the test is the microscope;

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result;

(5) Control materials are not available to monitor the entire testing process; and

(6) Limited specimen handling or processing is required.

(c) *Physician performed microscopy examinations.* A laboratory may qualify to perform tests under this provision if it restricts physician-performed microscopy examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others;

(1) Wet mounts, including preparations of vaginal, cervical or skin specimens;

(2) All potassium hydroxide (KOH) preparations;

(3) Pinworm examinations;

(4) Fern tests;

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous; and

(6) Urine sediment examinations.

(d) *Revisions to criteria and the list of physician-performed microscopy procedures.*

(1) The Clinical Laboratory Improvement Advisory Committee (CLIAC) will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of procedures.

(2) HHS will determine whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a physician-performed microscopy procedure. Revisions to the list of physician-performed microscopy procedures proposed by HHS will be published in the FEDERAL REGISTER as a Notice with an opportunity for public comment.

(e) Laboratories eligible for test performance under the physician-performed microscopy examination provision must—(1) Meet the applicable requirements in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, subpart F, general administration, or if applicable, subpart D, certificate of accreditation, subpart H, participation in proficiency testing, subpart J, patient test management, subpart K, quality control, and subpart P, quality assurance, of this part.

(2) In lieu of the requirements contained in subpart M, personnel, meet the following requirements:

(i) The laboratory must have a director who—

(A) Possesses a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required;

(B) Is a doctor of medicine, doctor of osteopathy, or doctor of podiatry licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(C) Is responsible for ensuring that any procedure listed in paragraph (c) of this section is—

(*1*) Personally performed by a physician on a specimen from his or her own patient or from a patient of a group medical practice of which the physician is a member; and

(*2*) Performed in accordance with the applicable requirements in subparts H, J, K and P of this part.

(ii) Any procedure listed under paragraph (c) of this section must be personally performed by a physician during the patient visit on a specimen from his or her own patient or from a patient of a group medical practice of which the physician is a member.

(3) Be subject to inspection only under the circumstances specified under §493.1776 but are not routinely inspected to determine compliance with the requirements specified in paragraphs (e) (1) and (2) of this section.

[58 FR 5221, Jan. 19, 1993]

§493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) *Knowledge.*

(i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) *Training and experience.*

(i) *Score 1.* (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) *Reagents and materials preparation.*

(i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) *Characteristics of operational steps.*

(i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) *Calibration, quality control, and proficiency testing materials.*

(i) *Score 1.* (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) *Score 3.* (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) *Test system troubleshooting and equipment maintenance.*

(i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under §493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to certificate of waiver tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, or, if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections of this part. For physician-performed microscopy procedures, the personnel requirements contained in §493.16(e)(2) are applicable in lieu of subpart M of this part and inspections are required only under the circumstances specified in §493.1776.

(c) If the laboratory also performs certificate of waiver tests listed in §493.15 compliance with subparts H, J, K, M, P and Q of this part for routine inspections are not required for the waived tests. However, the laboratory must comply with the requirements in §§493.15(e) and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in §493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C, registration certificate and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections, of this part.

(c) If the laboratory also performs certificate of waiver tests, the requirements of subparts H, J, K, M, P, and Q of this part for routine inspections are not applicable for the waived tests. However, the laboratory must comply with the requirements in §§493.15(e) and 493.1775.

(d) If the laboratory also performs tests of moderate complexity, the personnel requirements of subpart M are applicable for the performance of tests of moderate complexity as well as subparts H, J, K, P, and Q of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

Subpart B—Certificate of Waiver

SOURCE: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.

§493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in §435.15(b) of this chapter must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in §493.15(c) and no other tests must—

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and §493.15(e);

(2) Agree to permit unannounced inspections by HHS in accordance with subpart Q of this part—

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health;

(ii) To evaluate complaints from the public;

(iii) On a random basis to determine whether the laboratory is performing tests not listed in §493.15; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §493.15.

(e) *Denial of application.* If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of §493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and §493.15(e) of subpart A of this part; and

(2) Must permit unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a noncompliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examination or test procedures not listed in the waiver test category must meet the requirements set forth in subparts C or D of this part.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in §493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under §493.15 for which it does not have a registration certificate as required in subparts C or D of this part; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

Subpart C—Registration Certificate, Certificate for Physician-performed Microscopy Procedures, and Certificate

SOURCE: 57 FR 7143, Feb. 28, 1992, unless otherwise noted.

§493.43 Application for registration certificate, certificate for physician-performed microscopy procedures, and certificate.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate or high complexity, or both, must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.45 Requirements for a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate or high complexity or both (Exception: For physician-performed microscopy procedures listed in §493.16(c), the laboratory is not issued a registration certificate but is subject to §§493.43 and 493.47 and must apply and obtain a certificate for physician-performed microscopy procedures prior to conducting the procedures listed in §493.16(c));

(2) For all certificate of waiver laboratories that intend to perform testing in addition to those tests listed in §493.15(c); and

(3) For any laboratory that intends to perform testing in addition to physician-performed microscopy procedures listed in §493.16(c) and waived procedures listed in §493.15(c).

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of §493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is—

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a non-compliance determination resulting in an HHS denial of a laboratory's certificate application, HHS will provide the laboratory with a statement of grounds on which the non-compliance determination is based and offer an opportunity for appeal as provided in subpart R.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.47 Requirements for a certificate for physician-performed microscopy procedures.

(a) A certificate for physician-performed microscopy procedures is required—

(1) Initially for all laboratories performing test procedures listed in §493.16(c); and

(2) For all certificate of waiver laboratories that intend to perform only test procedures listed in §493.16(c) in addition to those tests listed in §493.15(c).

(b) HHS will issue a certificate for physician-performed microscopy procedures if the laboratory—

(1) Complies with the requirements of §493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for physician—performed microscopy procedures are subject to—

(1) The notification requirements of §493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and P of this part. In lieu of the requirements contained in subpart M of this part, for physician-performed microscopy procedures, the laboratory must

meet the requirements of §493.16(e)(2); and

(3) Inspection only under the circumstances specified under §493.1776, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c) (1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for physician-performed microscopy procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for physician-performed microscopy procedures is valid for a period of no more than 2 years.

[58 FR 5223, Jan. 19, 1993]

§493.49 Requirements for a certificate.

(a) HHS will issue a certificate to a laboratory only if the laboratory—(1) Meets the requirements of §§493.43 and 493.45 (§493.45 is not applicable to physician-performed microscopy procedures);

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M (not applicable to physician-performed microscopy procedures), P and Q of this part. In lieu of the personnel requirements contained in subpart M, for physician—performed microscopy procedures, the laboratory must meet the requirements of §493.16(e)(2).

(b) Laboratories issued a certificate—(1) Are subject to the notification requirements of §493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q (provision for conducting inspections of the physician-performed microscopy procedures listed in §493.16(c) is located at §493.1776) of this part—

(i) To determine compliance with the requirements of this part. Exception: In accordance with §493.16(e)(3), inspections of physician-performed microscopy procedures are not routinely conducted);

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the addition, deletion, or continued inclusion of tests listed in §493.15 or §493.16 or tests of moderate or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate issued under this subpart is valid for no more than 2 years.

(e) In the event of a non-compliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of non-compliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate or reissued certificate until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at §493.1840(a)(4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate; and

(2) Meet the requirements of §493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate is to be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate or reissued certificate until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993]

§493.51 Notification requirements for laboratories issued a certificate.

Laboratories issued a certificate must:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity testing only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate, so that compliance with requirements can be determined; and

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§493.53 Notification requirements for laboratories issued a certificate for physician-performed microscopy procedures.

Laboratories issued a certificate for physician-performed microscopy procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under §§493.15(c) and 493.16(c) for which it does not have a registration certificate as required in subparts C or D of this part; and

(b) Within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

Subpart D—Certificate of Accreditation

SOURCE: 57 FR 7144, Feb. 28, 1992, unless otherwise noted.

§493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory performing one or more tests of moderate complexity or high complexity, or both may be issued a certificate of accreditation in lieu of a certificate provided the laboratory—

(1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) *Exceptions.* (1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of §493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of subpart C, §493.49 of this part.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in §493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of §493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with §488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or §493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 57 FR 34014, July 31, 1992, unless otherwise noted.

§493.501 General requirements for accredited laboratories.

(a) *Deemed status.* HCFA may deem a laboratory to meet all the applicable CLIA program requirements of this Part if the laboratory is accredited by a private, nonprofit accreditation organization for laboratories that—

(1) Provides reasonable assurance to HCFA that it requires the laboratories it accredits to meet all of the requirements equivalent to the CLIA condition level requirements specified in this part and would, therefore, meet condition level requirements if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and

(2) Meets the requirements of §493.506 of this subpart.

(b) *Laboratory requirements.* To be deemed to meet the applicable CLIA program requirements, a laboratory accredited by a private, nonprofit accreditation organization must—

(1) Authorize its accreditation organization to release to HCFA all records and information required by HCFA;

(2) Permit inspections as required by these regulations;

(3) Obtain a certificate of accreditation as required by §493.632 of this part; and

(4) Pay the applicable fees as required by §§493.638 and 493.645 of this part.

(c) *Application and reapplication process for accreditation organizations.* In applying or reapplying to HCFA for deeming authority, a private nonprofit accreditation organization must provide the following information to the Administrator of HCFA—

(1) The specialty(ies) or subspecialty(ies) for which the organization is requesting "deeming authority";

(2) A detailed comparison of individual accreditation requirements with the comparable condition level requirements; i.e., a crosswalk;

(3) A detailed description of the inspection process, including the frequency of inspections, copies of inspection forms, instructions, and guidelines, a description of the review and decision-making process of accreditation inspections and a description of the steps taken to monitor the correction of deficiencies;

(4) A description of the process for monitoring proficiency testing (PT) performance, including action to be taken in response to unsuccessful participation in an approved PT program;

(5) A description of the accreditation organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the system;

(6) Detailed information concerning the personnel who perform accreditation inspections, including but not limited to the size and composition of individual accreditation inspection teams, education and experience requirements that those inspectors must meet and the content and frequency of the training provided to inspection personnel;

(7) Procedures to investigate and respond to complaints against accredited laboratories;

(8) A list of any currently accredited laboratories and the expiration date of each laboratory's accreditation;

(9) Procedures for making PT information available, including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person;

(10) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards;

(11) A proposed agreement between the accreditation organization and HCFA with respect to the notification requirements specified in §493.506(b)(3) of this subpart; and

(12) Whether accreditation inspections are announced or unannounced.

(d) *Application review process.* Once HCFA receives an application for deeming authority from a private nonprofit accreditation organization—

(1) HCFA will determine if additional information is necessary to make a determination for approval of the accreditation organization's application for deeming authority and will so notify the organization and give it an opportunity to provide the additional information.

(2) HCFA may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(3) The accreditation organization will receive a formal notice from HCFA stating whether the request for deeming authority has been approved or denied and the rationale for any denial.

(4) HCFA may approve an accreditation organization for a period not to exceed six years.

(5) An accreditation organization may withdraw its application for approval of deeming authority at any time prior to the official notification specified in paragraph (d)(3) of this section.

(6) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for approval of deeming authority is denied may request, within 60 days of the notification of the denial, that its original application be reconsidered.

(7) Except as provided in paragraph (d)(8) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(i) Has revised its accreditation program to address the rationale for denial of its previous request;

(ii) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet condition level requirements; and

(iii) Resubmits the application in its entirety.

(8) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of HCFA's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority until a final reconsideration determination is issued.

(e) *Publication of names of approved accreditation organizations.* HCFA publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization under paragraph (a) of this section. The notice—

(1) Names the accreditation organization;

(2) Describes the basis for granting deeming authority to the accreditation organization;

(3) Describes how the accreditation organization provides reasonable assurance to HCFA that laboratories accredited by the organization meet CLIA requirements equivalent to those specified in this part and would, therefore, meet CLIA requirements if those laboratories had not been granted deemed status, but had been inspected against condition level requirements; and

(4) Specifies a term of approval not to exceed six years.

§493.503 Proficiency testing requirements of laboratories with deemed status.

(a) *General.* A laboratory deemed to meet condition level requirements must meet the proficiency testing (PT) requirements of this part.

(b) *Release of PT results.* (1) A laboratory deemed to meet condition level requirements must authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring a laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person.

(2) A laboratory that refuses to authorize the release of its PT results will no longer be deemed to meet the condition level requirements and will be subject to full review by HCFA, the State survey agency, or other HCFA agent in accordance with §493.1777 of this chapter and may be subject to the suspension or revocation of its certificate of accreditation under §493.1840 of this part.

(3) A laboratory with deemed status that has failed to achieve successful participation in an approved PT program must authorize its accreditation organization to release to HCFA its PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of "unsuccessful participation in an approved PT program" as specified in this part. Such a laboratory must also authorize its accreditation organization to release to HCFA a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of such actions.

(4) HCFA may, on the basis of the notification of adverse actions received from the accreditation organization, take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

§493.504 Revocation of accreditation.

After a private, nonprofit accreditation organization withdraws or revokes its accreditation of a laboratory, the certificate of accreditation required by this part will continue in effect until the earlier of—

(a) 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation; or

(b) The effective date of any action taken by HCFA.

§493.506 Federal review and approval of private, nonprofit accreditation organizations.

(a) An accreditation organization may request and may be granted "deeming authority" for all specialties and subspecialties or for specific specialty or subspecialty areas. In the latter case, the accreditation organization

will be accountable for the monitoring of compliance with all requirements equivalent to condition level requirements within the scope of the specialty or subspecialty.

(b) HCFA's review of a private, nonprofit accreditation organization includes, but is not necessarily limited to, an evaluation of the following—

(1) Whether the accreditation organization's requirements for laboratories are equal to or more stringent than the condition level requirements for laboratories;

(2) The accreditation organization's inspection process to determine—

(i) The composition of the inspection team, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to inspectors;

(ii) The comparability of the organization's full inspection and complaint inspection requirements to those of HCFA, including but not limited to inspection frequency, and the ability to investigate and respond to complaints against accredited laboratories;

(iii) The organization's procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures are to be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, HCFA, the State survey agency, or other HCFA agent monitors corrections as authorized at §493.507(b)(4) of this subpart);

(iv) The ability of the organization to provide HCFA with electronic data and reports, including the crosswalk specified in §493.501(c)(2), in ASCII-comparable code that are necessary for effective validation and assessment of the organization's inspection process;

(v) The ability of the organization to provide HCFA with electronic data in ASCII-comparable code related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action;

(vi) The ability of the organization to provide HCFA with electronic data in ASCII-comparable code for all accredited laboratories, including the area of specialty or subspecialty;

(vii) The adequacy of numbers of staff and other resources; and

(viii) The organization's ability to provide adequate funding for performing required inspections; and

(3) The organization's agreement with HCFA that requires it to:

(i) Notify HCFA of any laboratory accredited by the organization that has had its accreditation withdrawn, revoked or limited by the accreditation organization denied, suspended, withdrawn or revoked or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;

(ii) Notify HCFA within 10 days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;

(iii) Notify HCFA of all newly accredited laboratories (or laboratories whose areas of specialty or subspecialty are revised) within 30 days;

(iv) Notify each laboratory accredited by the organization within 10 days of HCFA's withdrawal of recognition of the organization's deeming authority;

(v) Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;

(vi) Provide HCFA, the State survey agency or other HCFA agent with any facility-specific data to include, but not be limited to, the following (upon request):

(A) PT results that constitute unsuccessful participation in an approved PT program; and

(B) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation;

(vii) Provide HCFA written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and

(viii) Disclose any laboratory's PT results upon the reasonable request by any person.

§493.507 Validation inspections of laboratories with certificates of accreditation.

(a) *Basis for inspection.* HCFA, the State survey agency, or a HCFA agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation. The results of these inspections will be used to validate the accreditation organization's accreditation process. These inspections may be conducted on a representative sample basis or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the inspection is comprehensive, addressing all condition level requirements, or may be focused on a specific condition level requirement or requirements, and the number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of each accreditation organization.

(2) When conducted in response to a substantial allegation of noncompliance, HCFA, the State survey agency or other HCFA agent inspects for any condition level requirement or requirements that HCFA determines to be related to the allegation. If HCFA, the State survey agency or other HCFA agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, HCFA, the State survey agency or other HCFA agent will conduct a full CLIA inspection.

(b) *Effect of selection for inspection.* A laboratory selected for inspection must:

(1) Authorize its accreditation organization to release to HCFA, the State survey agency or other HCFA agent, on a confidential basis, a copy of the results of the laboratory's most recent full, and any subsequent partial, accreditation inspection(s);

(2) Authorize the validation inspection to take place;

(3) Provide HCFA, the State survey agency, or other HCFA agent access to all facilities, equipment, materials, records and information that HCFA determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit HCFA, the State survey agency or other HCFA agent to copy any such material or require it to be submitted; and

(4) Authorize HCFA, the State survey agency or other HCFA agent to monitor the correction of any deficiencies found through the validation inspection.

(c) *Refusal to cooperate with the inspection.* (1) If a laboratory selected for inspection fails to comply with the requirements specified in paragraph (b) of this section it—

(i) Will be subject to full review by HCFA, the State survey agency or other HCFA agent in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) An accredited laboratory will be once again deemed to meet the condition level requirements by virtue of its accreditation when—

(i) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure;

(ii) It withdraws any prior refusal to allow a validation inspection; and

(iii) HCFA finds that the laboratory meets all the condition level requirements.

(d) *Consequences of a finding of noncompliance.* If a validation inspection results in a finding that the laboratory is out of compliance with one or more condition level requirements, the laboratory is subject to the same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following a State agency inspection under this part and to full review by HCFA, the State survey agency or other HCFA agent in accordance with this part; i.e., the laboratory will be subject to the principal and alternative sanctions specified in §493.1806 of this part.

(e) *Disclosure of accreditation and validation inspection results.* The accreditation inspection results are disclosable to the public only if they are related to an enforcement action taken by the Secretary. The results of all validation inspections conducted by HCFA, the

State survey agency or other HCFA agents are disclosable.

(f) *Onsite observation of accreditation organization operations.* As part of the validation review process, HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. Such an onsite inspection may include, but is not limited to, the review of documents, the auditing of meetings concerning the accreditation process, the evaluation of accreditation inspection results or the accreditation decision-making process, and interviews with the organization's staff.

§493.509 Continuing Federal oversight of private, nonprofit accreditation organizations.

(a) *Comparability review.* In addition to reviewing the equivalency of specified accreditation requirements to the comparable condition level requirements when an accreditation organization initially applies to HCFA for "deeming authority", HCFA reviews the equivalency of requirements—

(1) When HCFA promulgates new condition level requirements;

(2) When HCFA identifies accreditation organizations whose requirements do not continue to be equal to or more stringent than condition level requirements;

(3) When an accreditation organization adopts new requirements;

(4) When an accreditation organization adopts changes to its inspection process as required by §493.511(b); or

(5) Every six years or sooner if HCFA determines the organization requires an earlier review.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization.

(c) *Reapplication procedures.* (1) Every six years, or sooner as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority. HCFA will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(2) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(d) *Notice.* HCFA provides written notice to the accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that an accreditation organization is not meeting the requirements of this subpart and that a deeming authority review is being initiated. The notice contains the following information—

(1) A statement of the discrepancies that were found as well as other related documentation;

(2) An explanation of HCFA's review process on which the final determination will be based and a description of the possible actions as specified in §493.511 that may be imposed by HCFA based on the findings from the comparability or validation review;

(3) A description of the procedures available if the accreditation organization desires an opportunity to explain or justify the findings made during the comparability or validation review; and

(4) The reapplication materials the organization must submit and the deadline for that submission.

§493.511 Removal of deeming authority and final determination review.

(a) *Deeming authority review.* (1) HCFA reviews, as appropriate, the criteria described in §493.506 to reevaluate whether the accreditation organization continues to meet all these criteria. HCFA conducts a deeming authority review of an accreditation organization's program if the comparability or validation review produces findings as described at §493.509(a) of this subpart.

(2) HCFA conducts, at its discretion, a deeming authority review of an accreditation organization's program if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(3) HCFA conducts a deeming authority review whenever validation inspection results over a one-year period indicate a rate of disparity of 20 percent or more between the findings of the accreditation organization and the findings of HCFA, State survey agencies, or other HCFA agents.

(b) Following the deeming authority review, if HCFA determines that the accreditation organization has failed to adopt requirements equal to or more stringent than CLIA requirements, HCFA may give the accreditation organization a conditional approval effective 30 days following the date of HCFA's determination of its deeming authority for a probationary period, not to exceed one year, to adopt comparable requirements.

(c) Following the deeming authority review, if HCFA determines that there are widespread systematic problems in the organization's inspection process, HCFA may give the accreditation organization conditional approval of its deeming authority during a probationary period not to exceed one year that is effective 30 days following the date of HCFA's determination.

(d) Within 60 days after the end of any probationary period, HCFA will make a final determination as to whether or not an accreditation organization continues to meet the criteria described at §493.506 of this subpart and issues an appropriate notice (including reasons for the determination) to the accreditation organization. This determination is based on the evaluation of any of the following:

(1) The most recent validation inspection and review findings as described at §493.509(b) of this subpart. In order for the accreditation organization to continue to have deeming authority, it must continue to meet the criteria in §493.506 of this subpart;

(2) Facility-specific data and other related information;

(3) The accreditation organization's surveyors in terms of qualifications, ongoing education and training, composition of inspection team, etc.;

(4) The organization's inspection procedures; and

(5) The organization's accreditation requirements.

(e) HCFA may remove recognition of deeming authority effective 30 days from the date that it provides written notice to the accreditation organization that its deeming authority will be removed if the accreditation organization has not made improvements acceptable to HCFA during the probationary period.

(f) The existence of any validation review, deeming authority review, probationary status, or any other action by HCFA with respect to an accreditation organization does not affect or limit the conduct of any validation inspection of its accredited laboratories.

(g) HCFA will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing the deeming authority from an accreditation organization.

(h) After HCFA withdraws approval of an accreditation organization's deeming authority, the certificates of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notification of the withdrawal of approval. HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for inspection to another approved accreditation organization for an application for a certificate, certificate for physician-performed microscopy procedures, or certificate of waiver to HCFA, the State agency or other HCFA agent before the initial 60 day period ends.

(i) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the laboratories accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of deeming authority of that accreditation organization.

(j) Any accreditation organization that is dissatisfied with a determination to withdraw its deeming authority may request a reconsideration of that

determination in accordance with subpart D of part 488.

[57 FR 34014, July 31, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§493.513 General requirements for CLIA-exempt laboratories.

(a) HCFA may exempt from CLIA program requirements, for a period not to exceed six years, all State-licensed or approved laboratories in a State if the State—

(1) Has in effect laws that provide for requirements equal to or more stringent than condition level requirements;

(2) Has an agency that licenses or approves laboratories that meet requirements equal to or more stringent than the CLIA condition level requirements specified in this part and would, therefore, meet condition level requirements if those laboratories had not been exempted from CLIA, but rather had been inspected for compliance with condition level requirements;

(3) Meets the requirements and is approved in accordance with §493.515 of this subpart;

(4) Demonstrates that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements;

(5) Permits HCFA or HCFA agents to inspect laboratories in the State;

(6) Requires laboratories in the State to submit to inspections by HCFA or HCFA agents as a condition of licensure or approval;

(7) Agrees to pay the cost of the validation program administered by HCFA in that State as specified in §§493.645(b) and 493.646 of this part; and

(8) Takes appropriate enforcement action against laboratories found by HCFA or HCFA agents not to be in compliance with requirements equivalent to CLIA requirements.

(b) A laboratory in a State with an approved State laboratory program must—

(1) Authorize the laboratory program to release to HCFA or HCFA agent all records and information required by HCFA; and

(2) Permit inspection as required by these regulations.

(c) In applying to HCFA for exemption from the CLIA program, the State must provide the following information to HCFA—

(1) A detailed comparison of individual licensure or approval requirements with the comparable condition level requirements; i.e., a crosswalk;

(2) A detailed description of the inspection process including the frequency of inspections, copies of inspection forms, instructions and guidelines, a description of the review and decision-making process of licensure or approval inspections, whether inspections are announced or unannounced and a description of the steps taken to monitor the correction of deficiencies;

(3) A description of the State's enforcement authority, administrative structure and resources to enforce the State standards;

(4) A description of the process for monitoring proficiency testing (PT) performance, including action to be taken in response to unsuccessful participation in a HCFA-approved PT program;

(5) The State's procedures for responding to, and for the investigation of, complaints against licensed or approved laboratories;

(6) A list of all currently licensed or approved laboratories and the expiration date of each laboratory's current license or approval;

(7) Procedures under State confidentiality and disclosure requirements for the release of PT information, including explanatory information required to interpret PT results; and

(8) For Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(d) The State must also submit the following supporting documentation—

(1) A written presentation that demonstrates the agency's ability to furnish HCFA with electronic data in ASCII comparable code, including the crosswalk specified in paragraph (c)(1) of this section;

(2) A statement acknowledging that the State will notify HCFA through electronic data transmission of—

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of any such action taken;

(ii) Changes in licensure (or approval) or inspection requirements; and

(iii) Changes in the specialties or subspecialties under which any laboratory in the State performs testing.

(e) If HCFA determines that additional information is necessary to make a determination for approval or denial of the application for exemption, HCFA will notify the State and afford it an opportunity to provide the additional information.

(f) HCFA may visit the State laboratory program offices to review the application of the State's policies and procedures and other information provided by the State. Such review includes, but is not limited to, examination of documents and interviews with staff.

(g) HCFA will furnish the State a formal notice stating whether the request for exemption has been approved or denied and the rationale for any denial.

(h) Except as provided in paragraph (m) of this section, any State whose application for approval for exemption, or for renewal of that approval, from CLIA has been denied may resubmit its request as soon as the State has taken the necessary action to address the rationale for any previous denial.

(i) A State may withdraw its request for exempt status at any time prior to the official notification specified in paragraph (g) of this section.

(j) Any State whose application for approval for exempt status is denied may request, within 60 days of the notification of the denial, that its original application or application for renewal be reconsidered in accordance with part 488, subpart D of this chapter.

(k) HCFA publishes a notice in the FEDERAL REGISTER when it grants exemption to a State under paragraph (a) of this section. The notice—

(1) Names the State;

(2) Describes the basis for granting the exemption to the State;

(3) Describes how the laboratory requirements of the State are equal to or more stringent than those specified in this part; and

(4) Specifies a term of approval not to exceed six years.

(l) A State that has received approval for the exemption of its laboratories from the CLIA program must reapply to HCFA every two years for renewal of its exemption status and renew its agreement to pay the cost of the HCFA administered validation program in that State.

(m) If a State has requested a reconsideration of HCFA's determination that its request for exemption, or for renewal of its exemption, of its laboratories from CLIA is denied, it may not resubmit its request until a final reconsideration determination is issued.

§493.515 Federal review of laboratory requirements of State laboratory programs.

(a) HCFA's review of a State laboratory program includes, but is not necessarily limited to, an evaluation of the following:

(1) Whether the State's requirements for laboratories are equal to or more stringent than the condition level requirements;

(2) The State's inspection process requirements to determine—

(i) The comparability of the full inspection and complaint inspection procedures to those of HCFA, including but not limited to inspection frequency and the ability to investigate and respond to complaints against licensed or approved laboratories;

(ii) The State's enforcement procedures for laboratories found to be out of compliance with its requirements;

(iii) The ability of the State to provide HCFA with electronic data and reports in ASCII-comparable code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs and with other data HCFA determines are necessary for validation and assessment of the State's inspection process requirements;

(3) The State's agreement with HCFA to—

(i) Notify HCFA within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or has been in any way sanctioned;

(ii) Notify HCFA within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases where the deficiency poses an immediate jeopardy

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to the laboratory's patients or a hazard to the general public.

(iii) Notify each laboratory licensed by the State within 10 days of HCFA's withdrawal of the State's exemption;

(iv) Provide HCFA with written notification of any changes in its licensure (or approved) and inspection requirements;

(v) Disclose any laboratory's PT results in accordance with a State's confidentiality requirements;

(vi) Take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition level requirements and report such enforcement actions to HCFA;

(vii) Notify HCFA of all newly licensed laboratories, including the specialties and subspecialties, for which any laboratory performs testing within 30 days; and subspecialties, for which any laboratory performs testing within 30 days; and

(viii) Provide HCFA, as requested, inspection schedules for validation purposes.

§493.517 Validation inspections of CLIA-exempt laboratories.

(a) *Basis for inspection.* HCFA or a HCFA agent other than the State survey agency may conduct an inspection of any laboratory in a State with an approved laboratory program. The results of these inspections will be used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements. These inspections may be conducted on a representative sample basis or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the inspection may be comprehensive, addressing all condition level requirements, or may be focused on a specific requirement or requirements. The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the State.

(2) When conducted in response to a substantial allegation of noncompliance, HCFA or a HCFA agent inspects for any condition level requirement or requirements that HCFA determines to be related to the allegation. If HCFA substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, HCFA or other HCFA agent will conduct a full CLIA inspection.

(b) *Effect of selection for inspection.* A CLIA-exempt laboratory selected for a validation inspection must—

(1) Authorize the State to release to HCFA or a HCFA agent, on a confidential basis, a copy of the results of the laboratory's most recent full, and any subsequent partial, licensure or approval inspection(s);

(2) Authorize the validation inspection to take place; and

(3) Provide HCFA or a HCFA agent access to all facilities, equipment, materials, records and information that HCFA determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part and permit HCFA or a HCFA agent to copy any such materials or to require such copies to be submitted.

(c) *Refusal to cooperate with the inspection.* If a laboratory selected for a validation inspection fails to comply with the requirements specified in paragraph (b) of this section, HCFA will notify the State.

(d) *Consequences of a finding of noncompliance.* If a validation inspection results in a finding that the laboratory is out of compliance with one or more condition level requirements, HCFA will direct the State to take the appropriate enforcement action(s).

(e) *Disclosure of State and validation inspection results.* The disclosure of State inspection results will be the responsibility of the approved State laboratory program, in accordance with State law. The results of all validation inspections conducted by HCFA or other HCFA agents are disclosable.

(f) *Onsite observation of State laboratory program operations.* As part of the validation review process, HCFA may conduct an onsite inspection of a State's laboratory program offices and operations to verify the State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by HCFA or HCFA agents. Such an onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the licensure or approval process, the evaluation of State inspection results and the licensure or approval decisionmaking process, and interviews with State employees.

§493.519 Continuing Federal oversight of an approved State laboratory program.

(a) *Comparability review.* In addition to reviewing the equivalency of specified licensure or approval requirements to the comparable condition level requirements when a State initially applies to HCFA for exemption of its licensed or approved laboratories from condition level requirements, HCFA reviews the equivalency of requirements when—

(1) HCFA promulgates new condition level requirements;

(2) HCFA identifies a State whose requirements do not continue to be equal to or more stringent than condition level requirements;

(3) A State laboratory program adopts new requirements;

(4) A State laboratory program adopts changes to its inspection process requirements as required by §493.521(b); or

(5) Every six years or sooner if HCFA determines the State laboratory requires an earlier review.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved State laboratory program.

(c) *Reapplication procedures.* (1) Every six years, or sooner as determined by HCFA, an approved State laboratory program must reapply for continued approval of CLIA exemption. HCFA will notify the State of the materials the State must submit as part of the reapplication procedure.

(2) A State that is not meeting the requirements of this subpart as determined through a comparability or validation review must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(d) *Notice.* HCFA provides written notice to the State, indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories. The notice contains the following information—

(1) A statement of the discrepancies that were found, as well as other related documentation;

(2) An explanation of HCFA's review process on which the final determination will be based and a description of the possible actions as specified in §493.521 that may be imposed by HCFA based on the findings from the validation or comparability review;

(3) A description of the procedures available if the State desires an opportunity to explain or justify the findings made during the comparability or validation review; and

(4) The reapplication materials the State laboratory program must submit and the deadline for the submission of those materials.

§493.521 Removal of CLIA exemption and final determination review.

(a)(1) HCFA conducts a review of a State's laboratory program if the comparability review produces findings as described at §493.519(a), of this subpart. HCFA reviews, as appropriate, the criteria described in §493.515 to reevaluate whether the laboratory program continues to meet all these criteria.

(2) HCFA conducts, at its discretion, an exemption review of an approved State laboratory program if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the State's licensure or approval processes that provide evidence that the State's requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(3) HCFA conducts a review of an approved State laboratory program whenever validation inspection results over a two-year period indicate a rate of disparity of 20 percent or more between

the findings of the State and the findings of HCFA or other HCFA agents.

(b) Following the review, if HCFA determines that the State has failed to adopt requirements equal to or more stringent than CLIA requirements, HCFA may give the State, within 30 days of its determination, a conditional approval of its exempt status for a probationary period not to exceed one year to afford the State the opportunity to adopt equal or more stringent requirements.

(c) Following the review, if HCFA determines that there are widespread or systematic problems in the State's inspection process, HCFA may give the State conditional approval of the exemption of its licensed or approved laboratories during a probationary period not to exceed one year that is effective 30 days. following the date of the determination;

(d) Within 60 days after the end of any probationary period, HCFA makes a final determination as to whether or not a State continues to meet the criteria described at §493.515 of this subpart and issues an appropriate notice (including reasons for the determination) to the State. This determination is based on the evaluation of any of the following—

(1) The most recent validation inspection(s) and review findings. In order for the State to continue to be exempt, it must meet the criteria in §493.519 of this subpart;

(2) Facility-specific data, as necessary, as well as other related information;

(3) Inspection procedures;

(4) Licensure or approval requirements.

(e) HCFA may remove its approval of a State laboratory program effective 30 days from the date that it provides written notice to the State of this proposed action if the State has not made improvements acceptable to HCFA during the probationary period.

(f) The existence of any validation review, probationary status, or any other action by HCFA does not affect or limit the conducting of any validation inspection.

(g) HCFA will cancel the approval of a State laboratory program if the State fails to pay the applicable fees as specified in §§493.645 and 493.646.

(h) If HCFA determines at any time that the continued approval of a State laboratory program poses an immediate jeopardy to the patients of the laboratories in that State, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State laboratory program.

(i) HCFA will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing its approval of the State laboratory program.

(j) After HCFA withdraws approval of a State laboratory licensure program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for a certificate, certificate for physician-performed microscopy procedures, or certificate of waiver before the initial 60 day period ends.

(k) HCFA may withdraw a State laboratory program's approval if the State refuses to take enforcement action against a laboratory in that State where HCFA determined it to be necessary. Laboratories that are in a State where program approval has been removed are subject to the same requirements and survey and enforcement processes applied to laboratories that are not exempt from meeting CLIA requirements.

(l) Any State that is dissatisfied with a determination to remove the approval of its laboratory program may request a reconsideration of that determination in accordance with part 488, subpart D of this chapter.

[57 FR 34014, July 31, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

Subpart F—General Administration

SOURCE: 57 FR 7138 and 7213, Feb. 28, 1992, unless otherwise noted.

§493.602 Scope of subpart.

This subpart sets forth requirements all laboratories that test human specimens for health purposes must meet in order to apply for and be issued a registration certificate, certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or certificate under section 353 of the Public Health Service Act (42 U.S.C. 263a). It also sets forth the methodology for determining the amount of the fees for issuing registration certificates, certificates for physician-performed microscopy procedures, certificates of waiver, certificates of accreditation, or certificates and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of State-exempt laboratories.

[58 FR 5224, Jan. 19, 1993]

§493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in §493.3.

[58 FR 5212, Jan. 19, 1993]

§493.610 Certificate requirements for laboratories.

(a) Except as specified in paragraph (b) of this section, no person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a registration certificate, a certificate for physician-performed microscopy procedures, a certificate of waiver, or a certificate or a certificate of accreditation issued by HHS that is applicable to the specialty or subspecialties of services offered by the laboratory.

(b) A laboratory licensed by a State whose licensure program is approved by HHS is exempt from CLIA requirements (that is, State-exempt) and does not require a certificate issued by HHS.

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5224, Jan. 19, 1993]

§493.614 Application procedures.

(a) HHS or its designee will send an application to those laboratories it has identified as potentially being subject to the requirements of CLIA. Those laboratories that do not receive an application must contact HHS or its designee to receive application forms.

(b) A separate application must be filed for each laboratory location. However, laboratories within a hospital that are located at the same street address and under common direction have the option of applying for a single certificate or multiple certificates for the laboratory sites within the same physical location or street address. In addition, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing (that is, few types of tests) may operate under one certificate. A laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site (such as health screening fairs) or other temporary testing location must file a single application using the address of its designated primary site. A separate certificate, which reflects the address of the designated primary site, is required for each mobile unit providing laboratory testing.

(c) An application for the issuance of a registration certificate, a certificate for physician-performed microscopy procedures, a certificate of waiver, or a certificate or certificate of accreditation applicable to one or more laboratory test procedures or examinations included in the specialties or subspecialties listed in §493.643(d)(3) must be made to HHS or its designee on a form or forms prescribed by HHS and must be signed by the owner or authorized representative of the laboratory.

(d) The application must include information that describes the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory, including—

(1) The names of the test procedures and examinations performed and the total number of test procedures and examinations performed annually, excluding tests for quality control, quality assurance, and proficiency testing purposes;

(2) The methodologies for test procedures and examinations performed; and

(3) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5225, Jan. 19, 1993]

§493.618 Additional application requirements.

In submitting an application for a registration certificate, a certificate for physician-performed microscopy procedures, a certificate of waiver, certificate of accreditation, or a certificate, a laboratory must agree to the following:

(a) To make records available and submit reports to HHS as HHS may require.

(b) To permit inspections by HHS or its designee as specified in subpart Q of this part. (Laboratories that have been granted a certificate for physician-performed microscopy procedures or a certificate of waiver are not subject to routine inspections.)

(c) To treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. (Certificate of waiver laboratories are not subject to proficiency testing requirements.)

(d) To provide HHS with satisfactory assurances, through an attestation statement, signed by the laboratory owner or authorized representative, that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the PHS Act.

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5225, Jan. 19, 1993]

§493.622 Appeals procedures.

(a) If HHS denies a laboratory's application for a registration certificate, a certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or certificate, suspends or limits the laboratory's certificate because of deficiencies that pose immediate jeopardy to laboratory patients, or proposes to suspend, limit or revoke a laboratory's CLIA certificate, HHS gives the laboratory a statement of the grounds on which the denial, suspension, limitation, or revocation is based and an opportunity for an appeal, in accordance with the procedures set forth in subpart R of this part.

(b) If a laboratory that is seeking a registration certificate, a certificate for physician-performed microscopy procedures, a certificate of a waiver, a certificate of accreditation, or a certificate has its application denied or its certificate suspended, limited, or revoked, it cannot operate as a laboratory under the PHS Act (or, in the case of a limitation, perform testing in the areas covered by the limitation) unless the denial, suspension, limitation, or revocation is overturned at the conclusion of the administrative appeals process provided by subpart R of this part. (In addition, the laboratory is not eligible for payment under the Medicare or Medicaid programs or, in the case of a limitation, cannot receive Medicare or Medicaid payment for services which have been under the laboratory's certificate.)

(c) Additional provisions relating to appeal rights are set forth in §§493.626(b), 493.633(b), and 493.634(b).

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5225, Jan. 19, 1993]

§493.626 Registration certificate.

(a) HHS or its designee initially issues a registration certificate, a certificate for physician-performed microscopy procedures, or, if the laboratory meets the requirements, a certificate of waiver to each laboratory, provided that the laboratory meets the application requirements of §§493.614, 493.616, 493.618, and 493.630 and pays the applicable fee as specified in §493.638. A registration certificate does not include specialties/subspecialties of service, except as noted in §493.633, but authorizes the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made and the appropriate certificate issued. The registration certificate issued in accordance with §493.633(a)(2) to a laboratory that has a certificate of waiver allows the laboratory to add additional specialties or subspecialties of testing not listed in the waived test category and reflects only the added service(s) noted on the laboratory's application. A registration certificate issued in accordance with §493.633(a)(2) to a laboratory that has a certificate for physician-performed microscopy procedures to allow the laboratory to add service(s) not listed in the waived test or physician-performed procedure category reflects only the added service(s) noted on the laboratory's application. A registration certificate issued under this section is valid for a period of not more than 2 years or until such time as an inspection to determine program compliance can be conducted or the laboratory demonstrates that it qualifies to receive a certificate of waiver, a certificate for physician-performed microscopy procedures, or a certificate of accreditation, whichever is shorter. HHS reissues a registration certificate to any laboratory for which HHS or its designee has not had an opportunity to determine compliance, or for which HHS has determined that noncompliance exists and the administrative hearing decision is pending, if the laboratory has requested a hearing. Alternative sanctions, as set forth in subpart R of this part, may be imposed during this period.

(b) Prior to expiration of the registration certificate, HHS notifies the laboratory of the applicable requirements to obtain a certificate of accreditation or a certificate and the amounts of the fees for issuing these certificates and, if applicable, the amount of the fee for determination of compliance. HHS may suspend, revoke, or limit a laboratory's registration certificate for failure to comply with the applicable requirements and may deny the laboratory's application for the applicable certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and denial are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension or revocation, it may keep its registration certificate until a decision is made by an Administrative Law Judge (ALJ), unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for the applicable certificate, even if there has been no appeal decision issued.)

(c) In the event of a non-compliance determination resulting in denial of a laboratory's application for a certificate of accreditation or certificate, HHS may suspend, revoke, or limit a laboratory's registration certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and application denial are based and with an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it may keep its registration certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for

the applicable certificate, even if there has been no appeals decision issued.)

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5225, Jan. 19, 1993]

§493.629 Certificate.

(a) *Requirements.* HHS or its designee issued a certificate to each laboratory, provided—

(1) The laboratory has a registration certificate and meets the application requirements of §§493.614 and 493.618;

(2) Pays the applicable fee as specified in §493.638; and

(3) Meets all other applicable requirements of this part.

(b) *Expiration date.* A certificate is valid for not more than 2 years.

(c) *Reissuance when there are deficiencies.*—(1) *No immediate jeopardy.*—(i) If HCFA has proposed to suspend, limit, or revoke the certificate of a laboratory that is not in compliance with one or more condition level requirements which do not pose immediate jeopardy, HCFA reissues the certificate before the expiration date.

(ii) During the time specified in paragraph (c)(1)(i) of this section, alternative sanctions, as set forth under subpart R of this part, may be imposed against the laboratory.

(2) *Expiration date.* The certificate remains in effect until an administrative hearing decision is issued.

(3) *Suspension of payments.* All Medicare and Medicaid payments for services furnished by the laboratory during this period may be suspended or cancelled.

[58 FR 5225, Jan. 19, 1993]

§493.630 Certificate for physician-performed microscopy procedures.

(a) *Requirements.* HHS or its designee issues a certificate for physician-performed microscopy procedures to a laboratory if it performs only physician-performed microscopy procedures, or only physician-performed microscopy procedures and waived tests, provided that the laboratory—

(1) Meets the application requirements of §§493.614 and 493.618;

(2) Pays the applicable fee, as specified in §493.638; and

(3) Meets all other requirements of this part.

(b) *Expiration date.* A certificate for physician-performed microscopy tests is valid for not more than 2 years.

(c) *Reissuance when there are deficiencies.*—(1) *No immediate jeopardy.*—(i) If HCFA has proposed to suspend, limit, or revoke the certificate for physician-performed microscopy procedures of a laboratory that is found by HCFA through a validation or complaint survey to have one or more condition level deficiencies which do not pass immediate jeopardy, HCFA reissues the certificate before the expiration date.

(ii) When HCFA reissues the certificate, as specified in paragraph (c)(1)(i) of this section, alternative sanctions, as set forth in subpart R of this part may be imposed against the laboratory.

(2) *Expiration date.* The certificate remains in effect until an administrative hearing decision is issued.

(3) *Suspension of payments.* All Medicare and Medicaid payments for services furnished by the laboratory during this period may be suspended or cancelled.

[58 FR 5225, Jan. 19, 1993]

§493.631 Certificate of waiver.

(a) *Requirements.* HHS or its designee issues a certificate of waiver to a laboratory if it performs only waived tests, provided—

(1) The laboratory meets the application requirements of §§493.614 and 493.618;

(2) Pays the applicable fee as specified in §493.638; and

(3) Meets all other applicable requirements of this part.

(b) *Expiration date.* A certificate of waiver is valid for not more than 2 years.

(c) *Reissuance when there are deficiencies*—(1) *No immediate jeopardy.* If HCFA has proposed to suspend, limit, or revoke the certificate of waiver of a laboratory that is found by HCFA through a validation or complaint survey to have one or more deficiencies which do not pose immediate jeopardy, HCFA reissues the certificate before the expiration date pending a hearing decision.

(2) *Expiration date.* The certificate remains in effect until an administrative hearing decision is issued.

(3) *Suspension of payments.* All Medicare and Medicaid payments for services furnished by the laboratory during this period may be suspended or cancelled.

[58 FR 5226, Jan. 19, 1993]

§493.632 Certificate of accreditation.

(a) *Requirements.* HHS or its designee issues a certificate of accreditation to a laboratory accredited by an HHS-approved accreditation organization, provided—

(1) The laboratory has a registration certificate and meets the application requirements of §§493.614 and 493.618;

(2) Pays the applicable fee as specified in §493.638; and

(3) Meets all other applicable requirements of this part.

(b) *Expiration date.* A certificate of accreditation is valid for not more than 2 years.

(c) *Reissuance when there are deficiencies*—(1) *No immediate jeopardy.* If HCFA has proposed to suspend, limit, or revoke the certificate of accreditation of a laboratory that is found during a validation or complaint survey not to be in compliance with one or more condition level deficiencies which do not pose immediate jeopardy, HCFA reissues the certificate of accreditation before the expiration date.

(2) *Expiration date.* The certificate of accreditation remains in effect until an administrative hearing decision is issued.

(3) *Suspension of payments.* All Medicare and Medicaid payments for services furnished by the laboratory during this period may be suspended or cancelled.

[58 FR 5226, Jan. 19, 1993]

§493.633 Applicability of certificate, certificate for physician-performed microscopy procedures, certificate of waiver, and certificate of accreditation.

(a) The certificate of waiver issued is applicable only to tests listed in the waived test category. The certificate for physician-performed microscopy procedures is applicable only to those procedures listed in the physician-performed microscopy procedures category, or in the physician-performed microscopy procedures and the waived test category. The certificate or certificate of accreditation issued is applicable to those specialties and subspecialties of service offered by the laboratory in accordance with this part.

(1) A laboratory performing only waived tests may not perform any examination or procedure not listed in the waived test category until it has requested and HHS has issued to it a certificate for physician-performed microscopy procedures or a registration certificate, as appropriate, that covers the additional examinations or procedures requested by the laboratory. The laboratory may continue to perform waived tests that are covered by the certificate of waiver already issued to the laboratory. The registration certificate is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. After HHS or its designee determines compliance, HHS issues a certificate that includes the additional specialties or subspecialties for which compliance has been determined.

(2) A laboratory that has been granted a certificate for physician-performed microscopy procedures may not perform any examination or procedure not listed in the physician-performed microscopy procedure category or the waived test category until it has requested and HHS has issued to it a registration certificate that covers the additional examinations or procedures requested by the laboratory. The laboratory may continue to perform procedures that are covered by the certificate for physician-performed microscopy procedures already issued to the laboratory. The registration certificate is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. After HHS or its designee determines compliance, HHS issues a certificate that includes the additional specialties or subspecialties for which compliance has been determined.

(3) A laboratory possessing a certificate must notify HHS or its designee within 6 months of any changes in methodologies for any test procedure or examination it performs and any ad-

ditions or deletions of tests or examinations performed. If the laboratory adds testing in a specialty or subspecialty not listed on its certificate, HHS or its designee will determine compliance. After HHS or its designee determines compliance, a revised certificate is issued that includes the additional specialties or subspecialties for which compliance has been determined.

(4) A laboratory possessing a certificate of accreditation must notify its approved accreditation organization within 6 months of any changes in methodologies for any test procedure or examination it performs or any additions or deletions of tests or examinations performed so that appropriate actions can be taken by the accreditation organization and a revised certificate can be issued when appropriate.

(b) HHS may suspend, revoke, or limit a laboratory's registration certificate and may impose certain alternative sanctions for failure to comply with the notice requirements of this section. HHS provides the laboratory with a statement of grounds on which the sanctions are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for an appeal, in accordance with the procedures set forth in subpart R of this part. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments may be suspended or cancelled during the pendency of any hearing for failure to comply with the requirements of this part.

[58 FR 5226, Jan. 19, 1993]

§493.634 Notification of changes.

(a) A laboratory must notify HHS or its designee within 30 days if changes occur in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Supervisor (only applicable for a high complexity laboratory).

(b) HHS may suspend, revoke, or limit a laboratory's registration certificate, certificate for physician-performed microscopy procedures, certificate of waiver, or certificate of accreditation or may impose certain alternative sanctions for failure to comply with the notice requirements of this section. In such an event, HHS provides the laboratory with a statement of grounds on which the sanction is based and an opportunity for an appeal, in accordance with the procedures set forth in subpart R of this part. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. (In addition, for laboratories participating in Medicare or Medicaid, payments may be suspended or cancelled during the pendency of any hearing for failure to comply with the notice requirements.)

(c) If a revised certificate is necessary because of the changes identified in paragraph (a) of this section, the laboratory must pay the fee for a revised certificate as required in §493.639.

[58 FR 5212, Jan. 19, 1993, as amended at 58 FR 5227, Jan. 19, 1993]

§493.638 Registration certificate and certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or a certificate, as applicable. Laboratories must also pay a fee to reapply for a certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or a certificate. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act. For registration certificates and certificates, this includes evaluating and monitoring proficiency testing programs and accreditation bodies and implementing, monitoring, and enforcing compliance with section 353 of the PHS Act and collection of fees and issuing registration certificates and certificates. For a certificate of waiver, this includes the cost of issuing the certificate, collection of fees and the administrative costs associated with evaluating tests to determine if a certificate of waiver should be issued. For a certificate for physician-performed microscopy procedures, this includes the cost of issuing the certificate, collection of fees, non-routine inspections, data management, and the administrative costs associated with evaluating tests to determine if a certificate for physician-performed microscopy procedures should be issued, and other direct administrative costs. For a certificate of accreditation this includes the cost of issuing the certificate of accreditation, collection of fees and the administrative costs associated with evaluating programs of accrediting bodies and the costs to conduct sample validation surveys of accredited laboratories.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on schedules or ranges of laboratory test volume (excluding tests performed for quality control, quality assurance, and proficiency testing purposes) and scope of specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in §493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in §493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or certificate is the amount in effect at the time the application is received. Upon receipt of an application for a registration certificate, certificate for physician-performed microscopy procedures, certificate of waiver, certificate of accreditation, or certificate, HHS or its designee notifies the laboratory of the amount of the required fee. The amount of the fee is based on whether the laboratory is considered small, medium, or large (based on the volume and scope of testing performed by the laboratory).

[58 FR 5227, Jan. 19, 1993]

§493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the circumstances specified in paragraphs (b)(1) and (2) of this section. The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory. (An additional fee is also required under §493.643(d) if it is necessary to determine compliance with additional requirements. If a laboratory with a certificate of waiver wishes to perform tests not listed in the waived test category or the physician-performed microscopy procedure category, it must, as set forth in §493.626, pay an additional fee for a registration certificate to cover the new testing. If a laboratory with a certificate for physician-performed microscopy procedures wishes to perform tests not listed in the physician-performed microscopy procedure category or the waived test category, it must, as set forth in §493.626, pay an additional fee for a registration certificate to cover the new testing.)

(1) If after a certificate, certificate of accreditation, certificate for physician-performed microscopy procedures, or certificate of waiver is issued, a laboratory changes its name, location, or its director;

(2) If after a certificate is issued, a laboratory deletes services or wishes to add services and requests that its certificate be changed.

[57 FR 7213, Feb. 28, 1992, as amended at 58 FR 5227, Jan. 19, 1993]

§493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under §493.638, a laboratory regulated subject to the requirements of this part must pay a fee to cover the cost of determining program compliance, unless it is issued a certificate for physician-performed microscopy procedures, certificate of waiver or a certificate of accreditation.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D.* The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Cytogenetics.

(d) *Additional fees.* (1) If after a certificate, certificate for physician-performed microscopy procedures, or certificate of waiver is issued a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions or conduct a hearing, HHS assesses the laboratory, other than a CLIA-exempt laboratory, a fee to cover the cost of these activities. States whose laboratory licensure programs are approved by HCFA are assessed fees for annual random validation inspections, complaint surveys in which the complaints are substantiated, and the cost of the prorata share of general overhead to develop and implement CLIA. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 58 FR 5227, Jan. 19, 1993]

§493.645 Fee(s) applicable to accredited laboratories/approved State licensure programs.

(a) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If, in the case of a laboratory that has been issued a certificate of accreditation, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the cost of these activities are not imposed upon the laboratory. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

(3) If, in the case of a laboratory subject to an inspection under paragraph (a), followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based

on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(b) *Approved State licensure programs.* State licensure programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, State-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's State-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

§493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. Registration certificates, certificates for physician-performed microscopy procedures, certificates of waiver, certificates of accreditation, or certificates are not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination surveys is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required, or if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of certificates of waiver, certificates for physician-performed microscopy tests, certificates of accreditation, or certificates and determining program compliance. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

Subpart G—(Reserved)

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

SOURCE: 57 FR 7146, Feb. 28, 1992, unless otherwise noted.

§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.

(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

(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 of its testing procedures, in accordance with §493.1709.

(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

(4) Authorize the proficiency testing program to release to HHS all data required to—

(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 ex-

amining 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.

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

(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.

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis 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.

(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.

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

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in subpart R of this part.

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

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended 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 cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation 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

cancellation, limitation or suspension of the CLIA certificate.

[58 FR 5228, Jan. 19, 1993]

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE OR HIGH COMPLEXITY, OR BOTH

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.827 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.829 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.831 Standard; Virology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated

with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1994. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, HCFA will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for

two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.863 Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Subpart I—Proficiency Testing Programs for Tests of Moderate or High Complexity, or Both

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

§493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to reg-

ulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§493.903 Administrative responsibilities.

The proficiency testing program must—

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by HCFA for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within *15* working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§493.901 through 493.959 for approval of the proficiency testing program, HCFA will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§493.911 through 493.919.

§493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of

organisms that might be included in an approved program over time are—

Anaerobes:
Bacteroides fragilis group
Clostridium perfringens
Peptostreptococcus anaerobius
Enterobacteriaceae
Citrobacter freundii
Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Salmonella typhimurium
Serratia marcescens
Shigella sonnei
Yersinia enterocolitica
Gram-positive bacilli:
Listeria monocytogenes
Corynebacterium species CDC Group JK
Gram-positive cocci:
Staphylococcus aureus
Streptococcus Group A
Streptococcus Group B
Streptococcus Group D (S. bovis and enterococcus)
Streptococcus pneumoniae
Gram-negative cocci:
Branhamella catarrhalis
Neisseria gonorrhoeae
Neisseria meningitidis
Miscellaneous Gram-negative bacteria:
Campylobacter jejuni
Haemophilis influenza, Type B
Pseudomonas aeruginosa

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be 1/(1+1)×100=50 percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§493.911(c) (1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an *Enterobacteriaceae*, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be 2/3×100=67 percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen test is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section kbased on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are five types of laboratories for proficiency testing purposes:1

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis*, but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;

(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and

(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium sculgai
Group III
Mycobacterium avium-intracellulare

Mycobacterium terrae
Group IV
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c) (1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain, for isolation and identification, and for antimycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $1/(1+1)\times100=50$ percent

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in §493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $\frac{2}{3}\times100=67$ percent.

(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporum sp.
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis[1]
Zygomycetes sp.

NOTE: [1] Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $1/(1+1)\times100=50$ percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4), or both, of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§493.917 Parasitology.

(a) *Types of services offered by laboratories.* In parasitology there are two

types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be 1/(1+1)×100=50 percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

§493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c) (1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be 1/(1+1)×100=50 percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of

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correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

§493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§493.923 and 493.927.

§493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b) (1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ±1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

Alpha-1 antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker).	Target value ±3 SD.
Antinuclear antibody	Target value +/−2 dilutions or positive or negative.
Antistreptolysin O	Target value +/−2 dilution or positive or negative.
Anti-Human Immunodeficiency virus.	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value +/−25%.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value +/−2 dilutions or positive or negative.
Rheumatoid factor	Target value +/−2 dilutions or positive or negative.
Rubella	Target value +/−2 dilutions or immune or nonimmune or positive or negative

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§493.931 through 493.939.

§493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be pro-

vided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT)	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT).	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or +/−8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein.	Target value ±30%
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use.	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH)	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ± 30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test
Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more refere laboratories or 90 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value +/−25%.
Free Thyroxine	Target value +/−3 SD.
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value +/−3 SD positive or negative.
T3 Uptake	Target value +/−3 SD
Triiodothyronine	Target value +/−3 SD
Thyroid-stimulating hormone	Target value +/−3 SD.
Thyroxine	Target value +/−20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure

Alcohol (blood)	Phenytoin
Blood lead	Primidone
Carbamazepine	Procainamide (and metabolite)
Digoxin	Quinidine
Ethosuximide	Theophylline
Gentamicin	Tobramycin
Lithium	Valproic Acid
Phenobarbital	

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target Value ± 25%.
Blood lead	Target Value ± 10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ± 25%.
Digoxin	Target Value ± 20% or ± 0.2 ng/mL (greater).
Ethosuximide	Target Value ± 20%.
Gentamicin	Target Value ± 25%.
Lithium	Target Value ± 0.3 mmol/L or ± 20% (greater).
Phenobarbital	Target Value ± 20%
Phenytoin	Target Value ± 25%.
Primidone	Target Value ± 25%.
Procainamide (and metabolite).	Target Value ± 25%.
Quinidine	Target Value ± 25%.
Tobramycin	Target Value ± 25%.
Theophylline	Target Value ± 25%.
Valproic Acid	Target Value ± 25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	90% or greater consensus on identification.
White blood cell differential	Target +/− 3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target +/− 6%.
Hematocrit (Excluding spun hematocrits).	Target +/− 6%
Hemoglobin	Target +/− 7%.
Leukocyte count	Target +/− 15%.
Platelet count	Target +/− 25%.
Fibrinogen	Target +/− 20%.
Partial thromboplastin time	Target +/− 15%.
Prothrombin time	Target +/− 15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §493.1257. If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in §493.855.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under §493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3) (i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under §493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is

weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp. or *Herpes simplex* virus). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion—Includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN–1.
D	High Grade Lesion and Carcinoma—Includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN–2 and severe dysplasia/carcinoma in-situ/CIN–3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (−5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is "high grade squamous intraepithelial lesion" (category "D" on the scoring system chart) and an examinee calls it "normal or negative" (category "B" on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (−5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under §493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	0	0
B	5	10	0	0
C	5	0	10	5
D	0	−5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	−5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (−10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under §493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	0	0
B	2.5	5	0	0
C	2.5	0	5	2.5
D	0	−10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	2.5	2.5

Examinee's response:	A	B	C	D
B	2.5	5	2.5	2.5
C	2.5	0	5	5
D	0	−10	5	5

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure
ABO group (excluding subgroups)
D (Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Total number of challenges for the analyte}} = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Total number of all challenges}} = \text{Testing event score}$$

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

SOURCE: 57 FR 7162, Feb. 28, 1992, unless otherwise noted.

§493.1101 Condition: Patient test management; moderate or high complexity testing, or both.

Each laboratory performing moderate or high complexity testing, or both, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards of this subpart as they apply to the testing performed.

§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; conditions for specimen transportation; and specimen processing. 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.

(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.

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

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§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 requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization. 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—

(a) The patient's name or other unique identifier;

(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;

(c) The test(s) to be performed;

(d) The date of specimen collection;

(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

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

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§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, in-

cluding, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing 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). The record system must provide documentation of information specified in §493.1105 (a) through (f) and include—

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

(b) The date and time of specimen receipt into the laboratory;

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

(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.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports and transfusion records must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing 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). For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.

(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.

(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.

(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with §493.1213, as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§493.1111 Standard; Referral of specimens.

A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

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

SOURCE: 57 FR 7163, Feb. 28, 1992, unless otherwise noted.

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

(a) *Applicability of subpart K of this part.* Subpart K is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§493.1201 through 493.1285 unless—

(1) An alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement,

Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b)

or

(2) HHS approves an equivalent procedure that is specified in Appendix C of the State Operations Manual (HCFA Pub. 7).

(b) 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. 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 certain CLIA requirements for quality control or HHS 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.

[58 FR 5230, Jan. 19, 1993]

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

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), or 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 but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(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;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures or check calibration at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing;

(5) Perform and document applicable specialty and subspecialty control procedures as specified under §493.1223;

(6) Perform and document that remedial action has been taken when problems or errors are identified as specified in §493.1219; and

(7) Maintain records of all quality control activities for two years. Quality control records for immunohematology and blood and blood products must be maintained as specified in §493.1221.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994.

For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it:

(a) Meets all applicable quality control requirements specified in this subpart when using a standardized method, a method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), a manufacturer's product modified by the laboratory, or a device (instrument, kit or test system) not cleared by the FDA as meeting certain CLIA quality control requirements; or

(b) Follows manufacturer's instructions when using a device (instrument, kit, or test system) cleared by the FDA as meeting the CLIA requirements for quality control located at §§493.1215, 493.1217, and 493.1223, and applicable parts of §§493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with the requirements of §§493.1204, 493.1213, 493.1219, and 493.1221 and those parts of §§493.1205, 493.1211, and 493.1218 that are unique to the laboratory facility and cannot be met by following manufacturer's instructions.

[58 FR 5230, Jan. 19, 1993]

§493.1204 Standard; Facilities.

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

(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.

(b) Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical and electrical hazards and biohazardous materials.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§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.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each

test method as determined under §493.1213.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.

(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.

(1) These conditions include, if applicable—

(i) Water quality;

(ii) Temperature;

(iii) Humidity; and

(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(2) Remedial actions taken to correct conditions that fail to meet the criteria specified in paragraph (c)(1) of this section must be documented.

(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;

(2) Recommended storage requirements;

(3) Preparation and expiration date; and

(4) Other pertinent information required for proper use.

(e) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that—

(1) Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality. The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and

(2) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§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.

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

(1) Requirements for specimen collection and processing, and criteria for specimen rejection;

(2) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

(5) Calibration and calibration verification procedures;

(6) The reportable range for patient test results as established or verified in §493.1213;

(7) Control procedures;

(8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(9) Limitations in methodologies, including interfering substances;

(10) Reference range (normal values);

(11) Imminent life-threatening laboratory results or "panic values";

(12) Pertinent literature references;

(13) Appropriate criteria for specimen storage and preservation to ensure

specimen integrity until testing is completed;

(14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;

(15) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.

(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.

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

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

(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.

§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) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) cleared by the FDA as meeting certain CLIA requirements for 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) Each laboratory that introduces a new method or device as specified in either §493.1202(a) or (b), or §493.1203(a), must, prior to reporting patient test results—

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

(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.

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

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§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.

(a) *Maintenance of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting certain CLIA requirements for 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 methods or devices, as specified in either §493.1202(a) or (b) or §493.1203(a), 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;

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

(iii) Document all maintenance performed.

(b) *Function checks of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting certain CLIA requirements for 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 methods or devices, as specified in either §493.1202 (a) or (b) or §493.1203(a), 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;

(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

(iii) Document all function checks performed.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5231, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1217 Standard; Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test rests. Calibration is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range of patient test results is the range of test result values over which the laboratory can establish or verify the accuracy of the instrument, kit or test system measurement response. Calibration and calibration verification must be performed and documented as required in this section unless otherwise specified in §§493.1223 through 493.1285.

(a) For laboratory test procedures that are performed using instruments, kits, or test systems that have been cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.

(b) For each method or device, as specified in either §493.1202 (a) or (b) or §493.1203(a), the laboratory must—

(1) Perform calibration procedures—

(i) At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer; and

(ii) In accordance with criteria established by the laboratory, as required under §493.1213(b)(2)(i)—

(A) Including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and

(B) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(iii) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and

(2) Perform calibration verification procedures—

(i) In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified in paragraph (b)(2)(ii) of this section; or

(ii) In accordance with criteria established by the laboratory—

(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification;

(B) Using calibration materials appropriate for—

(*1*) The methodology and, if possible, traceable to a reference method or reference material of known value; and

(*2*) Verifying the laboratory's established reportable range of patient test results, which must include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and

(C) At least once every six months and whenever any of the following occur:

(*1*) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes;

NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number.

(*2*) There is major preventive maintenance or replacement of critical parts that may influence test performance;

(*3*) Controls reflect an unusual trend or shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or

(*4*) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in paragraphs (b)(2)(ii)(C) (*1*), (*2*), or (*3*) of this section; and

(3) Document all calibration and calibration verification procedures performed.

[58 FR 5231, Jan. 19, 1993]

§493.1218 Standard; Control procedures.

Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this section unless otherwise specified in §§493.1223 through 493.1285 of this subpart.

(a) For each device cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for control procedures. In addition, the laboratory must meet the requirements under paragraphs (c) through (e) of this section and, as applicable, paragraph (f) of this section.

(b) For each device, as specified in either §493.1202 (a) or (b) or §493.1203(a), the laboratory must evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer. For each procedure, the laboratory must monitor test performance using calibration materials or control materials or a combination thereof.

(1) For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.

(2) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in §493.1218(b), but not less frequently than once each run of patient specimens.

(3) For electrophoretic determinations—

(i) At least one control sample must be used in each electrophoretic cell; and

(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.

(4) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism.

(5) If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results.

(c) Control samples must be tested in the same manner as patient specimens.

(d) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing.

(1) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory.

(2) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.

(e) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.

(f) *Reagent and supply checks.* (1) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

(2) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(3) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this subpart).

(4) The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile, and sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

NOTE: A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§493.1219 Standard; Remedial actions.

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory's established performance specifications, as determined in

§493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and

(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;

(c) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and

(d) Errors in the reported patient test results are detected. The laboratory must—

(1) Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports promptly to the authorized person ordering the test or the individual utilizing the test results; and

(3) Maintain exact duplicates of the original report as well as the corrected report for two years.

§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).

§493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, 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. Except as specified in §493.1202(c), the laboratory must meet the applicable general requirements specified in §§493.1201 through 493.1221. In addition, the laboratory must meet the applicable requirements of §§493.1225 through 493.1285 unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). Failure to meet any of the applicable conditions in §§493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.

[58 FR 5232, Jan. 19, 1993]

§493.1225 Condition: Microbiology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and in §§493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

§493.1227 Condition: Bacteriology.

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and

(3) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

§493.1229 Condition: Mycobacteriology.

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates, the laboratory must check the procedure each week of use with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

§493.1231 Condition: Mycology.

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

§493.1233 Condition: Parasitology.

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a

fecal sample control that will demonstrate staining characteristics.

§493.1235 Condition: Virology.

To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

§493.1237 Condition: Diagnostic immunology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1239 through 493.1241 of this subpart for the subspecialtics for which it is certified under the specialty of diagnostic immunology.

§493.1239 Condition: Syphilis serology.

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

§493.1241 Condition: General immunology.

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

§493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§493.1245 Condition: Routine chemistry.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§493.1247 Condition: Endocrinology.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§493.1249 Condition: Toxicology.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—

(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

§493.1251 Condition: Urinalysis.

Except for those tests categorized a waived, to meet the quality control re quirements for urinalysis, the labora tory must comply with the applicabl requirements in §§493.1201 throug 493.1221.

[58 FR 5232, Jan. 19, 1993]

§493.1253 Condition: Hematology.

To meet the quality control require ments for hematology, the laboratory must comply with the applicable re quirements in §§493.1201 throug 493.1221 of this subpart and with para graphs (a) through (d) of this section All quality control activities must b documented.

(a) Cell counts performed manually using a hemocytometer must be teste in duplicate. One control is required fo each eight hours of operation.

(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels o controls each eight hours of operation

(c) For all non-manual coagulatio testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(d) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(2) Patient and control specimens must be tested in duplicate.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993]

§493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology. All quality control activities must be documented.

§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.

(a) The laboratory must assure that—

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

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

(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;

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

(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(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 (one patient per slide, 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 negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissues patholoty 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).);

(2) For purposes of workload calculations, each slide preparation (gynecologic and 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.

(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;

(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;

(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—

$$\frac{\text{No. of hours examining slides} \times 100}{8}$$

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;

(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;

(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

(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.

(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.

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

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

(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).

(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;

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

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

(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.

(3) For each patient with a current high grade intraepithelial lesion or above (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.

(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 rescreener 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.

(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.

(e) The laboratory report must—

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

(2) Contain narrative descriptive nomenclature for all results.

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

(g) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing pro

grams, 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.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5232, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1259 Condition: Histopathology.

To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§493.1449(b) or 493.1449(l)(1) of this part. In addition, an individual who meets the requirements of §§493.1449(b), 493.1449(l)(1) or 493.1449(l)(2), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(l)(3) may examine and provide reports for ophthalmic pathology; an individual meeting the requirements of §§493.1449(b) or 493.1449(m) may examine and provide reports for oral pathology specimens.

(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of the section. If a computer report is generated with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

§493.1261 Condition: Oral pathology.

To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 and §493.1259 of this subpart. All quality control activities must be documented.

§493.1263 Condition: Radiobioassay.

To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

§493.1265 Condition: Histocompatibility.

In addition to meeting the applicable requirements for general quality control in §§493.1201 through 493.1221, for quality control for general immunology in §493.1241 of this subpart and for immunohematology in §493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) For renal allotransplantation, the laboratory must meet the following requirements:

(1) The laboratory must have available and follow criteria for—

(i) Selecting appropriate patient serum samples for crossmatching;

(ii) The technique used in crossmatching;

(iii) Preparation of donor lymphocytes for crossmatching; and

(iv) Reporting crossmatch results;

(2) The laboratory must—

(i) Have available results of final crossmatches before an organ or tissue is transplanted; and

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing,

for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(3) The laboratory's storage and maintenance of both recipient sera and reagents must—

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Ensure that all specimens are properly identified and easily retrievable;

(4) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;

(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(6) The laboratory must—

(i) HLA type all potential transplant recipients;

(ii) Type cells from organ donors referred to the laboratory; and

(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;

(7) The laboratory must have available and follow criteria for—

(i) The preparation of lymphocytes for HLA-A, B and DR typing;

(ii) Selecting typing reagents, whether locally or commercially prepared;

(iii) The assignment of HLA antigens; and

(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A,B and DR specificities for which reagents are readily available;

(8) The laboratory must—

(i) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected;

(A) At the time of the recipient's initial HLA typing; and

(B) Thereafter, following sensitizing events and upon request; and

(ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—

(A) If the laboratory does not us commercial panels, it must maintain list of individuals for fresh panel blee ing; and

(B) If the laboratory uses frozen pa els, it must have a suitable storage sy tem;

(9) The laboratory must check—

(i) Each typing tray using—

(A) Positive control sera;

(B) Negative control sera; and

(C) Positive controls for specific cel types when applicable (i.e., T cells, cells, and monocytes); and

(ii) Each compatibility test (i.e mixed lymphocyte culture homozygous typing cells or DNA analy sis) and typing for disease-associate antigens using controls to monitor th test components and each phase of th test system to ensure an acceptabl performance level;

(10) Compatibility testing for cel lularly-defined antigens must utiliz techniques such as the mixed lym phocyte culture test, homozygous typ ing cells or DNA analysis;

(11) If the laboratory reports the re cipient's or donor's, or both, ABO bloo group and D(Rho) typing, the testin must be performed in accordance wit §493.1269 of this subpart;

(12) If the laboratory utilize immunologic reagents (such as anti bodies or complement) to remove con taminating cells during the isolation o lymphocytes or lymphocyte subsets the efficacy of the methods must b verified with appropriate quality con trol procedures;

(13) At least once each month, th laboratory must have each individua performing tests evaluate a previously tested specimen as an unknown to ver ify his or her ability to reproduce tes results. Records of the results for eac individual must be maintained; and

(14) The laboratory must participat in at least one national or regional cel exchange program, if available, or de velop an exchange system with another laboratory in order to validate inter laboratory reproducibility.

(b) If the laboratory performs histocompatibility testing for—

(1) Transfusions and other non-renal transplantation, excluding bone mar row and living transplants, all the re quirements specified in this section, as

applicable, except for the performance of mixed lymphocyte cultures, must be met;

(2) Bone marrow transplantation, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and

(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.

(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.

(d) For laboratories performing organ donor HIV testing the requirements of §493.1241 of this subpart for the transfusion of blood and blood products must be met.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§493.1267 Condition: Clinical cytogenetics.

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

§493.1269 Condition: Immunohematology.

To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 *et seq.*

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

§493.1271 Condition: Transfusion services and bloodbanking.

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in §§493.1273 through 493.1285.

[58 FR 5233, Jan. 19, 1993]

§493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.

In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must meet the applicable requirements of part 493.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.

§493.1275 Standard; Blood and blood products storage facilities.

(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(2) Inspections of the alarm system must be documented.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

§493.1277 Standard; Arrangement for services.

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

§493.1279 Standard; Provision of testing.

There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with §493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of §§493.1449(b) or 493.1449(q).

§493.1283 Standard; Retention of samples of transfused blood.

According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

§493.1285 Standard; Investigation of transfusion reactions.

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in trans-

fusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

Subpart L—(Reserved)

Subpart M—Personnel for Moderate and High Complexity Testing

SOURCE: 57 FR 7172, Feb. 28, 1992, unless otherwise noted.

§493.1401 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate or high complexity testing, or both.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

§493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.

§493.1405 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

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

(ii) Be certified in anatomic or clinical pathology, or both, 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

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

(ii) Have had laboratory training or experience consisting of:

(A) At least one year directing or supervising non-waived laboratory testing; or

(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or

(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or

(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(1) Be a physician certified in anatomical or clinical pathology (or both) 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;

(2) Be a physician who:

(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

NOTE: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before Janu-

ary 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

[58 FR 5233, Jan. 19, 1993]

§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.

(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.

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

(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;

(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;

(3) Ensure that—

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

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

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

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

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

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

(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

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

(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;

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

(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;

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

(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;

(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;

(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;

(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;

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

(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.

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

§493.1411 Standard; Technical consultant qualifications.

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

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must—

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

(ii) Be certified in anatomic or clinical pathology, or both, 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

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

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated

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specialty or subspecialty areas of service for which the technical consultant is responsible.

NOTE: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1413 Standard; Technical consultant responsibilities.

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

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

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

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

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

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters 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;

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

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

(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;

(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;

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

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

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

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

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for moderate 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.

§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

§493.1417 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1405(b) (1), (2), or (3)(i); or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

§493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(4)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

Laboratories Performing High Complexity Testing

§493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

§493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

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

(ii) Be certified in anatomic or clinical pathology, or both, 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

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

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and—

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by HHS; or

(ii) Until September 1, 1994 must have at least—

(A) Two years of laboratory training or experience, or both;

(B) Two years of experience directing or supervising high complexity testing; and

(C) On September 1, 1994, individuals must meet the qualifications specified in paragraph (b)(3)(i) of this section;

(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§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.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, 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.

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

(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;

(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;

(3) Ensure that—

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

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

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

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

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

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

(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

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

(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;

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

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

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

(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;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under §493.1489(b)(4);

(11) 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;

(12) 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;

(13) 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;

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

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.

§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.

(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

(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.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

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

(ii) Be certified in clinical 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

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

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must—

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

(ii) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high com-

plexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must—

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

(ii) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(1)(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) Be certified in clinical 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

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

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—

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

(ii) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must—

(1)(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) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or

clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must—

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

(ii) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must—

(1)(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) Be certified in clinical 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

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

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(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.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i) (A) 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

(B) 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;

(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

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

(B) Meet one of the following requirements:

(*1*) 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

(*2*) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*3*) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

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

(B) Must meet one of the following requirements:

(*1*) 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

(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(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) 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

(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(3) An individual qualified under §493.1449(b) or paragraph (m) (1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must—

(1)(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) Be certified in clinical 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

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

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

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

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility;

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

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

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must—

(1)(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) Be certified in clinical 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

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

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

NOTE: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§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.

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

(b) The technical supervisor is responsible for—

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

(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;

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

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters 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;

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

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

(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;

(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;

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

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

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

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

(vi) Assessment of problem solving skills; and

(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.

(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;

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

(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

(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.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

§493.1455 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

§493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

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

(b) The general supervisor must be qualified as a—

(1) Laboratory director under §493.1443; or

(2) Technical supervisor under §493.1449.

(c) If the requirements of paragraphs (b)(1) or (b)(2) of this section are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2) (i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution; and

(ii) Have at least two years of laboratory training or experience, or both, in high complexity testing; or

(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.

(ii) *Exception.* An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994."

(d) For blood gas analysis, the individual providing general supervision must—

(1) Be qualified under §§493.1461(b) (1) or (2), or 493.1461(c); or

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and oph-

thalmic pathology because all tests and examinations, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1462 General supervisor qualifications on or before February 28, 1992.

To qualify as a general supervisor under §493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and

(b) The laboratory supervisor—

(1) Who qualifies as a laboratory director under §493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or

(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or

(4)(i) Is qualified as a laboratory technologist under §493.1491; and

(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or

(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

[58 FR 39155, July 22, 1993]

§493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor—(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under §493.1489;

(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(4); and

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

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

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

(c) *Exception.* For individuals qualified under §493.1489(b)(4), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of §493.1469 of this subpart, and provides supervision in accordance with §493.1471 of this subpart.

§493.1469 Standard: Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

(a) Be qualified as a technical supervisor under §493.1449 (b) or (k); or

(b) (1) Be qualified as a cytotechnologist under §493.1483; and

(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

§493.1471 Standard: Cytology general supervisor responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under §493.1469.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The cytology general supervisor must—

(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1257(d));

(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(4) Document the number of hours spent examining slides in each 24-hour period.

§493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in §493.1483 to perform the functions specified in §493.1485.

§493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of §493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 6 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under §493.1449(b) or (k)(1), and before January 1, 1969, must have—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1); and

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in §493.1257(d));

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(c) The number of hours spent examining slides in each 24-hour period.

§493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.

§493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution;

(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(4) Until September 1, 1997—

(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality sample values prior to reporting patient test results.

On September 1, 1997, must meet the qualifications of §493.1489(b) (1) or (2);

(5) For blood gas analysis, the individual must—

(i) Be qualified under §493.1489(b) (1), (2), (3), or (4);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(6) For histopathology, tissue examinations must be performed by an individual who meets the qualifications of §493.1449 (b) or (l) of this subpart.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993]

§493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under §493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must—

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(*1*) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(*2*) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(*1*) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(*2*) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(*3*) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(4), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) *Exception.* For individuals qualified under §493.1489(b)(4), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993]

Subparts N–O—(Reserved)

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

SOURCE: 57 FR 7183, Feb. 28, 1992, unless otherwise noted.

§493.1701 Condition: Quality assurance; moderate or high complexity testing, or both.

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 test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

[57 FR 7183, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993]

§493.1703 Standard; Patient test management assessment.

The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under subpart J, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

§493.1705 Standard; Quality control assessment.

The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under §493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for—

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

§493.1707 Standard; Proficiency testing assessment.

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

§493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart I of this part, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

[58 FR 5236, Jan. 19, 1993]

§493.1711 Standard; Relationship of patient information to patient test results.

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

§493.1713 Standard; Personnel assessment.

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

§493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and

the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve the problems and minimize communication breakdowns.

[58 FR 5236, Jan. 19, 1993]

§493.1717 Standard; Complaint investigations.

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

§493.1719 Standard; Quality assurance review with staff.

The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrences.

§493.1721 Standard; Quality assurance records.

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of 2 years.

[58 FR 5236, Jan. 19, 1993]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.

§493.1775 Condition: Inspection of laboratories issued a certificate of waiver.

(a) HHS or its designee may conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to assess compliance with the applicable requirements of part 493.

(b) The laboratory may be required, as part of this inspection, to—

(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(2) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and

(iii) Testing and reporting areas.

(3) Permit employees to be observed performing tests, data analysis and reporting;

(4) Permit HHS or its designee upon request to review all information and data necessary to—

(i) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;

(ii) Evaluate complaints from the public;

(iii) Determine whether the laboratory is performing tests not listed in §493.15; and

(iv) Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.15; and

(5) Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.

(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493.

(d) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke laboratory's CLIA certificate of waiver in accordance with subpart R of this part.

[57 FR 7184, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993]

§493.1776 Condition: Inspection of physician-performed microscopy procedures.

(a) HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to—(1) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;

(2) Evaluate complaints from the public;

(3) Determine whether the laboratory is performing tests in addition to procedures listed in §493.16 that are not included on the laboratory's certificate; and

(4) Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.16.

Applicable requirements for the purpose of this section are located in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; and subpart P, quality assurance of this part, as well as §493.16(e).

(b) The laboratory may be required, as part of this inspection, to—(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493 as noted in §493.16 (e) of this part;

(2) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen processing areas;

(ii) Storage facilities for specimens, requests, supplies, records, and reports; and

(iii) Testing and reporting areas.

(3) Permit physicians to be observed performing tests and reporting results;

(4) Permit HHS or its designee upon request to review all information and data necessary to—

(i) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;

(ii) Evaluate complaints from the public;

(iii) Determine whether the laboratory is performing tests in addition to procedures listed in §493.16 that are not included on the laboratory's certificate;

(iv) Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.16; and

(5) Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.

(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493.

(d) Failure to permit an inspection under this subsection may result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R of this part.

[58 FR 5236, Jan. 19, 1993; 58 FR 39156, July 22, 1993]

§493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver, certificate for physician-performed microscopy procedures, or a certificate of accreditation.

(a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate.

(b) The laboratory may be required, as part of this inspection, to—

(1) Test samples (including proficiency testing samples) or perform procedures as HHS or its designee requires;

(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(3) Permit employees to be observed performing tests (including proficiency testing specimens), data analysis and reporting;

(4) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and

(iii) Testing and reporting areas; and

(5) Provide copies to HHS or its designee of all records and data it requires.

(c) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) The laboratory must retain—

(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;

(2) Pathology test reports for at least 10 years after the date of reporting as required in §493.1109; and

(3) All other laboratory records for at least 2 years.

(e) The laboratory must provide upon request all information and data needed by HHS or its designee to make a determination of the laboratory's compliance with the applicable requirements of part 493.

(f) HHS or its designee may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results.

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R.

[57 FR 7184, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§493.1780 Condition: Inspection of accredited and CLIA-exempt laboratories.

(a) HHS or its designee may conduct unannounced or announced, random validation inspections of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) HHS or its designee will conduct unannounced complaint inspections of an accredited or CLIA-exempt laboratory at any time during its hours of operation upon receiving a complaint about that laboratory.

(c) The laboratory may be required, as part of either of the above inspections, to—

(1) Test samples (including proficiency testing samples) or perform procedures as required by HHS or its designee;

(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(3) Permit employees to be observed performing tests (including proficiency testing specimens), and performing data analysis and reporting activities; and

(4) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens reagents, supplies, records, and reports; and

(iii) Testing and reporting areas; and

(5) Provide copies to HHS of all records and data required under these requirements.

(d) The laboratory must have all records and data accessible and retrievable within a reasonable time during the inspection.

(e) The laboratory must retain—

(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;

(2) Records of blood and blood product testing for a period of not less than 5 years after processing records have been completed, or 6 months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d);

(3) Pathology test reports for at least 10 years after the date of reporting, as required in §493.1109; and

(4) All other laboratory records for at least 2 years unless otherwise specified in part 493.

(f) The laboratory must provide, upon request, all information and data needed by HHS to make a determination of compliance or noncompliance with the applicable requirements of part 493.

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's Medicare and Medicaid approval for payment; and suspension of or action to revoke the laboratory's CLIA certificate of accreditation in accordance with subpart R of this part.

[57 FR 7184, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 58 FR 39156, July 22, 1993]

Subpart R—Enforcement Procedures

SOURCE: 57 FR 7237, Feb. 28, 1992, unless otherwise noted.

§493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act and

(2) The appeal rights of laboratories on which HCFA imposes sanctions.

§493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) HCFA's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) HCFA imposes one ore more of the alternative or principal sanctions specified in §§493.1806 and 493.1807 when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.* (1) HCFA may impose alternative sanctions in lieu of, or in addition to principal sanctions. (HCFA does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) HCFA may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in §493.1844.

(d) *Choice of sanction: Factors considered.* HCFA bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by HCFA, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other HCFA agents, and to HCFA.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that HCFA hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* HCFA may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in §493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1806 Available sanctions: All laboratories.

(a) *Applicability.* HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at §493.1832.

(2) State onsite monitoring as set forth at §493.1836.

(3) Civil money penalty, as set forth at §493.1834.

(d) *Civil suit.* HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

§493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1810 Imposition and lifting of alternative sanctions.

(a) *Notice of noncompliance and of proposed sanction: Content.* If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction*—(1) *Content.* HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions*—(1) *General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, HCFA's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by HCFA or its agent) that it achieved compliance before the date of

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ–216–FC]

RIN 0938–AG71

CLIA Program; Categorization of Tests and Personnel Modifications

AGENCY: Health Care Financing Administration (HCFA) and Public Health Service (PHS), HHS.

ACTION: Final rule with comment period.

SUMMARY: In this rule we are responding to some of the comments on categorization of tests and personnel requirements received in response to rules published on February 28, 1992 and January 19, 1993. (In a future rule, we will be responding to the remaining comments.) We are revising our regulations to: Allow dentists and midlevel practitioners to perform tests in the "physician-performed" microscopy (PPM) subcategory of moderate complexity procedures (we now call the subcategory "provider-performed"); include three additional tests in PPM; and expand provisions relating to general supervisor and high complexity testing personnel.

DATES: *Effective date:* These regulations are effective April 24, 1995.

Comment date: Comments on the addition of three PPM tests will be considered if we receive them at the appropriate address, as provided under ADDRESSES, no later than 5 p.m. on June 23, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–216–FC, P.O. Box 26676, Baltimore, MD 21207

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,

or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–216–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

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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.

Comment: A number of commenters requested that additional tests be added to PPM. Microscopic tests that were suggested include synovial fluid analysis, qualitative and quantitative semen analysis, nasal smears or sputum for eosinophils or basophils, wet mount examination of prostatic fluid or secretions, stools for leukocytes, scabies examinations, Gram stain, Tzanck preparations, white blood cell counts and leukocyte differentials, microscopic examinations of hair morphology, dark-field examinations and molluscum smears. A number of non-microscopic procedures were also requested, including microbiology cultures, serum glucose and BUN levels, qualitative drug screens, a variety of serologic tests, and miscellaneous tests performed using hand-held or elementary instrumentation.

Other organizations and professionals were opposed to adding tests or criteria to PPM. Two organizations suggested explicit language to limit procedures included in PPM to specific microscopic examinations and exclude any testing that involves automated instrumentation or biochemical reactions.

Response: Tests in PPM are limited to specific microscopic examinations that are moderately complex procedures and meet the criteria for PPM. Most of the tests named by commenters for addition to PPM do not meet these established criteria. However, nasal smear examinations for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility) do meet the criteria for inclusion in PPM. They are all moderate complexity microscopic examinations that are performed during the course of a patient examination. They are performed on labile specimens, require very limited specimen processing and handling, and controls are not available to monitor the entire testing process. Fecal leukocyte examinations and qualitative semen analyses are actually forms of wet mount examinations. The CLIAC recommended that these three examinations be included in PPM, and HHS agrees with CLIAC that these procedures meet the PPM criteria. The other examination that the CLIAC recommended be added to PPM, the wet mount examination of expressed prostatic secretions, is now included in PPM because it meets the clarified definition of wet mounts in § 493.19(c)(1). Tests that the CLIAC reviewed, and recommended not be included in PPM, are the Gram stain, quantitative semen analysis, histodermatology slides, white blood cell (WBC) differential, and polarization of synovial fluid for crystals. These examinations do not meet the criteria for inclusion in the PPM subcategory. The quantitative semen analysis, histodermatology slides, and polarization of synovial fluid for crystals are all high complexity procedures. Although some Gram stains and WBC differentials are categorized as moderate complexity, these examinations do not meet the additional criteria required for inclusion in PPM. They are not performed on labile specimens, and quality control materials are readily available for Gram stains and WBC differentials. Both of these examinations are performed on specimen preparations that must be stained in order to differentiate and identify cellular elements. These staining procedures require multiple, critical steps. Therefore, HHS concurs with the CLIAC recommendations that these tests not be included in the PPM subcategory, and has not added these tests to the list of PPM examinations.

Comment: Several organizations requested that tests relevant to specific medical specialties, including pediatrics, internal medicine, family practice, rheumatology, and infectious disease, be added to PPM for physicians with appropriate training.

Response: The CLIAC considered a proposal by HHS to expand PPM to include additional medical specialty-specific microscopic examinations when performed by physicians with specialty training. The CLIAC recommended that PPM not be expanded to include medical specialty-specific procedures, due to the difficulty in establishing a mechanism to assure adequate training and competency in performing each of these specialized procedures. HHS agrees with this recommendation and we have not added medical specialty-specific procedures to PPM; however, physicians may continue to perform these procedures in accordance with the applicable requirements for the level of complexity in which the test is categorized.

Comment: One organization stated that, in order to contain costs, physicians should be able to perform essential laboratory tests in their offices without restrictions and recommended that a free-standing physician category be established with the range of tests performed in each laboratory based on the physician's specialty, training and experience. The organization indicated that there should be no specific test list; any testing other than cytopathology would be included in this category. Testing could be performed by the physician, or by other personnel under the direction and control of the physician. Quality control and proficiency testing would be required, and laboratories would be subject to on-site inspections if it was suspected that they were not in compliance with the regulations.

Response: The CLIA regulations were developed in an effort to ensure the quality of laboratory services in every testing situation and assure that accurate and reliable testing is available to all patients. To do this, minimum requirements were established for laboratory testing that, in accordance with the law, depend on the complexity of the procedures being performed and are independent of the testing location. As test procedures become more complex, more stringent testing requirements are imposed. PPM contains a unique group of microscopic procedures that are routinely performed in the course of a patient examination. They are tests for which it is difficult to enforce regulatory requirements because biological controls that monitor the entire testing process are not readily available and because the inspection process would interfere with a patient examination. The PPM subcategory was established to exempt physicians (and, as discussed below, mid-level practitioners and dentists are now included) from the requirement for routine inspections if the PPM procedures are the only tests, in addition to waived tests, that they perform. Physicians, mid-level practitioners, and dentists are not prohibited from performing other laboratory procedures in their offices or clinics. However, for procedures that can be regulated through an inspection process, routine inspections are required, since this is one mechanism to assure that the quality of testing is maintained.

Changes to the Regulations

In this regulation, we have moved the PPM subcategory, formerly located at § 493.16, to a new § 493.19.

In the list of PPM procedures now located at § 493.19(c), we are changing the description of wet mounts at § 493.19 (c)(1) to clarify the types of examinations that are included in this procedure. Also, to the list of PPM procedures, we are adding three tests: nasal smears for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

Other Revisions to the Regulations

Currently, PPM procedures are subsumed in the category of moderate complexity, with changes made to moderate complexity testing requirements as needed. To aid readers in finding requirements pertinent to their needs, we have created a discrete subcategory of requirements for PPM procedures, by breaking out the requirements for PPM as necessary.

Currently, a laboratory that meets the requirements to perform high or moderate complexity tests is issued a "certificate". We also have certificates for PPM procedures. For clarity, to distinguish between the generic use of the word certificate and the type of certificate issued to a laboratory that performs tests of moderate or high complexity, or both, we are changing "certificate" (for tests of moderate or high complexity, or both) to "certificate of compliance." This is the certificate that will be issued following the determination of successful compliance with the CLIA regulations for testing that includes moderate and/or high complexity. Where necessary, we make revisions concerning each specific certificate and/or subcategory (including waived tests). We are changing, as required, references to specific certificates to refer to "appropriate" certificates.

We make these technical changes in the following existing sections and headings: §§ 493.2, definition of "certificate" under "CLIA certificate", 493.3(a)(1); 493.5(a)(2) and (c) (formerly 493.10); 493.20(a) and (b); 493.25(c) (formerly 493.25(d)); subpart C heading; 493.43 heading and paragraph (a); 493.45 introductory paragraph and paragraphs (a)(1), (2) and (3) (the last is deleted) and (d) and (f); 493.49; 493.51 heading, introductory paragraph, and paragraphs (b) and (c); 493.55(a); 493.57 introductory paragraph and subparagraph (b)(1)(ii); 493.511(h); 493.521(j); 493.602; 493.638; 493.639(b); 493.643(d); 493.645 heading and paragraph (c) (redesignated from paragraph (a)(2)); 493.646(a); 493.649(a) and (b); subpart H heading; 493.803(a); 493.807 heading; subheading preceding 493.821; subpart I heading; subpart J heading; 493.1101, including the heading; subpart K heading; 493.1201 heading; subpart M heading; subpart P heading; 493.1701, including heading; 493.1777 heading, introductory paragraph and paragraphs (a) and (g); 493.1814(b)(3); 493.1834(b) and (f)(2)(iii); 493.1836(c)(2) and (3); and 493.2001.

B. Personnel

1. Physician-Performed Microscopy Procedures

Comment: Approximately 68 percent of the 2,200 comments received in response to the regulation establishing PPM addressed personnel requirements, especially expansion of the PPM subcategory to include other health care practitioners. The comments were divided between individuals who suggested expansion of PPM to include other health care professionals and those commenters who believed that PPM should be limited to physicians. While national laboratory organizations and individual laboratory professionals commented that PPM should be limited to physicians, professional organizations representing physicians and midlevel health care practitioners stated that PPM should be expanded to include other health care providers. We also received comments requesting that dentists be included in PPM to allow them to perform wet mount examinations as part of their dental evaluations.

Several commenters representing physicians and midlevel health care practitioners included information and responded to questions posed in the preamble to the January 19, 1993, Federal Register rule creating the PPM subcategory. In that publication, we specifically asked commenters to comment on the type of health care professionals who usually perform the PPM tests as part of a physical examination, how often the tests are performed, and the quality, access and cost implications in establishing the PPM subcategory.

The commenters who responded to these questions stated that depending on the type of health care setting, physicians, or quite often nurse practitioners, nurse midwives, or physician assistants, perform physical examinations and the laboratory tests related to these examinations. In some cases, State laws authorize these midlevel practitioners to practice independently. These commenters added that, because of the variety of settings, it is impossible to estimate the percentage of testing done by each group of health professionals. However, they did say that many midlevel practitioners perform patient examinations and certain microscopic tests on a daily basis and in equal or greater numbers than physicians in some places. They also said that midlevel practitioners receive the training needed to perform these tests and the quality of their test results is at least equivalent to testing performed by physicians. Commenters indicated that, in addition to the physicians and the midlevel practitioners listed above emergency personnel, registered nurses, licensed practical nurses, and medical assistants perform PPM tests. Commenters indicated that although the cost of testing might vary, this was not related to who performed the test.

Lastly, the commenters stressed that the quality, cost and access implications of not including midlevel practitioners under the certificate for the PPM subcategory were extensive, especially in rural areas, among low-income populations, and in other areas where there is a shortage of physicians. In some of these settings, midlevel practitioners are the only available health care providers. Excluding these professionals from obtaining a certificate for the PPM subcategory has substantial cost implications. Since laboratories that have a certificate for the PPM subcategory are not subject to fees for routine inspections, the cost of providing services under the PPM certificate is lower than under a certificate of compliance. If facilities cannot afford to provide testing under a certificate of compliance, patient access to health care would be limited.

Response: In considering these comments, we sought the advice of the CLIAC. In an effort to provide an opportunity for public discussion and consideration of these issues, we scheduled two CLIAC meetings on the PPM subcategory. Presentations were made by HHS, and the public was invited to comment and provide information. The CLIAC recommended that individuals and organizations representing practitioners seeking to be included in the PPM subcategory submit documentation concerning the specific course work and the amount of training such individuals receive in the performance of microscopic examinations. Over 100 individuals and organizations responded to the request for information, with many of the commenters providing documentation of specific training curricula in microscopic procedures. The CLIAC asked CDC to evaluate the materials submitted. In reviewing the training programs of nurse midwives, nurse practitioners and physician assistants, CDC concluded that these practitioners, like physicians, perform the procedures currently included in the PPM subcategory in conjunction with patient evaluations, and the training they receive in microscopic examinations is comparable to that of physicians. The CLIAC considered this information and recommended that midlevel practitioners, defined as nur

practitioners, nurse midwives, and physician assistants, be included in the PPM subcategory. The CLIAC suggested that these midlevel practitioners be permitted to perform PPM procedures under the supervision of a physician or to function independently in States that authorize individual practice.

In view of the CLIAC recommendation and the CDC evaluation that nurse midwives, nurse practitioners and physician assistants receive sufficient training to properly perform and interpret the microscopic examinations currently included in the PPM subcategory, we are adding midlevel practitioners to the PPM subcategory. We define them in § 493.2 as nurse practitioners, nurse midwives and physician assistants, licensed by a State if such licensing is required.

As a result of the comments received, we also considered the inclusion of dentists in the PPM subcategory. After evaluating the education and training that dentists receive in clinical laboratory procedures, we concluded that dentists, with either a Doctor of Dental Medicine (DDM) or Doctor of Dental Surgery (DDS) degree, are qualified to perform the examinations in the PPM subcategory and we are adding dentists as persons who may perform PPM procedures.

Upon evaluation of the education and training of emergency personnel, registered nurses, licensed practical nurses, and medical assistants, we determined that these practitioners do not receive sufficient training to properly perform and interpret the microscopic examinations currently included in the PPM subcategory. For this reason, we are not adding them as persons who may perform PPM procedures.

Changes to the Regulations

To accommodate the above additions, we are changing the name from "physician-performed microscopy procedures" to "provider-performed microscopy procedures."

To be consistent with other personnel requirements, we are moving the personnel requirements for the PPM subcategory, formerly located at § 493.16(e)(2) (§ 493.16(e)(3) is redesignated as § 493.19(e)(2)), to subpart M. At § 493.1355, we are specifying the condition requirements for laboratory director of PPM procedures, with director qualification requirements located at § 493.1357 and director responsibilities at § 493.1359. To the director responsibility requirements, we are adding the requirement limiting the number of laboratories that an individual can direct to five, which was inadvertently not included in previous regulations; currently, directors of laboratories performing other moderate complexity testing may only direct five. The condition requirements for testing personnel performing PPM procedures are now located at § 493.1361, while testing personnel qualifications are located at § 493.1363 and responsibilities are at § 493.1365.

We are also making numerous conforming changes to part 493 to accommodate the revision to include midlevel practitioners and dentists. We are revising the following additional sections and headings: §§ 493.2—definition of "CLIA certificate—certificate for physician-performed microscopy procedures" by adding "dentist" and "midlevel practitioner", and revising "physician" (for consistency to include doctors of osteopathy and to require the physician to be licensed in the State in which the laboratory is located); 493.20(b); 493.25(c) (redesignated from 493.25(d)); heading for subpart C; 493.43 heading; 493.45(a)(2); 493.47; 493.49(a)(3); 493.53 heading and introductory paragraph; 493.638; 493.639(b); 493.643(a); 493.646(a); 493.1776 heading and paragraphs (a) (3) and (4) and (b); 493.1814(b)(3); 493.1834(b) and (f)(2)(iii); and 493.1836(c) (2) and (3).

2. General Discussion of General Supervisor and High Complexity Testing Personnel Comments

In response to the personnel requirements contained in the final regulations published February 28, 1992, we received approximately 55,000 comments from individuals and organizations. The qualification requirements for general supervisor and high complexity testing personnel received the most extensive comments. Approximately 8,000 comments concerned general supervisor, 14,000 comments related to high complexity testing personnel and more than 10,000 comments pertained to testing personnel, with the complexity of testing not specified. Some commenters indicated that the regulations were too stringent, while others thought the requirements were too lenient. Among the commenters who thought that the minimum qualifications should be raised, there was a general consensus that the increase in requirements should be prospective and that the regulations should include alternative qualifying pathways to avoid affecting currently employed individuals adversely. Many commenters were concerned that the regulations would eliminate the jobs of many laboratory employees who possess extensive work experience but lack the requisite degree or formal laboratory training. This would particularly exacerbate the shortage of qualified laboratory personnel in rural and underserved areas and limit patient access to testing.

In evaluating the many comments we sought advice from the CLIAC concerning whether changes were needed in the regulations pertaining to general supervisor and high complexity testing personnel. Many individuals and organizations provided detailed information and suggestions to CLIAC about the qualifications that should be required for supervision and performance of high complexity testing. The CLIAC recommended revising the regulations to recognize currently employed individuals who do not meet the qualifications contained in the final regulations but who have clinical laboratory training and extensive laboratory experience.

We acknowledge that extensive experience can qualify individuals to competently perform these functions. Therefore, in response to the comments provided to the regulations published February 28, 1992, and to the CLIAC advice, and to mitigate the impact of the regulations on currently employed people, especially those in rural and underserved areas, we are making in this regulation the changes necessary to provide alternative qualification pathways.

We are revising the general supervisor (§ 493.1461) and high complexity testing personnel (§ 493.1489) requirements to: qualify individuals currently performing high complexity testing and those currently employed general supervisors if they have the requisite laboratory training or experience; recognize 50-week U.S. military medical laboratory training programs and accredited laboratory training programs; and establish equivalent requirements for the associate degree. More specific comments and responses concerning revisions to the regulations to create alternative qualifications for general supervisor and high complexity testing personnel follow.

We also are making conforming cross-reference changes to §§ 493.1463 and 493.1495.

3. Specific Comments and Responses

General Supervisor Qualifications

Comment: Although many commenters agreed that the minimum requirement for general supervisor should be an associate degree in clinical laboratory science or medical laboratory technology, others indicated that the

requirement should be an associate degree with area of study not specified. Some commenters said that requirements equivalent to the associate degree should be established. Several commenters indicated that individuals having a bachelor of arts or education degree with a specified number of science courses should be qualified.

Response: We agree with the commenters who suggested the establishment of requirements equivalent to the associate degree with appropriate study in the sciences because we believe individuals who have completed the requisite courses and training are qualified to supervise high complexity testing. In this regulation, we are defining the following as equivalent to the academic requirements for an associate degree: 60 semester hours, which must include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of courses in chemistry, biology or medical laboratory technology, or any combination. In addition, individuals must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours specified above) or three months of documented training in each specialty in which the individual performs high complexity testing. We are specifying the equivalent requirements for the associate degree under high complexity testing personnel, which are adopted by cross-reference to the general supervisor requirements. Therefore, individuals who do not have a degree or who have a bachelor's degree that is not in a science can now qualify as a general supervisor if they meet the equivalency requirements for an associate degree and have at least two additional years of laboratory training or experience in high complexity testing.

Comment: Many commenters recommended qualifying medical laboratory technicians without an associate degree to serve as general supervisor. Some commenters recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited hospital or approved technical school training program. Other commenters recommended qualifying individuals with military training.

Response: We agree with the commenters that the regulations should recognize individuals who were serving as a general supervisor of high complexity testing on or before September 1, 1992 (the effective date of the CLIA personnel regulations) but do not have an associate degree, or equivalent, provided they have completed an accredited clinical laboratory training program. We believe individuals having this training and experience have the appropriate qualifications to serve as a general supervisor. Therefore, we are adding a provision to the general supervisor qualification requirements to qualify individuals who, on or before September 1, 1992, were serving as a general supervisor of high complexity testing. The individual must on or before April 24, 1995, have completed a 50-week U.S. military medical laboratory training program or have graduated from a medical laboratory or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation or other organization approved by HHS. To help assure equivalency to other qualification pathways, individuals having this type of training are required to have two additional years of laboratory training or experience in high complexity testing in order to qualify as general supervisor This additional training or experience may be acquired before or after completing the accredited or U.S. military medical laboratory training program.

Comment. Several commenters misread the regulations and thought that individuals qualified under regulations published March 14, 1990 (55 FR 9576) were required to obtain an associate degree.

Response Individuals who qualified as general supervisors under the previous Federal regulations are qualified under these regulations and are not required to obtain an associate degree.

Comment: Some commenters recommended that all laboratory personnel currently employed as general supervisors be qualified through a "grandfather" provision.

Response: We agree with the commenters and the CLIAC recommendation that regulations should include provisions to allow currently employed supervisors who have pertinent laboratory experience to continue their employment. We are adding a provision to the general supervisor requirements to qualify high school graduates, or equivalent, who, on or before September 1, 1992, were serving as a general supervisor and have at least ten years of laboratory training or experience in high complexity testing, including at least 6 years of supervisory experience in high complexity testing within the last 10 years because we believe this amount of experience is appropriate to qualify individuals as general supervisors and is commensurate with the general supervisor responsibility requirements.

Comment: A few commenters agreed with the responsibilities for general supervisor, while a few commenters disagreed. Most of the commenters who disagreed with the responsibilities were opposed to requiring the general supervisor to be onsite when high complexity tests are performed by personnel who do not have at least an associate degree. Conversely, many commenters indicated that an individual with an associate degree should be allowed to perform high complexity testing only when a technologist or supervisor is onsite.

Response. In the revised regulation published in the **Federal Register** on January 19, 1993, we changed the requirement for onsite supervision to require 24-hour review of any high complexity testing performed by personnel who do not have at a minimum an associate degree and were performing high complexity testing on or before January 19, 1993. However, in the January 19, 1993 regulation, we retained the onsite supervision requirement for those high school graduates, or equivalent, who began performing high complexity testing after January 19, 1993. In this regulation, we are not changing the requirements for onsite supervision or 24-hour review However, we believe individuals who have completed accredited or 50-week U.S. military medical laboratory training programs or have academic qualifications equivalent to the associate degree are qualified to perform high complexity testing. Therefore, we are revising the regulations to qualify as high complexity testing personnel individuals having these qualifications. Individuals who qualify under these new provisions may perform high complexity testing without onsite supervision or 24-hour review.

We do not agree with the commenters that onsite supervision should be required for high complexity testing performed by individuals having an associate degree; such a requirement would be unnecessarily burdensome and could exacerbate personnel shortages and limit patient access to testing. It should be emphasized that these are minimum requirements that do not restrict laboratories from establishing their own policies requiring higher personnel qualifications. In all cases, the laboratory director is responsible for ensuring that all testing

personnel have the necessary education and training or experience required for test performance.

Testing Personnel Qualifications (High Complexity)

Comment: Numerous commenters believed an associate degree in laboratory science or medical laboratory technology should be the minimum education requirement. Several commenters suggested recognizing associate degrees in fields other than clinical laboratory science or medical laboratory technology, with others suggesting equivalent requirements be established for the associate degree.

Response: Currently, the qualification requirements for high complexity testing personnel contain provisions that prospectively require high school graduates to obtain an associate degree. As mentioned above, in evaluating the comments received concerning high complexity testing personnel, we sought the advice of the CLIAC about the appropriateness of the qualifications required. The CLIAC recommended that the associate degree be established as the minimum education requirement and, in addition, that equivalent academic requirements be established for the associate degree. In this regulation, we are adding a provision to qualify individuals who have completed specific college courses but do not have an associate degree or who have an associate degree that is not in medical laboratory technology or a laboratory science. As previously mentioned, we have defined requirements equivalent to the associate degree (60 semester hours that must include 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology and twelve semester hours of courses in chemistry, biology or medical laboratory technology, or any combination); individuals qualifying under the equivalency provisions also must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours) or three months of documented training in each specialty in which the individual performs high complexity testing. The laboratory training may be acquired before, during or after completing the academic requirements.

Comment: Many commenters recommended recognizing medical laboratory technicians without an associate degree. Commenters also recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited hospital or technical school training program. A large number of commenters suggested qualifying individuals with military training.

Response: We agree with the commenters that, in addition to the revisions made to the general supervisor requirements, revisions are needed in the qualification requirements for high complexity testing personnel to recognize individuals who have completed a nondegree clinical laboratory training program and, therefore, have equivalent training. Therefore, we are adding to the high complexity testing personnel requirements, a provision to qualify individuals who, on or before April 24, 1995 have completed a 50-week U.S. military medical laboratory training program or have graduated from a medical laboratory or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation or other organization approved by HHS.

Comment: A number of commenters recommended that the regulations be revised to qualify all currently employed high complexity testing personnel. Other commenters said currently employed high school graduates, who were trained on the job, should be allowed to continue performing high complexity testing but only under supervision.

Response: We agree with the CLIAC recommendation that the regulations should be revised to alleviate the impact on currently employed personnel. We also believe that high school graduates with appropriate training, who were performing high complexity testing on or before April 24, 1995 have obtained sufficient work experience to allow them to continue performing testing with supervisory oversight. Therefore, we are revising the regulations to allow these individuals to continue performing high complexity testing even after September 1, 1997 (the current limit) and do not require that they obtain additional training or education However, performance of any high complexity testing by these individuals must be in accordance with the supervision requirements discussed below.

Comment: A few commenters agreed with the responsibility requirements for high complexity testing personnel, while numerous commenters disagreed. The majority of the commenters who disagreed were opposed to requiring onsite supervision when individuals who do not have an associate degree perform high complexity testing.

Response: As previously mentioned above under the discussion of qualifications of the general supervisor, in the regulation published in the Federal Register on January 19, 1993, we changed the requirement for onsite supervision to only require 24-hour review of any high complexity testing performed by personnel who do not have an associate degree and who were performing high complexity testing on or before January 19, 1993. The onsite supervision requirement was retained only for those high school graduates, or equivalent, who began performing high complexity testing after January 19, 1993. In this regulation, we are not changing the requirements for onsite supervision or 24-hour review However, we believe individuals who have completed accredited or U.S. military laboratory training programs or have qualifications equivalent to the associate degree and have appropriate laboratory training are qualified to perform high complexity testing without supervision. Therefore, we are revising the qualification requirements for high complexity testing personnel to allow individuals having these qualifications to perform high complexity testing without onsite supervision or 24-hour review.

III. Other Revisions

We are making the following technical changes in addition to those discussed above:

- We are making minor editorial changes to improve clarity and remove redundancies. This includes removing §§ 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634.
- We are revising the definition of "certificate of registration" in § 493.2 to exclude reference to laboratories that are exempt from CLIA requirements because they are licensed by a HCFA-approved laboratory licensure program, these laboratories are not required to obtain a registration certificate.
- From the definition of "physician" in § 493.2 we are deleting the phrase "or equivalent degree" as there are no degrees equivalent to doctor of medicine, osteopathy or podiatric medicine.
- To §§ 493.35(d)(2) and 493.37(b)(2) we are adding a requirement that a laboratory seeking a certificate of waiver must permit announced inspections by HHS (as well as unannounced) because it was inadvertently omitted from the January 19, 1993 rule.
- In §§ 493.35(d)(2)(iv), 493.49(b)(2)(iv), 493.1776(a)(4) and 493.1776(b)(4)(iv), we indicate that we will collect information during

inspections to determine the "appropriateness" of tests, rather than their "addition, deletion or continued inclusion".

- In § 493.602 we clarify Federal validation survey activity to include accredited laboratories and change "State-exempt" to "CLIA exempt" to agree with references that were changed in previous regulations.
- In §§ 493.638, 493.639, and 493.645(c), we revise the text so that it more accurately reflects what costs fees do and do not cover; for example, they do cover the cost of categorizing tests.
- In the title of § 493.645 and paragraph (a) we are changing the word "licensure" to "laboratory" and, in paragraph (a), "State-exempt" to "CLIA-exempt" to conform to changes made in previous regulations.

IV. Waiver of Delay in Effective Date

We find good cause to waive the usual 30-day delay in effective date for most of the revisions. Those persons who become qualified under the revised regulations are no less qualified now than they will be in 30 days. Hence, it serves no purpose to delay our regulations. Other revisions are very technical in nature and to delay their effective date is also unnecessary. Also, under the provisions of the current regulations, revisions of the list of PPM tests may be done outside of a rulemaking process through publication of a **Federal Register** notice that does not require a 30 day delay. As indicated earlier, we also will consider comments received on the addition of three new PPM procedures. Therefore, we find good cause to waive the delay in effective date of this rule.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Collection of Information Requirements

The portions of §§ 493.7, 493.35, 493.39, 493.43, 493.53, 493.55, and 493.57 of this document that have been revised contain information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These reporting and recordkeeping requirements are not effective until a notice of OMB's approval is published in the **Federal Register**. The information collection requirements concern the performance of recordkeeping. The respondents who will provide the information include any entity performing laboratory testing used for assessment, diagnostic or treatment purposes. Public reporting burden for this collection of information is estimated to be 61 hours per laboratory per year.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VII. Regulatory Impact Statement

Background

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

General

This rule modifies CLIA regulations published February 28, 1992 and January 19, 1993. There are approximately 157,000 entities enrolled under CLIA that may be affected by the provisions of this rule. The significance of the effect will vary depending on the volume and complexity of tests performed; whether the entity employs midlevel practitioners to perform provider-performed microscopy (PPM) procedures; and whether employees meet the personnel requirements contained in the February 28, 1992 regulations. While we cannot estimate the number of entities that may make changes in their laboratory testing practices as a result of this rule, we believe the modifications to the CLIA program will benefit the affected entities in several ways. This rule will help to ease implementation of the CLIA program at no loss to public health and safety by offering alternative qualification standards for laboratory employees who would be adversely affected by the original personnel requirements. It also increases patient access to laboratory services, especially in rural and underserved areas, by expanding the list of personnel qualified to conduct certain laboratory tests. In addition, it reduces the regulatory burden for laboratories by enabling them to provide an expanded menu of tests under a PPM certificate without incurring the costs associated with obtaining a certificate of compliance.

Categorization of Tests

Expanding the list of PPM procedures may affect a laboratory's choice of certificate. Laboratories with certificates for PPM are not subject to costs associated with the routine inspections required under a certificate of compliance. Therefore, laboratories holding a certificate of compliance that change to a certificate for PPM will have a decrease in compliance costs and the number of inspections. Certificate of waiver laboratories choosing to expand their test menu to include PPM procedures and obtain a certificate of PPM will have increased certificate fees, as well as additional costs inherent in meeting applicable requirements, such as personnel and proficiency testing. The current biennial fee for a certificate of waiver is $100, as compared to $150 for a certificate for PPM. Although the cost of obtaining a certificate for PPM is more than for a certificate of waiver, it is less than the cost associated with a certificate of compliance.

Provider-Performed Microscopy Procedures

All providers performing microscopy examinations in conjunction with patient evaluations may be affected by the expansion of the subcategory of microscopy procedures to include midlevel health care practitioners and dentists. Many midlevel practitioners routinely perform patient examinations and associated laboratory testing, and in some States, are authorized to practice independently. Because there is such a wide variety of settings in which these services are offered, we cannot quantify the percentage of tests done by each type of health professional. However, there are no data to indicate that the quality of their tests results is not at least equivalent to the tests performed

by physicians. As a result of this expansion, patient access to care and services will increase, particularly in rural and underserved areas where there are shortages of physicians and, as many commenters pointed out, midlevel practitioners are the only health care providers available.

Personnel Requirements

As a result of our evaluation of the 32,000 comments received on the general supervisor and testing personnel requirements contained in the February 28, 1992 regulations, and after consultation with the CLIAC, we are revising the regulations to mitigate the impact of the regulations on currently employed individuals. Adding alternative qualification standards to the general supervisor and high complexity testing personnel requirements enables currently employed individuals with equivalent training and experience to continue to qualify for these positions. As stated in the impact analysis that accompanied the February 28, 1992 regulations, we recognize that flexibility is needed by the laboratory industry to effectively take advantage of the personnel resources available to it, and it was not our intention to disenfranchise anyone currently employed. By providing equivalent qualification standards, we will increase the available pool of qualified laboratory personnel which will enable laboratories to meet the certification requirements without compromising the health and safety of patients. We expect many laboratories to benefit from this revision to the regulations, especially those in rural and underserved areas who are experiencing personnel shortages and the resultant limited patient access to laboratory services.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 493

Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 493 is amended as set forth below:

PART 493—LABORATORY PROCEDURES

1. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. Section 493.2 is amended by revising the definition of "CLIA certificate" and "physician" and adding in alphabetical order definitions of "Dentist" and "Midlevel practitioner" to read as follows:

§ 493.2 Definitions.

* * * * *

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with § 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in § 493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with § 493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent; or in accordance with § 493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.37, to a laboratory to perform only the waived tests listed at § 493.15(c).

* * * * *

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

* * * * *

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

* * * * *

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

* * * * *

3. In § 493.3, the introductory text of paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

* * * * *

4. A new § 493.5 is added to read as follows:

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

§ 493.10 [Removed]

5. Section 493.10 is removed.

§ 493.16 [Redesignated as § 493.19]

6. Section 493.16 is redesignated as § 493.19 and is revised to read as follows:

§ 493.19 Provider-performed microscopy (PPM) procedures.

(a) *Requirement.* To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) *Revisions to criteria and the list of PPM procedures.*

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the **Federal Register** as a notice with an opportunity for public comment.

(e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and P of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

7. Section 493.20 is revised to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at § 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, M, and P of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

8. In § 493.25, paragraphs (c) and (d) are redesignated as (d) and (c), respectively, and paragraphs (b), (c) and (d) are revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, P, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at § 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

9. In § 493.35, paragraphs (a) and (d) are revised to read as follows:

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

* * * * *

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

* * * * *

10. In § 493.37, the introductory text of paragraph (b) is republished and paragraphs (b)(2) and (g) are revised to read as follows:

§ 493.37 Requirements for a certificate of waiver.

* * * * *

(b) Laboratories issued a certificate of waiver—

* * * * *

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

* * * * *

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

11. In § 493.39, the introductory paragraph is republished and paragraph (a) is revised to read as follows:

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

* * * * *

12. The heading of subpart C is revised to read as follows:

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

13. In § 493.43, the heading and paragraph (a) are revised to read as follows:

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests, must file a separate application for each laboratory location.

* * * * *

14. In § 493.45, a new introductory paragraph is added, the introductory paragraph (a) is republished, paragraph (a)(3) is removed, and paragraphs (a)(1), (a)(2), (d), and (f) are revised to read as follows:

§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in § 493.15(c) or specified as PPM procedures.

* * * * *

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

* * * * *

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

* * * * *

15. In § 493.47, the heading, paragraph (a), the introductory text of paragraphs (b) and (c), paragraph (c)(2), and paragraphs (d) and (e) are revised to read as follows:

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

* * * * *

(c) Laboratories issued a certificate for PPM procedures are subject to—

* * * * *

(2) The applicable requirements of this subpart and subparts H, J, K, M, and P of this part; and

* * * * *

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

16. Section 493.49 is revised to read as follows:

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

17. In § 493.51, the introductory paragraph of paragraph (a) is republished and the heading, the section's introductory paragraph and paragraphs (a)(5), (b) and (c) are revised to read as follows:

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

* * * * *

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

18. In § 493.53, the heading, the introductory paragraph, and paragraph (a) are revised to read as follows:

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

* * * * *

19. The introductory text of § 493.55(a) is revised to read as follows:

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

* * * * *

20. In § 493.57, the introductory paragraph and paragraph (b) are revised to read as follows:

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

* * * * *

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

* * * * *

21. In § 493.511, paragraph (b) is revised to read as follows:

§ 493.511 Removal of deeming authority and final determination review.

* * * * *

(b) After HCFA withdraws approval of an accreditation organization's deeming authority, the certificates of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notification of the withdrawal of approval. HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for inspection to another approved accreditation organization or an application for the appropriate certificate to HCFA, the State agency, or other HCFA agent before the initial 60-day period ends.

* * * * *

22. Paragraph (j) of § 493.521 is revised to read as follows:

§ 493.521 Removal of CLIA exemption and final determination review.

* * * * *

(j) After HCFA withdraws approval of a State laboratory licensure program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for the appropriate certificate before the initial 60-day period ends.

* * * * *

23. Section 493.602 is revised to read as follows:

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

§§ 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634 [Removed]

24. Sections 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634 are removed.

25. Section 493.638 is revised to read as follows:

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

26. Section 493.639(b) is revised to read as follows:

§ 493.639 Fee for revised certificate.

* * * * *

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is necessary to determine compliance with additional requirements.)

27. In § 493.643, paragraphs (a) and (d) are revised to read as follows:

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

* * * * *

(d) *Additional fees.* (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

28. Section 493.645 is revised to read as follows:

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that

standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

29. Section 493.646(a) is revised to read as follows:

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

* * * * *

30. In § 493.649, paragraph (a) and the introductory paragraph of paragraph (b) are revised to read as follows:

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

* * * * *

31. The heading of subpart H is revised to read as follows:

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

32. Section 493.803(a) is revised to read as follows:

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing tests of moderate complexity (including the subcategory) and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

* * * * *

33. The heading of § 493.807 is revised to read as follows:

§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests, after failure to participate successfully.

* * * * *

34. The undesignated center heading immediately preceding § 493.821 is revised to read as follows:

Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

35. The heading to subpart I is revised to read as follows:

Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

36. The heading for subpart J is revised to read as follows:

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

37. Section 493.1101 is revised to read as follows:

§ 493.1101 Condition: Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

38. The heading to subpart K is revised to read as follows:

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

39. The heading to § 493.1201 is revised to read as follows:

§ 493.1201 Condition: General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

40. The heading to subpart M is revised to read as follows:

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

41. New § 493.1351 is added to subpart M to read as follows:

§ 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

42. Following § 493.1351, a new undesignated center heading and new §§ 493.1353, 493.1355, 493.1357, 493.1359, 493.1361, 493.1363, and 493.1365 are added to subpart M to read as follows:

Laboratories Performing Provider-Performed Microscopy (PPM) Procedures

§ 493.1353 Scope.

In accordance with § 493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§ 493.1355 through 493.1365.

§ 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1357 and provides overall management and direction in accordance with § 493.1359.

§ 493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in § 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(3) Be a dentist, as defined in § 493.2.

§ 493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

(a) Direct no more than five laboratories; and

(b) Ensure that any procedure listed under § 493.19(c)—

(1) Is personally performed by an individual who meets the qualification requirements in § 493.1363; and

(2) Is performed in accordance with applicable requirements in subparts H, J, K, M, and P of this part.

§ 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1363 to perform the functions specified in § 493.1365 for the volume and complexity of testing performed.

§ 493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must—

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(3) Be a dentist as defined in § 493.2 of this part.

§ 493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—

(a) Personally performed by one of the following practitioners:

(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

(b) Performed using a microscope limited to a brightfield or a phase contrast microscope.

§ 493.1401 [Removed]

43. Section 493.1401 is removed.

44. In § 493.1461, the introductory text of paragraph (c) and paragraph (c)(2) is revised, and new paragraphs (c)(4) and (c)(5) are added to read as follows:

§ 493.1461 Standard; General supervisor qualifications.

* * * * *

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—

* * * * *

(2)(i) Qualify as testing personnel under § 493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

* * * * *

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory

experience between September 1, 1982 and September 1, 1992.

* * * * *

§ 493.1463 [Amended]

45. In § 493.1463, all references to "§ 493.1489(b)(4)" are amended to read "§ 493.1489(b)(5)."

46. In § 493.1489, the introductory text to the section and to paragraph (b) are republished, paragraphs (b)(2) and (b)(4) through (b)(6) are revised, and paragraph (b)(7) is added to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

* * * * *

(b) Meet one of the following requirements:

* * * * *

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) Six semester hours of chemistry;

(*ii*) Six semester hours of biology; and

(*iii*) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

* * * * *

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(*1*) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(*2*) The skills required for implementing all standard laboratory procedures;

(*3*) The skills required for performing each test method and for proper instrument use;

(*4*) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(*5*) A working knowledge of reagent stability and storage;

(*6*) The skills required to implement the quality control policies and procedures of the laboratory;

(*7*) An awareness of the factors that influence test results; and

(*8*) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(ii) As of September 1, 1997, be qualified under § 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

(6) For blood gas analysis—

(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations.

§ 493.1495 [Amended]

47. In § 493.1495, all references to "§ 493.1489(b)(4)" are amended to read "§ 493.1489(b)(5)."

48. The heading to subpart P is revised to read as follows:

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

49. Section 493.1701 is revised to read as follows:

§ 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program that 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 as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

50. In § 493.1776, the introductory text of paragraphs (a), (b), and (b)(4) are republished and the heading and paragraphs (a)(3), (a)(4), (b)(1), (b)(4)(iii) and (b)(4)(iv) are revised to read as follows:

§ 493.1776 Condition: Inspection of laboratories issued a certificate for PPM procedures.

(a) HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to—

* * * * *

(3) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; and

(4) Collect information regarding the appropriateness of tests specified as PPM procedures.

(b) The laboratory may be required, as part of this inspection, to—(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493. Requirements for the purposes of this section are located in subpart C or

subpart D, if applicable, and subparts H, J, K, M, and P of this part:

* * * * *

(4) Permit HHS or its designee upon request to review all information and data necessary to—

* * * * *

(iii) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; (iv) Collect information regarding the appropriateness of tests specified as PPM procedures; and

* * * * *

51. In § 493.1777, introductory text to the section is added and the heading and paragraphs (a) and (g) are revised to read as follows:

§ 493.1777 Condition: Inspection of laboratories requesting or issued a certificate of compliance.

Laboratories requesting or issued a certificate of compliance must permit an inspection to assess compliance with part 493 of this chapter. Testing in the subcategory of PPM procedures, may be included in the laboratory's routine or complaint inspection. PPM procedures are assessed for compliance with only the applicable requirements specific to the subcategory of testing.

(a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate of compliance.

* * * * *

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate of compliance in accordance with subpart R of this part.

§ 493.1804 [Amended]

52. In § 493.1804(b)(2), the word "ore" is revised to read "or".

53. In § 493.1814, the introductory text of paragraph (b) is republished and paragraph (b)(3) is revised to read as follows:

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

* * * * *

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

* * * * *

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

* * * * *

54. In § 493.1834, the heading and introductory text of paragraph (f)(2) are republished and paragraphs (b) and (f)(2)(iii) are revised to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

* * * * *

(f) *Accrual and duration of penalty*—

* * * * *

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

* * * * *

(iii) HCFA suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

* * * * *

55. In § 493.1836, the heading of paragraph (c) is republished and paragraphs (c)(2) and (c)(3) are revised to read as follows:

§ 493.1836 State onsite monitoring.

* * * * *

(c) *Duration of sanction.*

* * * * *

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

56. In § 493.2001, paragraph (e) and paragraph (e)(1) are revised to read as follows:

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

* * * * *

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategory) and high complexity;

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 23, 1994.

Philip R. Lee,

Assistant Secretary for Health.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 27, 1994.

Donna E. Shalala,

Secretary.

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Commenters - Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

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Re: Comments on Rule #57: Clinical Laboratory Technician and Technologist; Licensure and Certification (64 CSR 57)

Date Submitted: July 20, 1995

Thank you for the opportunity to provide comments on the above listed rule. The difficulty in drafting language for technically complex rules such as this one is fully appreciated. With this in mind, we respectfully submit the following comments and questions.

64-59-6/ 6.4 & 6.5

Reference is made to "continuing education from a program or programs approved by the secretary". It is troubling that the programs or mechanisms which are "acceptable" and the term "hour" have not been clearly defined This requirement for formal documentation of annual Continuing Education (CE) places a new burden on the current and future laboratory workers within the State of WV, and is therefor a major area of concern. The degree of difficulty and expense incurred by individual laboratorians in meeting this requirement could range from minimal to quite severe, depending on what the "Secretary" approves. Consequently, we feel that the criteria for acceptability should be well defined and re-submitted for public comment prior to implementation of this rule.

64-59-5 & 64-59-6

With reference to individuals who:

a) are experienced and entering a new job but come form a State not requiring licensure
b) a new-hire fresh out of school with no work experience in a Laboratory
c) an employee of a Physician office wherein the Physician decides to begin Laboratory testing

It is assumed that these individuals would be temporarily classified as "Clinical Laboratory Scientist Trainees" (CLST) by their employer as defined under 64-59-3/ 3.6 and consequently would be allowed to perform laboratory testing under the provisions of 64-59-5/ 5.2. Presumably, these individuals would maintain the employer classification of CLST until such time as competency was assessed and documented under 64-59-6/ 6.1.2. However, there is no time limit specified for how long and individual could maintain a classification of CLST. As a result, it may be possible under current wording of the rule for a CLST to operate under that classification for an indefinite period. We suggest that the process for getting certified and licensed under the above listed scenarios be more clearly defined and that a time limit be imposed upon the classification of a CLST.

General:

Point of Care Testing (POC) is typically and increasingly performed by non-laboratory personnel in several WV Hospitals. CLIA-88 makes allowance for these tests classified in the waived category.. Unless we have misread this rule, it appears that personnel who are now performing POC testing would be subject to certification and licensure. If this is the case, this may decrease the access to care in many WV Hospitals by disallowing non-laboratory personnel to perform waived POC tests. Many persons currently performing these tests may not meet the qualifications for certification and licensure. Additionally, this fact may present an unintended financial burden on hospitals by virtue of the fact that they would probably have to bear the cost of licensure and certification for those non-laboratory personnel who are already performing these tests should the hospital decide that they should continue to provide such testing to their patients. We believe that this situation should be addressed and clarified as to its intent, and its possible impact on WV Hospitals should be assessed..

Respectfully submitted by:

Dan Butler
Laboratory Manager
Reynolds Memorial Hospital
Glen Dale, WV

Bob Dorisio
Laboratory Manager
Wheeling Hospital
Wheeling, WV

Sherry Baker
Administrative Director
Ohio Valley Medical Center
Wheeling, WV

Dan Butler
Laboratory Manager
Wetzel County Hospital
New Martinsville, WV

Contact: Dan Butler, MT(ASCP), SC, DLM
Laboratory Manager
Reynolds Memorial Hospital
Glen Dale, WV 26038
304-843-3211 Ext 5324

General:

There are several references in the rules (64-59-3/ 3.3,3.4,3.5,3.7 & 64-59-5/ 5.2 & 64-59-6/ 6.1.2) to persons who are qualified as Clinical Laboratory Consultants, Clinical Laboratory Director and Clinical Laboratory Supervisor, but there are no provisions in the rule that indicate they can perform Laboratory testing. Does this rule intend that they not be allowed to perform testing? Is it the intent of the rule that they must also get certification and licensure as a Clinical Laboratory Scientist in order to perform testing? We suggest that this question be addressed and clarified.

64-59-3/ 3.5

a) A Clinical Laboratory Scientist is defined as "a person whose job tasks include ***specimen processing***.....". It is a common finding in Laboratories for Phlebotomists, Secretaries and others to perform specimen processing in some fashion. These personnel will not generally meet the qualifications for a Clinical Laboratory Scientist. To require persons who perform specimen processing to meet CLS qualifications would place and enormous economic burden on Laboratories and Hospitals. CLIA-88 does not require specimen processing personnel to meet specific qualifications. Additionally, many Histologists are involved in specimen processing and there are no CLIA-88 qualification requirements for them either. We believe that these issues should be addressed and/or clarified.

b) The phrase "or Physicians licensed under WV Code.....who perform laboratory tests only on their own patients" is referenced here and other places in this rule. Usually, it is not the Physician who actually performs the laboratory tests on his/her patients, but rather his/her staff that does the actual testing. We do not assume that the intent of this rule is to exempt the Physicians office personnel from certification and licensure. We suggest that this issue be addressed and clarified.

64-59-7

The Certification requirements do not address the possibility of future changes in the CLIA-88 regulations. There should be language in the rule that allows the OPTION of adopting potential future changes under CLIA-88.

Budgetary:

a) In the Budget estimates, $36,000 annually for an 800 number seems excessive. One can get a personal 800 number during peak hours for about $0.30 per minute. Under this assumption, a phone line which is in use every minute of every hour for 8 hours per day and for 52 weeks per year calculates out to about $37,440. Of course, it is not feasible that this 800 line would be used anywhere near that much.

b) The lease rate for space seems excessively high ($24,840 annually) for an area the size of a small bedroom. Is this a typographical error?

64-59-8

The language in this section will essentially exclude most persons from having to provide evidence of their qualifications to perform laboratory testing. We are concerned that this may lead to abuses of the qualifying route and some possible mis-representations.

Charleston Area Medical Center

Memorial Division

3200 MacCorkle Avenue, S.E.
Charleston, West Virginia 25304
(304)348-5432

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6.2 Wont apply if 6.1.2 is eliminated.

6.3.1 Eliminate "are exempt from such certification under this rule".

6.4 – 6.5 Additional clarification is needed to define what the secretary will approve and the process for approving. Also, addition clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs?

7.2.2 Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

8.2.1+8.2.2 What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to include provide documentation of "registry eligible".

Under certification requirements we recommend not certifying those working in "waived labs" based on 42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of 2 years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA,493.1489 - allowance for high school degreed individuals to continue moderately complex testing beyond those working and trained by April 24 th, 1995 needs to be deleted. It is contradictory to the original intent of the law as approved by the State of West Virginia.

Thank you for your review and consideration of my opinions,

Marilyn Zimmerman MT(SM)(ASCP)

Marilyn Zimmerman, M.T. SM(ASCP)
Section Supervisor, Microbiology Laboratory, CAMC
CLMA Member

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Joyce Battlo

Joyce Battlo M.T.
Quality Management Coordinator, CAMC

Charleston Area Medical Center

Memorial Division
3200 MacCorkle Avenue, S.E.
Charleston, West Virginia 25304
(304) 348-5432

Comment: Laboratory Tech Technical license

The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of a 1-800 number is not justified. Additionally I question the validity of cost for the investigator's responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e.. elimination of inappropriate hospitalization and unnecessary medication.

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Nasser Larijani, M.T. ASCP
Unit Supervisor, General Division Laboratory, CAMC

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Thank you for your review and consideration of my opinions.

Brenda Larijani

Brenda Larijani M.T. (N. C. A. .CLS)
Quality Management Coordinator, CAMC
Treasurer WVCLMA

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
1001 Pennsylvania Avenue, N.W. • Suite 725 • Washington, D.C. 20004-2508
(202) 347-4450 • Fax (202) 347-4453

WASHINGTON OFFICE

FAX TRANSMISSION COVER SHEET

NUMBER OF PAGES INCLUDING COVER SHEET: 4

DATE: 7/24/95

TO: Kay Howard

COMPANY: Office of Regulatory Development

FAX: 304/558-1130

PHONE: 304/558-3223

FROM: Geri Mied

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

PHONE: (202) 347-4450
FAX: (202) 347-4453

MESSAGE

URGENT!: _____ TIME SENT: 4:18 p.m.

Webster County Memorial Hospital
324 Miller Mountain Drive
Phone 304-847-5682
Webster Springs, West Virginia 26288

July 12, 1995

Regulatory Development
Department of Health & Human Res.
Room 265, Bld. 3 Capitol Complex
Charleston, WV. 25305

ATTN: Kay Howard

I am a Laboratory Tech in rural West Virginia at Webster County Memorial Hospital where I have worked for the last 14 years doing high complexity testing. I was trained on the job, and also by attending various workshops. I am a current member of ISCLT as a POLT. I think my experience shows that I am capable of doing the work, therefore I should be recognized by the State of West Virginia.

Sincerely,

Charlotte Bennett, POLT

Charlotte Bennett, POLT

Charlotte Bennett
PO Box 277 Birch River Rd
Cowen, WV 26206

offers several alternative routes of study and training. However, all routes require a baccalaureate degree.

ASCP also certifies medical laboratory technicians (MLTs) with an associate degree or at least 60 semester hours of academic credit from a regionally accredited college. Certified medical laboratory technicians must also complete an accredited MLT program and courses in biology and chemistry. This certification also offers alternative routes of study and training.

Clearly, these two groups of professionals have achieved different academic and work experiences. If the department is searching for a term to encompass both professions, perhaps "medical laboratory personnel" would be more appropriate.

Because there are more than 1000 ASCP-certified medical technologists and medical laboratory technicians in West Virginia, the terms "medical technologist," and "medical laboratory technician," may be more suitable. As a compromise, the department may consider using clinical laboratory medicine, clinical laboratory technologist, and clinical laboratory practitioner (omit science). If this compromise terminology is agreed to, then equivalent titles such as clinical laboratory scientist and medical technologist can be referenced in the definition of clinical laboratory technologist.

If the "clinical laboratory scientist" terminology remains in the bill without including the recommended terminology change, the legislation could cause confusion and may exclude medical technologists and medical laboratory technicians from fully participating in licensure activities.

II. Laboratory Director

ASCP is also concerned with the definition of a clinical laboratory director. The proposed regulation only asks that a clinical laboratory director meet the qualifications of directors of high and moderate complexity testing laboratories.

The Society believes that the definition should be more specific. A more encompassing definition would describe a laboratory director as a person "qualified under federal regulations to personally administer the technical and scientific operation of the medical laboratory including reporting of findings of laboratory tests."

III. Point-of-Care Testing

The proposed rule does not provide guidelines for point-of-care testing or the supervision of such testing. ASCP suggests that point-of-care tests should be

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1001 Pennsylvania Avenue, N.W. • Suite 725 • Washington, D.C. 20004-2508
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WASHINGTON OFFICE

July 24, 1995

Ms. Kay Howard
Director, Office of Regulatory Development
Department of Health and
Human Services
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard:

The American Society of Clinical Pathologists (ASCP) is writing to respond to the proposed West Virginia Department of Health and Human Resources Clinical Laboratory Technician and Technologist Licensure and Certification regulations.

ASCP is a nonprofit medical specialty society organized for educational and scientific purposes. Its 66,000 members include board certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and as the leading organization of the certification of laboratory personnel. ASCP's certifying board registers more than 150,000 laboratory professionals annually.

I. Terminology

ASCP applauds the state's efforts to license medical laboratory personnel. However, the Society is concerned with the proposed rule's use of the term "clinical laboratory scientist" to describe medical technologists and medical laboratory technicians. These two professional roles are not interchangeable and cannot be described by one professional title.

ASCP certifies medical technologists who hold a baccalaureate degree from an accredited college. In addition, certificants must also have taken courses in biological science, chemistry, and mathematics as well as successfully completed an accredited medical technology program. The certification also

Jackson General Hospital

P.O. BOX 720, RIPLEY, WEST VIRGINIA 25271 · PHONE (304) 372-2731

July 24, 1995

Kay Howard
Regulatory Development
Department of Health & Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

Included with this facsimile are my comments regarding the Clinical Laboratory Technician and Technologist Licensure and Certification rules being proposed.

I am a member of the Board of Directors of the West Virginia Clinical Laboratory Management Association. We, in the Laboratory Management community, are concerned about the preservation of quality personnel standards within this Licensure and Certification Proposal. The exemptions allowed by this document are not acceptable. Personnel exemption for waived testing is the only area which appears logical. Certification by the A.S.C.P., N.C.A., or A.M.T. should be the standard qualification for licensure. A "grandfather" rule could be inserted to allow licensure of all existing workers, with a cut-off date to begin mandatory certification requirements.

I endorse the comments proposed by the Board of Directors of the West Virginia Clinical Laboratory Management Association.

Thank you.

Sincerely,

Craig E. Boyd, MT(ASCP)
Manager of Laboratory Services
Board of Directors, WVCLMA

performed under the supervision of "a laboratory director or a medical technologist if this duty has been so delegated by the laboratory director."

To ensure quality point-of-care testing, the state's requirements should include the following list of responsibilities:

(A) A protocol of implementation including tests to be performed and who will perform the tests;

(B) Criteria to be used in selecting the method of testing to be used for point-of-care testing;

(C) Minimum training and education requirements for those who will perform point-of-care testing, (e.g. documented training, licensure, certification, or other medical professional background not limited to laboratory professionals);

(D) Documented in-service training; initial and ongoing competency validation of personnel performing point-of-care testing;

(E) An appropriate internal and external quality control protocol; and

(F) Record keeping requirements.

IV. Conclusion

Because medical laboratory personnel licensure is important in preserving the public health, safety, and welfare, ASCP recommends that any department overseeing the licensure process is specifically prepared to deal with such issues as qualifications for licensure and oversight, as well as disciplinary and due process procedures.

We appreciate your attention to our recommendations. If you have questions or need additional information, please call us or contact Geri Mied, Manager of State Affairs at the ASCP Washington office at 202/347-4450.

Sincerely,

James A. Benz, M.D.
James A. Benz, MD
President

Pat Ellinger
Patricia Ellinger, MSEd, MT(ASCP)SBB
Chair, ASCP-AMS Administrative Board

separate lab discipline ie My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

6.2: Won't apply if 6.1.2 is eliminated.

6.3.1: Eliminate "are exempt from such certification under this rule".

6.4 & 6.5: Additional clarification is need define what the secretary will approve and the process for approving. Also additional clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs.

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Under certification requirements we recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

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Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of a 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities.

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

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I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

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Charleston Area Medical Center

Memorial Division

3200 MacCorkle Avenue, S.E.
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July 24, 1995

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RECEIVED
JUL 24 1995
REGULATORY DEVELOPMENT

Facsimile Cover Sheet

To: Kay Howard, Regulatory Development
Company: WV Dept. Health & Human Resources
Phone: 304/558-3223
Fax: 304/558-1130

From: Bruce J. Brown
Company: Clinical Lab. Sciences Dept., Marshall University

Phone: 304 696-3188
Fax: 304 696-3243

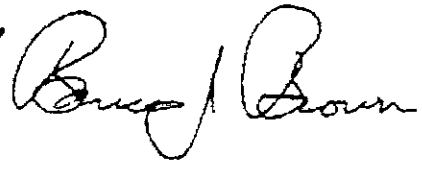
Date: 07/24/95
Pages including this cover page: 1

Comments:

Regarding proposed legislative rule number 64, licensure of clinical laboratory scientists, I offer the following comment.

I agree with the content and general details of the proposed rule regarding licensure of clinical laboratory scientists in West Virginia as filed June 23, 1995. I believe this rule will provide a necessary personnel standard for the qualifications of individuals who perform laboratory testing at clinical laboratories in the state.

Sincerely



Bruce J. Brown, MT(ASCP), Ed. D.
Director of Clinical Laboratory Programs
Marshall University
Huntington, WV 25755

CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Rosa Lee Campbell
Blood Bank Section Chief
Cabell Huntington Hospital

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

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Thank you for your review and consideration of my opinions,

Connie Calabrese CLT/HEW

Connie Calabrese
Unit Supervisor, Microbiology Laboratory, CAMC
CLMA Member

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64-59-4: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

6.1.12: Strike this completely. I am not sure of the intent of this line. If adopted as written, would that mean that laboratorians would become specialized and could not practice in a separate lab discipline? i.e. My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

6.2: Won't apply if 6.1.2 is eliminated.

6.3.1: Eliminate "are exempt from such certification under this rule".

6.4 & 6.5: Additional clarification is needed to define what the secretary will approve and the process for approving. Additional clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs?

7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

Regulatory Department
Dept. of Health and Human Resources
Room 265 Building 3 Capitol Complex
Charleston, WV 25305
ATTN: Kay Howard
FAX: 558-1130

July 19, 1995

Comments Regarding Proposed rules for the WV Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10):

It seems to me that personnel licensure should be the responsibility of a State Licensing Board, and NOT included under the HFLAC (facilities), as this proposal states.

Not only would a Professional Licensing Board would be better equipped to implement personnel licensure than the Health Facility Licensure and Certification, but doing so would also relieve the fear of loss of State funding for the CLIA inspection process.

As a Physician Office Laboratory Consultant in West Virginia, I see the need for Laboratory Personnel Licensure, and **strongly** urge the State of West Virginia to establish qualifications for testing personnel that are higher than those in CLIA'88, including Continuing Education requirements.

Sincerely,

Cathy J. Carver, BS MT(ASCP)
625 Louisiana Ave.
Chester, WV 26034
(304)387-3047 phone and fax

Regulatory Department
Dept. of Health and Human Resources
Room 265 Building 3 Capitol Complex
Charleston, WV 25305
ATTN: Kay Howard
FAX: 558-1130

July 17, 1995

Comments Regarding Proposed rules for the WV Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10):

1. The estimated cost of $165,567 for the first year, and $185,774 each year thereafter appear to be overestimated, while the $100,000 per year revenue figure (based on 4000 participants) seems far too conservative. My experience as a Physician Office Laboratory Consultant in West Virginia leads me to believe that there are **many** more testing personnel, than this estimate reflects. As stated in the fiscal statement, the estimate of revenue may be flawed due to lack of available information on the total number of individuals to be licensed.

2. I believe that the fiscal note errs in stating that the State could lose revenue generated from performing CLIA inspections if it was also performing state licensure inspections: **CLIA'88 is a facility certification program, NOT a personnel licensure issue!!!**

3. The negative, **theoretical**, outcomes stated in the fiscal note (possible increase in health care costs, and reduction in lab services), while highly unlikely, would **certainly** be minimal and offset by the **positive outcomes** such as increased accuracy and reliability of laboratory results. Enhanced quality in laboratory testing will always lead to a **decrease** in health care costs, since erroneous lab results attribute to repeat testing, misdiagnosis and unnecessary hospitalization.

4. The term "Clinical Laboratory Scientist" has an industry-wide definition of an individual with a baccalaureate degree and certified by the NCA. Therefore, I suggest that a more general term be utilized to define testing personnel under WV Code 16-5J-10. Also, I support the inclusion of Clinical Laboratory Supervisor in the group of testing personnel required to be licensed. If not, they could neither perform testing nor be included in the grandfather clause. Inclusion of this group into the general definition would allow individuals to remain in positions that they currently hold.

5. The proposed rule lists a set of **Certification Requirements** that includes: anyone meeting the minimum requirements set forth the CLIA'88 regulations to be licensed as a Clinical Laboratory Scientist in the State of West Virginia. However, in the April 29,1993 Report From The Clinical Laboratories Quality Assurance Act Advisory Board -TO- William T. Wallace, Jr., M.D., M.P.H. Commissioner, Bureau of Public Health:

"The qualifications and duties of the various categories of laboratory personnel were carefully considered by the Board. There was consensus that the federal government's legislation in the Clinical Laboratory Improvement Act of 1988 (CLIA'88) was generally **inadequate** to maintain the health and safety of the people of West Virginia...."

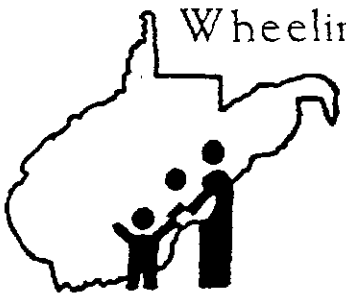
The new proposal appears to conflict with the decisions of this Advisory Board Appointed on January 3, 1992, by Governor Gaston Caperton. I **strongly urge** the State of West Virginia to establish qualifications for testing personnel that are of a higher standard than CLIA'88, such as those stated in the above-mentioned Report from the Clinical Laboratories Quality Assurance Act Advisory Board.

6. The proposed rule exempt from the certification requirements personnel who are employed in a laboratory holding a CLIA certificate other than a certificate of waiver. This, again, defaults to the CLIA regulations, which have already been found as "inadequate to maintain the health and safety of the people of West Virginia" by the governors appointed committee. I feel that such a rule would undermine the very purpose of the Act.

Cathy J. Carver, BS MT(ASCP)
Laboratory Director
Cardiovascular and Medical Specialists, Inc.
485 Colliers Way Suite A
Weirton, WV 26062
(304)387-3047 phone and fax

Cathy Carver BS MT(ASCP)
7-17-95

Received Regulatory Dept 7/17/95



Wheeling - Ohio County WIC Program
HEALTH DEPARTMENT, ROOM 106
1500 CHAPLINE STREET
WHEELING, WV 26003
(304) 234-3888

DATE: July 20, 1995

TO: Nancy Lovell Tyler, M.S.W., Esq.
Director, Office of Health Facility Licensure
and Certification

FROM: Beth Dowler, Project Director
Wheeling-Ohio County WIC Program

RE: Clinical Laboratory Technician and Technologist
Licensure and Certification

The Wheeling-Ohio County WIC Program is required to obtain hemoglobin levels on clients for certification for the WIC Program. We hire and train individuals to obtain these levels via a finger stick and using the Hemcue machine.

The individuals hired to conduct these levels have at least a high school degree and go through a training period. They are also sent to the State Hygienic Laboratory for proficiency testing. The West Virginia State WIC Program also provides training for these individuals.

The proposed rule of making these individuals be licensed and certified could cause the WIC Program great hardship. We could lose personnel and this would cause a reduction of staff to provide service to our clients. We are trying to build caseload and this would definitely impact this effort. We not also not be able to find enough individuals with the required qualifications.

I would like to discourage this rule from being implemented.

July 20,1995

Kimberly Cheuvront, MT(AMT, ASCP)
Member, Clinical Laboratory QA
Advisory Board
Fairmont General Hospital
Laboratory Administrator
1325 Locust Avenue
Fairmont, WV 26554

Regulatory Development
Department of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305
Attention: Kay Howard

COMMENTS ON PROPOSED RULE #57 Clinical Laboratory Technician and Technologist Licensure and Certification.

The Clinical Laboratory Quality Assurance Advisory Board presented recommendations to the Department in December of 1992. I feel that the proposal of the board would ensure quality lab results in West Virginia. The standards in the proposed regulation seem too lenient. I would recommend to the Department to review and to consider using the contents of the proposal provided by the Advisory Board.

Respectfully,

Kimberly Cheuvront

My final concern is that by exempting CLIA lab personnel, the income base will be so drastically reduced as to make the cost prohibitive.

My other concerns are over wording of the proposed rules. I would prefer "licensure" to "certification." Certification implies passing a registry or other board-type examination administered by the NCA, ASCP, or other certifying body. These proposed rules do not address this process.

The term "Clinical Laboratory Scientist" is used to define all personnel to be licensed under WV Code § 16-5J-10. Clinical Laboratory Scientist is widely recognized as one of the categories of certification by the National Certifying Agency, and is limited to individuals with a baccalaureate degree or an associate degree plus 4-6 years of advanced laboratory practice. This definition does not apply to all personnel covered by these rules and creates confusion.

Finally, I think there needs to be clarification of the role of "Clinical Laboratory Supervisor." As written, the proposed rules seem to exclude the supervisor from licensure, and therefore from bench testing. I am sure this is not the intent.

Thank you very much for the opportunity to comment.

Sincerely,

Nancy Endrizzi

Nancy Endrizzi

To: Regulatory Development Dept.
of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

ATTN: Kay Howard

From: Nancy Endrizzi BSMT(ASCP), CLS(NCA)
RD 4, Box 95B
Wheeling, WV 26003

Regarding: The proposed rules for the West Virginia Clinical Laboratory Quality Assurance Act (WV Code § 16-5J-10).

July 21,1995

I am a clinical laboratory scientist with 17 years experience in large university based hospital settings and a small private laboratory. I currently practice at a physician's office laboratory in Wheeling.

I am very pleased to see that the state is moving ahead toward licensure of clinical laboratory testing personnel. Through this proposed licensure plan, the State of West Virginia can effect some very positive safeguards of the accuracy of laboratory testing, and improve the quality of patient care for its citizens.

I am very concerned about a few points. My main concern is over the exemption of persons employed in a CLIA certified lab. The CLIA regulations have proven to be too unstable over the past seven years. We should not base our rules on constantly changing criteria.

In addition, the CLIA personnel regulations are frankly too lax in certain areas. I was involved in the original drafting of this licensure bill, and it has always been the intent of the bill to establish personnel qualifications that were of a higher standard than the current CLIA regulations. Specifically, a minimum of a Baccalaureate degree to qualify to perform highly complex testing, a minimum of an Associate degree to perform moderately complex testing, and a minimum of a high school diploma and documentation of appropriate training in a clinical laboratory to perform waivered tests and to produce results of moderate complexity when directly supervised by a technician or technologist. A supervisor should possess a Baccalaureate degree to oversee highly complex testing and a minimum of an Associate degree to oversee waivered and moderately complex testing.

To dilute these qualification requirements by relying on CLIA regulations is to defeat the intent of the licensure, and to waste manpower and money for the State of West Virginia. As I read the current proposed rules, laboratories performing only waivered tests would be held to higher personnel requirements than those labs doing highly complex testing under CLIA.

Additionally, the continuing education requirement would be lost to personnel in CLIA certified labs, as CE is not addressed by CLIA. Continual updating of skills and knowledge base is critical to good practice. This requirement would benefit personnel, hospitals and other lab sites, and ultimately the patient. Please don't allow it to be exempted for any reason.

STATE, MARSHALL UNIVERSITY, AND WEST VIRGINIA UNIVERSITY
HEALTH CARE REFORM WILL CERTAINLY FORCE FACILITIES TO CUT

COSTS SEVERELY; THIS RULE EFFECTIVELY HANDS ADMINISTRATORS A KNIFE WITH WHICH TO CUT.

I WOULD LIKE TO SUGGEST THAT THE PROPOSED RULE BE TAKEN BACK A STEP. ALLOW RECOGNIZED HEALTH CARE PROVIDERS FROM ACROSS THE STATE TO ASSIST IN THE DEVELOPMENT OF THE NEW PROPOSAL. THE THEORY IS A GOOD ONE THAT WILL HAVE A POSITIVE AFFECT ON THE QUALITY OF HEALTH CARE IN THE STATE AS WELL AS BEING A SOURCE OF REVENUE. THESE SAME RESULTS ARE ATTAINABLE WITHOUT ADVERSELY AFFECTING MY PROFESSION AND MY ABILITY TO BE PROFESSIONAL IN MY ACTIONS.

IF PHYSICIANS ARE THE BRAINS AND NURSES ARE THE HEART OF HEALTH CARE, THEN, CERTAINLY, LABORATORIANS ARE THE MUSCLE. PLEASE DO NOT WEAKEN OUR PERFORMANCE BY STOPPING THE FLOW OF LIFE-GIVING QUALITY INTO OUR SYSTEMS.

SINCERELY,

Steven D. Ewers SM(ASCP)

STEVEN D. EWERS, SM (ASCP)

JULY 21, 1995
BOX 121 ALLENS RT.
SISSONVILLE, WV
25320

REGULATORY DEVELOPMENT DEPT.
HEALTH & HUMAN RESOURCES
ROOM 265, BUILDING 3, CAPITOL COMPLEX
CHARLESTON, WV 25305

TO WHOM IT MAY CONCERN:

IT HAS COME TO MY ATTENTION THAT A RULE HAS BEEN PROPOSED CONCERNING CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION. I AM A MEDICAL TECHNOLOGIST CERTIFIED BY THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS AND HAVE PRACTICED MY PROFESSION FOR 10 YEARS. I APPLAUD THE CONCEPT OF LICENSURE. A MAJORITY OF THE OTHER HEALTH CARE PROFESSIONS HAVE SUCH STANDARDS AND HAVE BENEFITTED GREATLY. I AM DISAPPOINTED, HOWEVER, IN THE APPARENT HASTE WITH WHICH THIS PROPOSAL WAS WRITTEN. THE DOCUMENT HAS MANY OVERSIGHTS AND SHORT-COMINGS THAT COULD, OVER TIME, RENDER ENTIRE CLINICAL LABORATORIAN LEVELS OBSOLETE, DISSOLVE COLLEGE AND UNIVERSITY PROGRAMS, AND ADVERSELY AFFECT THE QUALITY OF HEALTH CARE IN THE STATE OF WEST VIRGINIA.

IT HAS LONG BEEN MY BELIEF THAT THE WORD "PROFESSIONAL" SHOULD NOT BE A NOUN; IT IS AN ADJECTIVE. ONE SHOULD NOT BE DESIGNATED A "PROFESSIONAL" BY ANY GROUP OR BY THE YEARS OF EDUCATION COMPLETED. ONE SHOULD BEHAVE IN A PROFESSIONAL MANOR - MEANING A CONCERN FOR AND PRIDE IN THE GIVING OF QUALITY RESULTS AND CARE. THOSE OF US THAT HAVE BEEN TRAINED AS LABORATORY TECHNICIANS AND TECHNOLOGISTS HAVE THAT DEFINITION IN MIND EVERY DAY THAT WE ARE ON THE JOB. EACH PATIENT WHOSE SPECIMENS I DEAL WITH, I SEE AS EITHER MY 87-YEAR-OLD GRANDMOTHER OR MY 3-YEAR-OLD SON. WOULD YOU WANT ANYTHING LESS FROM A HEALTH CARE PROVIDER? I ASK THAT YOU NOT ALLOW HEALTH CARE FACILITIES THE OPTION OF GIVING UNDERTRAINED INDIVIDUALS THE RESPONSIBILITY INVOLVED IN PERFORMING LABORATORY TESTING AND, IN ESSENCE, ELIMINATING JOB POSSIBILITIES FOR THOSE OF US WHO HAVE COMPLETED TWO OR FOUR YEAR PROGRAMS OR THE EQUIVALENTS.

IT IS MY OPINION THAT PROPOSED RULE #57 WOULD OPEN THE DOOR FOR HEALTH CARE FACILITIES WHO MAY BE OVERLY CONCERNED WITH PROFIT AND LESS SO CONCERNED WITH QUALITY TO SEE LABORATORIANS AS ONE GROUP...REFERENCING THIS RULE AS JUSTIFICATION. THIS WOULD CERTAINLY LEAD TO A SINGLE PAY SCALE; MOST PROBABLY THE LOWEST POSSIBLE. WHAT MOTIVATION FOR SELF-IMPROVEMENT WOULD EXIST IF HIGHER SALARY RANGES WERE NON-EXISTENT; AND FURTHERMORE, WHAT WOULD BE THE FATE OF FOUR-YEAR MEDICAL TECHNOLOGY PROGRAMS AT WEST LIBERTY STATE, MARSHALL UNIVERSITY, AND WEST VIRGINIA UNIVERSITY? HEALTH CARE REFORM WILL CERTAINLY FORCE FACILITIES TO CUT

St.Mary's HOSPITAL

July 20, 1995

Kay Howard
Regulatory Department
Department of Health and Human Resources
Room 265 Building 3, Capital Complex
Charleston, WV 25305

To Whom it May Concern:

I am writing to you to comment on the West Virginia Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10).

As the Administrative Director at St. Mary's Hospital Laboratory, an officer in the Clinical Laboratory Manager's Association and a practicing member of the Laboratory community, I applaud the initiatives of the act, but feel that several areas need clarification.

Attached is a list of those issues that must be addressed to insure the quality of testing for the citizens of West Virginia per the original intent of the law. I have also included comments that pertain to costs of the program.

I thank you for consideration of the information contained in this letter. It is my hope that careful consideration of the proposed legislation will end in successful resolution.

Sincerely,

Julie Graham, M.T.
Administrative Director
Laboratory Services,
President, WV CLMA

JG/vly

July 13, 1995

Kay Howard
Regulatory Development
Department of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

I appreciate the opportunity to comment on Rule 57 on the Clinical Laboratory Technician and Medical Technologist Licensure and Certification Bill. I believe that the proper implementation of a licensure bill for laboratory personnel would help to strengthen the profession and thus maintain the excellent quality of care which is provided by qualified Medical Laboratorians. After scrutiny I believe this legislation will adequately serve the needs of the people of West Virginia and assure continued quality work. Your support of Rule 57 will be greatly appreciated.

Sincerely,

Garnet J. Given

Garnet J. Given, M.A., MT(ASCP)
Clinical Director, Laboratories
Charleston Area Medical Center
3200 MacCorkle Ave. S.E.
Charleston, WV 25304

separate lab discipline ie My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

6.2: Won't apply if 6.1.2 is eliminated.

6.3.1: Eliminate "are exempt from such certification under this rule".

6.4 & 6.5: Additional clarification is need define what the secretary will approve and the process for approving. Also additional clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs.

7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to include provide documentation of "registry eligible".

8.2.1: The state law was intended to establish personnel standards higher than those implemented within CLIA. What happens if CLIA personnel standards change?

Under certification requirements we recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of two years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA, 493.1489 (5) needs to be deleted as qualifications for high complexity testing since it is contradictory to the original intent of the law as approved by the State of West Virginia.

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of a 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities.

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

3.6: Define how long it will take to obtain a license, post graduation. Also insert the work accredited to the training program.

3.12: Define biophysical.

64-59-4: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

6.1.2: Strike this completely. We are not sure of the intent of this line. If adopted as written, would that mean that laboratorians would become specialized and could not practice in a

CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Maurice Hosky
EVENING/NIGHT SUPERVISOR

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

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Calhoun Gilmer Jackson Mason Pleasants Ritchie Roane Wirt Wood

WIC PROGRAM
Mid-Ohio Valley Health Dept.
211 6th St.
Parkersburg, WV 26101
304-428-3688

July 21, 1995

Ms. Kay Howard
Regulatory Development Department of H & HR
Room 205, Building 3 Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

The proposal regarding licensure/certification of lab technicians just reached my desk this afternoon.

I believe trained personnel doing the hemocue procedure for WIC clients should be waived from mandatory licensure requirement.

We have RN's, LPN's, Nutritionists plus trained OA II's and HS workers doing this. All are well trained for doing the procedures as well as to OSHA regulations.

It would be a hardship on the WIC program to require licensure in addition.

Sincerely,

Pat Hanlon RD

Pat Hanlon, R.D., MOVHD WIC Director

cc: Denise Ferris

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Thank you.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

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7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

Ms. Kay Howard
July 24, 1995
Page Two

We hope that you will give serious consideration to these recommendations. If they are not clarified, they could significantly increase our costs and negatively impact our ability to render effective patient care.

If you would like to discuss this matter, please do not hesitate to contact us.

Sincerely,

Donald H. Hofreuter, M.D.

Donald H. Hofreuter, M.D.
Administrator/C.E.O.

DHH/mr

c: Jane G. Harless
Director of Data Services, WVHA
Gary R. Gould
Robert Dorisio

WHEELING HOSPITAL
1 MEDICAL PARK
WHEELING, WV 26003-6300
304-243-3000
FAX 304-243-3060

July 24, 1995

Ms. Kay Howard
Regulatory Development
Department of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, West Virginia 25305

Dear Ms. Howard:

The purpose of this letter is to comment on the proposed rule regarding Clinical Laboratory Technicians and Technologist Licensure and Certification. Accordingly, I would like to offer the following suggestions:

1. Continuing Education

The rules should indicate that documented inservice education programs conducted by accredited hospitals would qualify to meet the continuing education requirements of the proposed rule.

2. Specimen Processing

The proposed rule should be clarified to indicate that individuals involved in specimen processing only would not be subject to the certification requirements. This would include phlebotomists, histology technicians, clerical, and other support staff.

3. Point-of-Care Testing

The proposed rule should be modified to be consistent with the CLIA guidelines which permit point-of-care testing by non-laboratory technicians under certain specified guidelines. The CLIA provisions which permit respiratory therapists to perform blood gas analysis should also be included in the proposed rules.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

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CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Judy Jordan, MT, C (ASCP)
Assistant Administrative Director Laboratory

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

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Rules: 2.2.3: Does this exempt employees and facilities or just facilities?

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

1041C Irwin St
Morgantown WV 26505

July 20, 1995

Regulatory Department
Dept of Health + Human Resources
Rm 265 Building 3 - Capitol Complex
Charleston WV 25305

Dear Ms Howard,

I am a medical technologist and am writing concerning the proposed rules for WV Clinical Laboratory Quality Insurance Act. I support the position of the West Virginia State Clinical Laboratory Society regarding these proposed rules.

These proposed rules water down the intent of W.V. licensure for clinical laboratory science practitioners. The propose rule exempts from certification requirements personnel employed in a laboratory holding a CLIA certificate other than Waiver. This adopts minimum CLIA regulations. The purpose of state licensure was/is to establish qualifications that are higher standard than CLIA 88. Our state medical technology organization supports the inclusion of supervisors

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to provide documentation of "registry eligible".

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Thank you.

Wheeling — Ohio County Health Department

City County Building - Room 106 1500 Chapline St.
Wheeling, WV 26003 Phone 234-3682 Fax # 234-6408

THOMAS L. THOMAS, M.D.
Director

July 20, 1995

Regulatory Development
WVDHHR
Room 265, Bldg. 3, Capitol Complex
Charleston, WV 25305

ATTEN: Kay Howard

RE: Clinical Laboratory Technician and Technologist
Licensure and Certification Proposed Rule 64CSR57

Dear Ms Howard,

Concerning Article 2.2.1 of the above referenced proposed rule, combined local boards of health should also be included in this article as organized under West Virginia Code 16-2-3. Our local health department, Wheeling-Ohio County Health Department, as well as others throughout the state are organized under this article of the West Virginia Code.

Reference could be made under this and other articles to local health departments rather than county health departments.

Sincerely,

Larry W. Lewis
Administrator

LWL/jf

in the group of testing personnel. These proposed rules do not allow this.

I ask you to carefully consider the position of the State society and make necessary changes in proposed rules to carry out the needed intent and purpose of state licensure for personnel working in clinical laboratory.

Thank you for your consideration.

Sincerely

Mary Ellen Kaern

Mary Ellen Kaern
1041 C Irwin St.
Morgantown WV
26505

separate lab discipline is My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

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Sincerely,

Marcia Lightner, M.T.(ASCP)

Laboratory Supervisor

HUNTINGTON INTERNAL MEDICINE GROUP
1115 20th Street
Huntington, W. V. 25703

To: Kay Howard
Comment:

July 21, 1995

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of a 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities.

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

3.6: Define how long it will take to obtain a license, post graduation. Also insert the work accredited to the training program.

3.12: Define biophysical.

64-59-4: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

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CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO:
Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Tom Lightner
Administrative Director Laboratory

SUBJ[redacted] ic Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

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Regulatory Department
Dept. of Health and Human Resources
Room 265 Building 3 Capitol Complex
Charleston, WV 25305
ATTN: Kay Howard
FAX: 558-1130

July 17, 1995

Comments Regarding Proposed rules for the WV Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10):

1. I believe that the Act should be under the jurisdication of a State Licensing Board, and not the HFLAC, which performs CLIA inspections. This would relieve existing potential loss of revenue from HCFA for CLIA inspections and put the personnel licensing issue into experienced hands.

2. The negative, **theoretical**, outcomes stated in the fiscal note (possible increase in health care costs, and reduction in lab services), while highly unlikely, would **certainly** be minimal and offset by the **positive outcomes** such as increased accuracy and reliability of laboratory results. Enhanced quality in laboratory testing will always lead to a **decrease** in health care costs, since erroneous lab results attribute to repeat testing, misdiagnosis and unnecessary hospitalization.

3. The term "Clinical Laboratory Scientist" has an industry-wide definition of an individual with a baccalaureate degree and certified by the NCA. Therefore, I suggest that a more general term be utilized to define testing personnel under WV Code 16-5J-10. Also, I support the inclusion of Clinical Laboratory Supervisor in the group of testing personnel required to be licensed. If not, they could neither perform testing nor be included in the grandfather clause. Inclusion of this group into the general definition would allow individuals to remain in positions that they currently hold.

4. The proposed rule lists a set of **Certification Requirements** that includes: anyone meeting the minimum requirements set forth the CLIA'88 regulations to be licensed as a Clinical Laboratory Scientist in the State of West Virginia. However, in the April 29,1993 Report From The Clinical Laboratories Quality Assurance Act Advisory Board -TO- William T. Wallace, Jr., M.D., M.P.H. Commissioner, Bureau of Public Health:

> "The qualifications and duties of the various categories of laboratory personnel were carefully considered by the Board. There was consensus that the federal government's legislation in the Clinical Laboratory Improvement Act of 1988 (CLIA'88) was generally **inadequate** to maintain the health and safety of the people of West Virginia...."

The new proposal appears to conflict with the decisions of this Advisory Board Appointed on January 3, 1992, by Governor Gaston Caperton. I **strongly urge** the State of West Virginia to establish qualifications for testing personnel that are of a higher standard than CLIA'88, such as those stated in the above-mentioned Report from the Clinical Laboratories Quality Assurance Act Advisory Board.

5. The proposed rule exempt from the certification requirements personnel who are employed in a laboratory holding a CLIA certificate other than a certificate of waiver. This, again, defaults to the CLIA regulations, which have already been found as "inadequate to maintain the health and safety of the people of West Virginia" by the governors appointed committee. I feel that such a rule would undermine the very purpose of the Act.

Sincerely,

Joanna Magnone, BS MT(ASCP)

Joanna Magnone, BS MT(ASCP)
Testing Personnel/Supervisor
Cardiovascular and Medical Specialists, Inc.
485 Colliers Way Suite A
Weirton, WV 26062
(304)723-5500 phone
723-5516 fax

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to provide documentation of "registry eligible".

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Under certification requirements I recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of two years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA, 493.1489 (5) needs to be deleted as qualifications for high complexity testing since it is contradictory to the original intent of the law as approved by the State of West Virginia.

Thank you.

Comment:

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Jackson General Hospital

P.O. BOX 720, RIPLEY, WEST VIRGINIA 25271 • PHONE (304) 372-2731

July 24, 1995

Kay Howard
Regulatory Development
Department of Health & Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

I am a member of the West Virginia Clinical Laboratory Management Association. We, in the Laboratory Management Community, are concerned about the preservation of quality personnel standards within this Licensure and Certification Proposal. I have reviewed the rules proposed by the WVCLMA and feel that they are preferable to the existing document. The exemptions allowed by this State's document are not acceptable. Personnel exemption for waived testing is the only area which appears logical. Certification by the A.S.C.P., N.C.A., or A.M.T. should be the standard qualification for licensure. A "grandfather" rule could be inserted to allow licensure of all existing workers, with a cut-off date to begin mandatory certification requirements.

Thank you.

Sincerely,

Peggy S. Manuel, MT(ASCP)

Peggy S. Manuel, MT(ASCP)
Chief Technologist of Laboratory Services
Member, WVCLMA

CABELL HUNTINGTON HOSPITAL

1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay
Regional Department
Department of Health & Human Services
Room 2[illegible] Building 3, Capital Complex
Charleston, WV 25305

FROM: Patricia M. Meadows
Director of Patient Administration

separate lab discipline ie My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

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7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

Regarding 64-59-5.2 which authorizes the use of students and yet-to-be certified personnel for testing purposes under "proper" supervision,this is a flagrant weakness. No restrictions are placed on the length of time a person may be classified as a trainee. Under these terms an individual unable to meet certification requirements could continue to perform testing, unlicensed, if his/her employer merely added the word "trainee" to his/her title.

Regarding 64-59-6.2 which contradicts 64-59-2.2.2, a literal interpretation of these two sections indicates that this rule does not apply to my tax-exempt primary-care employer, however, it does apply to me as an employee of such, except in regards to licensure requirements. This is extremely vague and desperately needs clarification.

Regarding 64-59-6.4, requiring an applicant to complete 10 hours of continuing education, currently nearly 10 real time hours must be invested to yield 1 continuing education hour. The time away from work and the cost of such education will make this a difficult, if not impossible pre-requisitive.

Regarding 64-59-8.2.1 exempting employees of CLIA certified labs from certification, this is another glaring weakness. Too many can claim exemption using this section.

Regarding 64-59-11.1 restricting licensure from authorizing the performance of tests by an individual unless he/she is determined qualified using additional criteria, this section strips nearly all control from the license. What powers will it have?

July 19, 1995

Ms. Howard,

As an ASCP certified medical technologist, with a four year bachelor of science degree, meeting the qualifications for and classified as a high complexity testing general supervisor in a primary health care center having tax exempt status, I have several concerns about proposed rule - Title 64 - West Virginia Administrative Rules Department of Health and Human Resources - Series 57 - Clinical Laboratory Technician and Technologist Licensure and Certification.

Regarding 64-59-3.5, defining a Clinical Laboratory Scientist, two points come to mind. The term Clinical Laboratory Scientist is widely associated with a certification category used by the National Certifying Agency. Use of this term may cause unnecessary confusion over an individual's educational background. Additionally this definition goes on to exclude supervisors from this category. In my current position I am classified as a general supervisor under CLIA regulations. I also perform the tasks enumerated in 64-59-3.5. As a general supervisor, I would be excluded from licensure and prohibited from performing said tasks by 64-59-5.1. Under these terms, I would be forced to choose between supervisory status and my bench job (i.e. salary). This will also be financially prohibitive in smaller laboratory situations where the supervisor assumes dual roles.

701 MILFORD STREET
CLARKSBURG, WV 26301-4041
JULY 17, 1995

Regulatory Development
Department of Health & Human Resources
Room 265, Bldg, 3, Capitol Complex
Charleston, WV 25305
ATTN: Kay Howard

Dear Ms. Howard:

The following comments apply to the proposed rules for the West Virginia Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10).

The Governor appointed an Advisory Board to recommend rules for this Act. The board, which consisted of professionals with a good understanding of the need and responsibility of a good licensure law, spent a great deal of time in recommending good guidelines. I am deeply disappointed that the work done by the advisory board was ignored. Tax dollars were spent on this Board and to have their input ignored is a crime. It is this kind of action that creates bad attitudes toward our State government.

The entire purpose of this legislation, which had been worked on since the early seventies by medical technologists within the state, was to assure professional quality laboratory results within West Virginia. The federal CLIA '88 Act falls short, especially in the area of personnel standards, in assuring such quality. The need for State Legislation has been demonstrated by other states that are working on or have passed similar legislation. Why should the citizens of Florida and California, to mention just two, have better quality health care than those in West Virginia.

The economic impact study demonstrates the lack of understanding of the laboratory profession. This study is totally negative and totally ignores the cost of inaccurate laboratory values that result in unneeded medication, inappropriate hospitalization, and death.

There appears to be several inconsistencies within the rules as to who is exempt. Primary health centers and county health departments seem to be exempt provided that the employed scientists are covered. (2.2.1 and 2.2.2) Elsewhere in the proposed rules they are totally exempt. (8.2.1) Only federal government and research laboratories should be exempt from these regulations. A little research would demonstrate that primary health centers **should not be exempt.**

Grouping all laboratory personnel into Clinical Laboratory Scientists is a mistake. Baccalaureate and associate degree individuals should be placed into different categories. The already existing certification programs offered by the ASCP, AMT, and NCA could be

Having been in the laboratory profession for ten years, I am in favor of a licensing process that screens unqualified personnel using a reasonable set of guidelines. It is my opinion the licensing process set forth by Title 64 is in many ways unreasonable. It is desirable, then, to review these regulations once more, perhaps considering recommendations made by the West Virginia Clinical Laboratory Quality Assurance Advisory Board, in order to develop a licensing procedure that will benefit all of us.

Sincerely,

Suzanne E. Messenger, MT (ASCP)

Suzanne E. Messenger, MT (ASCP)

S. E. Messenger
1263 Pleasant Valley Rd
Fairmont, WV 26554

To Whom it May Concern:

As a practicing laboratory professional, I am very concerned about the proposed rule affecting our profession: Rule No 57, titled the CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION rule.

After reading the documents outlining the proposed law, I find there are many inconsistencies, as well as ridiculous requirements. An Advisory Council was appointed to have input in the making of this law. Were their guidelines completely ignored?

I urge you to rethink the entire rule, and please let those who are in the profession help you come up with a rule that is both workable and reasonable.

Sincerely,

Helen M. Moran

Helen Moran, MLT(ASCP)

Moran
901 Marion Ave.
Fairmont, WV 26554

incorporated within the rules. These professional certification programs would provide the State with real professional guidelines at minimal expense.

Continuing education requirements for license renewal is good but needs to be better defined.(6.4) The criteria for what is approved is critical and should be addressed. Ten hours of CEU credits is approximately 100 hours of attendance. This could be both costly and difficult to obtain depending on what is approved by the secretary.

Laboratory Supervisors need to be incorporated under the licensure law since most perform testing.(3.5) Clinical Laboratory Scientist Trainees should have a specified time period to become licensed after graduation from an approved program.

The Exemption from Certification (64-59-8) is confusing. 8.2.1 implies that anyone working in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver is exempt. This would be everyone that should be licensed.

Because of the political nature of the CLIA '88 rules, it is of paramount importance that there not be reference to these rules within our state regulations. There is a better way. West Virginia and its citizens deserve quality health care. A proper set of rules can help assure that this goal is met at minimal cost in the short run and a savings long term.

Sincerely,

Irvin A. Miller

Irvin A. Miller, M.S., M.P.H., MT(ASCP)

Charleston Area Medical Center

Memorial Division

3200 MacCorkle Avenue, SE
Charleston, West Virginia 25304
304 348-5432

To: Kay Howard
Regulatory Development
Department of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

From: Phillip D. Scott
Charleston Area Medical Center
Director of Perfusion Services
3200 MacCorkle Ave. S.E.
Charleston, WV 25304

Date: July 24, 1995

Dear Mr. Kay,

I am responding to proposed legislation involving the licensure and certification of laboratory technicins. The issues I care to address stem from the PROPOSED RULE TITLE 64 CSR 57 CLINICAL LABORATORY AND TECHNOLOGIST LICENSURE AND CERTIFICATION.

****

The top of page three states that "clinical laboratory scientist" includes laboratory technicians and laboratory technologists, but does not... The top of page four defines a Laboratory Technician as "A clinical laboratory scientist." It also defines a Laboratory Technologists as "A clinical laboratory scientist." Is this generic terminology for the professions of "Medical Laboratory Technicians and Medical Technologists"? No where directly within the Proposed Ruling is the term Medical Technologists or Medical Laboratory Technician used.

Within the Certification Requirements listed on page six, item 7.2.4.a. includes "Testing personnel found at: 42 CFR 493.1423, 493.1489, or 493.1491. These classifications reflect a great number of personnel outside of the realm of Medical Technologists or Medical Laboratory Technicians. I would propose that the top of page three read: The term "clinical laboratory scientist" include laboratory technicians, laboratory technologists, and personnel meeting the requirements of 42 CFR 493.1423, 493.1489, or 493.1491. This statement would encompass all personnel deemed appropriate for laboratory testing in accordance to the CLIA '88 regulations.

****

There appears to be confusion between the Certification

Webster County Memorial Hospital
324 Miller Mountain Drive
Phone 304-847-5682
Webster Springs, West Virginia 26288

July 12, 1995

Regulatory Development
Department of Health & Human Res.
Room 265, Bld. 3 Capitol Complex
Charleston, WV 25305

ATTN: Kay Howard

I am a Laboratory Tech in rural West Virginia at Webster County Memorial Hospital where I have worked for the last 12 years doing high complexity testing. I was trained on the job, and also by attending various workshops. I am a current member of ISCLT as a POLT. I think my experience shows that I am capable of doing the work, therefore I should be recognized by the State of West Virginia.

Sincerely,

Joe Pugh, POLT

Joe Pugh
TC Airport Rd.
Webster Springs, WV
26288

Nicholas County Health Department
1 Stevens Road
Summersville, West Virginia 26651
(304) 872-5329

Public Health *Environmental Health*

July 18, 1995

Mr. Frank W. Lambert, Jr., Dr. P.H., Director
Office of Laboratory Services
Bureau for Public Health
Department of Health and Human Resources
State Capitol Complex, Building 3, Room 518
Charleston, WV 25305

Dear Dr. Lambert:

This is regarding the proposed rule 64 CSR 57, Department of Health and Human Resources Clinical Laboratory Technician and Technologist Licensure and Certification.

Section 6.4 and 6.5 specifies a requirement of "10 hours of continuing education from a program ... approved by the secretary...". For a Waived Laboratory performing pregnancy tests, Hemocue hemoglobins, dip-stick urinalysis and blood sugar testing with a glucose testing device, the 10 hours of continuing education requirement seems excessive.

Another point to make is that, since our laboratory is waived, it would be of little value for our department to send the staff to laboratory training sessions where the subject matter is beyond the scope of a "Waived Laboratory."

This is to suggest that the required number of training hours and subject matter be based on the CLIA complexity level of the laboratory.

If you have any questions regarding the this matter, please contact me at 872-5328.

Thank you,

Diana Sears
Administrator

Requirements and the Exemption from Certification. Is it intended that the same body of people required for certification are also eligible for exemption? Item 7.2.4.a. of the Certification Requirements reads identical to item 8.2.2.a. of the Exemption From Certification. If personnel within these classifications are considered "Optional", then this might be appropriately intended, however, somewhat confusing.

****

As a Perfusionist within the state of West Virginia, I am prompted to point out that many areas of the hospital perform laboratory testing with non-laboratory personnel. Point of Care testing has become an extremely time efficient capability while in most cases reducing the cost involved. There are several allied health professions that sufficiently train in the areas of physiological and laboratory sciences that permit non laboratory personnel to perform diagnostic tests. As long as these persons are incorporated within the certification and licensure expectations, all parties may and will continue working in harmony within numerous health care facilities. If, however, there is an attempt to isolate testing to the Medical Technologist and Medical Laboratory Technician professions, a severe manpower shortage will become imminent and the quality of professional health care within inpatient facilities will definitely become hindered.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

3.6: Define how long it will take to obtain a license, post graduation. Also insert the word "accredited" to the training program.

3.12: Define biophysical.

64-59-4: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

6.1.12: Strike this completely. I am not sure of the intent of this line. If adopted as written, would that mean that laboratorians would become specialized and could not practice in a separate lab discipline? i.e. My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

6.2: Won't apply if 6.1.2 is eliminated.

6.3.1: Eliminate "are exempt from such certification under this rule".

6.4 & 6.5: Additional clarification is needed to define what the secretary will approve and the process for approving. Additional clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs?

7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Margaret Smith
Section Chief, Cytology Dept.

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities?

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

ROBERT C. BYRD
HEALTH SCIENCES CENTER
OF WEST VIRGINIA UNIVERSITY
Department of Pathology

George Rider, Executive Secretary
West Virginia State Medical Association
P.O. Box 4106
Charleston, WV 25364

July 12, 1995

Re: (Proposed) 64 CSR 57, Clinical Laboratory Technician and Technologist Licensure and Certification

Dear George:

At your request, I have reviewed the above proposed West Virginia Administrative Rules from the Department of Health and Human Resources which you sent to me. I have comments as follows:

1. Since this deals with *licensure of personnel*, why put section 2.2 in the rule? County health departments, primary health care centers, and laboratories are not personnel.

2. The rule does not make a distinction, in its definitions, between Laboratory Technician and Laboratory Technologist. There is an important difference regarding their training. Consider changing the rule to read as follows:

   3.10. **Laboratory Technician** - A clinical laboratory scientist *with a two-year associate's degree.*

   3.11. **Laboratory Technologist** - A clinical laboratory scientist *with a four-year bachelor's degree.*

3. Why have section 6.2? Why should county health departments or tax exempt primary health care centers not supply their employees with job descriptions the same as everybody else?

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to provide documentation of "registry eligible".

8.2.1: The state law was intended to establish personnel standards higher than those implemented within CLIA. What happens if CLIA personnel standards change?

Under certification requirements I recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of two years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA, 493.1489 (5) needs to be deleted as qualifications for high complexity testing since it is contradictory to the original intent of the law as approved by the State of West Virginia.

Thank you.

Webster County Memorial Hospital
324 Miller Mountain Drive
Phone 304-847-5682
Webster Springs, West Virginia 26288

July 12, 1995

Regulatory Development
Department of Health & Human Res.
Room 265, Bld. 3 Capitol Complex
Charleston, WV 25305

ATTN: Kay Howard

I am a Laboratory Tech in rural West Virginia at Webster County Memorial Hospital where I have worked for the past 9 years doing high complexity testing. I received on the job training and have attended various workshops. I am a current member of ISCLT as a POLT. I think my experience shows that I am capable of doing the work, therefore I should be recognized by the State of West Virginia.

Sincerely,
Paulette Stout
Paulette Stout, POLT

Paulette Stout
10 Sugar Creek Rd
Webster Spgs, WV 26288

4. The whole section on exemption from certification may be unnecessary. Particularly sections 8.2.1 and 8.2.2. If requirements are less stringent than those of CLIA, then CLIA automatically supercedes them. The entire section on exemption would seem to be superceded by CLIA.

If we need to discuss any of this, you can call me at 293-3212. O therwise, I will plan on seeing you in Charleston on July 19.

Yours truly,

Jeffrey A. Stead, M.D.

I bet no laboratory came up with this IDea!!!
Proposed Rule. Title 64 Series 57

ATTN: Kay Howard This whole IDEA is Ridiculous

First of all, What do you mean by remuneration?

6.1.3 A licensure fee? you've got to be kidding. I have to already Pay yearly dues for ASCP AND NCA, now this! Lab employees in West Virginia are on the list of the lowest income per year. Factory workers make more money than we do. We should be paid more to come here or to stay here to work in this State!

License fee; Just Another way for the State to make more money

I can not believe that this proposed rule is being thought of. Small hospitals are merging into the large ones and people are being layed off. Quit wasting time and money that are so stupid.

6.6 Sounds like the secretarial position is more important than the whole issue!

7.1 So if MLT'S (ASCP)(NCA) and MT'S(ASCP) are both being considered as CLS, then why are there or is there a 2 year program for laboratory and a 4 year program for laboratory. Are colleges going to encourage their students to come to this State to get a job? I Don't think SO! The only reason why people stay in the lab field in this State is because of family.

So why get a Bachelor degree when an Associate degree is acceptable Boy, we sure are encouraging continued education!

So, how do propose to differentiate pay of MLT'S to MT'S and do you? You had better.

July 18, 1995

To Whom It May Concern,

I have had an opportunity to review the proposed rules for Clinical Laboratory Technicians and Technologists Lisensure and Certification (Reference 64 CSR 57). I feel these proposed rules are not appropriate for our profession. There are too many inconsistencies and rules which would not benefit our interests in upholding the integrity of our positions as Labratorians. I feel the input of the Advisory Committee is greatly needed and the rules should be submitted by those which know our profession and can use their knowledge to propose rules beneficial to our profession.

Thank You,
Kimberly E. Tennant MLT (ASCP)

Kimberly E. Tennant
Rt 1 Box 154
Metz, WV 26585

Robin Weisenborn
Route 8 Box 415
Fairmont, WV 26554

Kay Howard
Regulatory Department
Dept. of health & Human Resources
RM 265 Building 3 Capitol Complex
Charleston, WV 25305

Dear Ms. Howard:

I am writing in regard to the recently published proposed rules for the West Virginia Clinical Laboratory Quality Assurance Act (WV Code 16-5J-10). I am a Clinical Laboratory Scientist with twelve years of working experience. I hold a Bachelor of Science degree in Medical Technology. I have been actively involved in laboratory professional organizations for nearly fifteen years. I have served as President of the West Virginia Society for Clinical Laboratory Science (WVSCLS). As a result of my involvement in WVSCLS I have been exposed to the development of WV Code 16-5J-10. While I am pleased to see the licensure of clinical laboratory professionals moving forward, I have some concerns regarding the proposed rules.

The proposed rule adopts the CLIA 88 definitions for Clinical Laboratory Consultant, Supervisor and Director and defines a Clinical Laboratory Scientist as including technicians and technologists but excludes directors, consultants and supervisors.

I strongly urge the use of a general term other than Clinical Laboratory Scientist to define testing personnel to be licensed. Clinical Laboratory Scientist is a widely recognized term utilized by the National Certifying Agency for Medical Laboratory Personnel to define a category of certification limited to individuals with a baccalaureate degree or an associate degree plus 4-6 years of advanced laboratory practice.

I also support the inclusion of clinical laboratory supervisors inthe group of testing personnel to be licensed. If these individuals are not included in the general definition of those to be licensed it appears that they could not perform testing, nor would they be included in the grandfather clause. Including supervisors in the general definition would allow individuals to remain in positions that they currently hold.

The certification requirements proposed in the rule appear to accept the CLIA 88 regulations as the minimum standard for our state. It has consistantly been the intent of the West Virginia Society for Clinical Laboratory Science as well as other laboratroy groups in the state to pursue licensure regulations that require a higher standard than CLIA 88. Recommendations of the West Virginia Clinical laboratory Quality Assurance Advisory Board as well as a position paper from the West Virginia Society for Clinical Laboratory Science cite standards for testing personnel that

Davis Memorial Hospital

RECEIVED
JUL 24 1995
REGULATORY DEVELOPMENT

July 24, 1995

Ms. Kay Howard
Department of Health and Human Resources
Room 265, Building 3 Capital Complex
Charleston, WV 25305

Dear Ms. Howard:

I recently received a copy of the proposed legislation relating to certification and licensing of clinical laboratory technologists and technicians. There are several areas of concern ranging from the cost of operations, grouping technologists and technicians as one title "Clinical Laboratory Scientists", as well as several other concerns in my initial review.

I think it is necessary to extend the period for comments pertaining to this legislation so that a more detailed review can be made, particularly comparing proposed legislation to federal CLIA guidelines.

Thank you for your consideration of this request.

Yours Truly,

Charles Wamsley /sp.
Charles Wamsley,
Laboratory Manager

/sp

▲ Reed Street and Gorman Avenue ▲ P.O. Box 1484 ▲ Elkins, WV 26241
▲ (304) 636-3300 ▲ FAX: (304) 637-3435

CLINICAL LABORATORY AND CLINICAL LABORATORY PERSONNEL LICENSURE

Position Statement of the West Virginia State Society for Medical Technology*

The mission of health care professionals is to ensure the well-being of the patient. Quality patient information provided by clinical laboratory professionals allows physicians to ensure the wellness of the patient by providing for normal growth and development, treatment of repairable conditions and maintenance of conditions that cannot be restored to normal. This is why, we, the membership of the West Virginia State Society for Medical Technology (WVSSMT), support the West Virginia Clinical Laboratories Quality Assurance Act.

WVSSMT believes that it is the intent of this law to provide accurate and reliable laboratory test results regardless of who performs these tests or where they are performed. In order to provide for the intent of this law, it will be necessary to license both laboratory facilities and laboratory testing personnel in the State of West Virginia.

While WVSSMT finds the regulations regarding laboratory testing facilities as set forth by the final rule for CLIA 88, published on February 28, 1992, minimally acceptable, we feel that the personnel standards fall woefully short of those needed to insure quality health care for our citizens.

It is our position that personnel who perform clinical laboratory testing in the state of West Virginia should be graduates of a formal education program and be certified by a nationally recognized certifying agency and be licensed by the state.

We believe that the rules of state licensure should provide for three levels of testing personnel, two levels of supervisory personnel and two levels of directors, as outlined below.

I. **Testing Personnel**

A. Level A - <u>Technologist</u>

1. Minimum education and training - Baccalaureate degree in Medical Technology from an accredited program and pass a validated,competency based examination satisfactory to the board,

2. Tasks - perform waivered, moderately complex, and highly complex testing as set forth by the final rule of CLIA 88, February 28, 1992.

3. Responsibilities - may verify results of testing performed by laboratory assistants.

* Currently known as West Virginia Society for Clinical Laboratory Science

exceed those required by CLIA 88. I have attached copies of both of these documnets for your information.

Overall I believed that the proposed rules for WV Code 16-5J-10 will need to be restructured to clarify the levels of testing personnel who will need to be licensed. I also expect that the proposed rule could be clarified by simplifying the language to include generally acceptable terms to describe these individuals. Most significantly the rules need to reflect a higher standard than the CLIA 88 regulations. These regulations have been under attack by the medical and laboratory community since their initial publication as being too lenient. I would hope that the state of West Virginia would see fit to establish ourselves as exemplery providers of medical care via the delivery of the highest quality laboratory services available rather than accept the woefully inadequate standards adopted by others.

Thank you for you time and consideration of my comments.

Sincerely,

Robin Weisenborn

Robin Weisenborn

B. General Supervisor Level B

1. Minimum education and training - Associate degree from an accredited laboratory technician program and pass a validated, competency based examination acceptable to the board and clinical laboratory experience in the area to be supervised.

2. Responsibilities - may supervise the performance of waivered and moderately complex testing.

III. **Directors**

A. Clinical Administrator

1. Minimum education and training - Baccalaureate degree in Medical Technology with 5 years of clinical laboratory supervisory experience or Masters degree in clinical laboratory science, health care administration or business administration with 2 years clinical supervisory experience.

2. Responsibilities - assumes responsibilities for control of daily laboratory operations.

B. Medical Director

1. Minimum education and training - M.D., Pathologist, certified in clinical pathology or PhD with board certification in a recognized health science.

2. Responsibilities - acts as liaison between laboratory staff and physicians by assisting with formulation of physicians' diagnostic plans.

Continuing Education - It is the responsibility of every clinical laboratory professional to remain current in their field of practice. Therefore, WVSSMT suggests that a minimum of 20 hours of validated continuing education every 2 years be part of the licensure requirements for all levels of practice. This continuing education may be lectures, seminars, workshops, formal classes, in-service programs, or correspondence courses.

WVSSMT suggests that a Licensing Board be established to administer the personnel licensure activities and to be responsible for enforcement of requirements.

Respectfully submitted,
Jeannine R. Meloon
President, WVSSMT (91-92)

B. Level B - Technician

1. Minimum education and training - Associate degree from an accredited Medical Laboratory Technician program and pass a validated, competency based examination satisfactory to the board.

2. Tasks - may perform waivered and moderately complex testing as set forth by the final rule of CLIA 88, February 28, 1992.

3. Responsibilities - may verify results of testing performed by laboratory assistants.

C. Level C - Laboratory Assistant

1. Minimum education and training - High school diploma and documentation of appropriate training in a clinical laboratory.

2. Tasks - may perform waivered tests and operate instruments to produce results of moderate complexity testing requiring little or no operator intervention when directly supervised by a technician or technologist. Results of moderately complex tests must be verified by a technician or technologist before release.

II. **Supervisory Personnel**

A. General Supervisor Level A

1. Minimum education and training - Baccalaureate degree in Medical Technology from an accredited program and pass a validated, competency based examination acceptable to the board, and clinical laboratory experience in the area to be supervised.

2. Responsibilities - May supervise the performance of waivered, moderately complex, or highly complex testing. A technologist who meets the minimum requirements for education and training in this category must be present whenever moderately complex or highly complex testing is being performed. This person may supervise more than one area.

b) certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties,

c) is certified in Microbiology, the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysts, or other national accrediting board in one of the laboratory specialties, and may direct laboratory tests and procedures in the area in which he holds certification, or

d) certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for such certification, or

e) subsequent to graduation has had four or more years of full-time general laboratory training and experience of which at least two-years were spent acquiring proficiency in one of the laboratory specialties in a licensed medical laboratory, or

f) subsequent to graduation has had such other documented clinical laboratory training and experience as the Department determines by rule or regulation is appropriate, taking into consideration the complexity, diversity, and the circumstances related to access to care in rural West Virginia of the laboratory tests to be performed;

(2) For the speciality of oral pathology only, is a dentist who is certified by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification.

(3) He/she holds an earned doctoral degree from an institution accredited by the Southern Association of Colleges and Secondary Schools or an equivalent thereto with a chemical, physical, or biological science as his/her major subject and is certified by the American Board of Medical Microbiology, American Board of Clinical Chemistry, or other accrediting boards acceptable to the Department in one of the laboratory specialties, or subsequent to graduation has had four or more years of general laboratory training and experience of which at least two years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory with a director at the doctoral level of a hospital, a health department, university, or medical research institution and achieving a satisfactory grade on examination conducted or sponsored by the Department. Individuals qualified

* WV Clinical Laboratory Quality Assurance Advisory Board Recommendations

a. To proceed with implementation of the clinical laboratory licensure and licensure of personnel with amendments to the rule to address the provisions of CLIA-88 and to reformat in accordance with current regulatory standards.

The Board voted unanimously against this motion.

b. To repeal that portion of the clinical Laboratory Licensure rule which pertains to the licensure of clinical laboratories.

This motion was carried by a 3 to 2 vote.

c. To continue to study the CLIA-88 provisions in relation to the licensure of laboratory personnel.

This motion was carried unanimously.

2. Personnel Qualifications and Duties:

Personnel qualifications and duties for the Medical Laboratory Director, Medical Laboratory Supervisor, Medical Laboratory Technologist, Medical Laboratory Technician and Laboratory Aide were developed and voted on by the Board during the following meetings:

September 23, October 21, November 18, and December 16, 1992. The following is a compilation of the approved recommendations for personnel qualifications and duties.

QUALIFICATIONS OF MEDICAL LABORATORY DIRECTOR

(1) The laboratory director is a physician licensed to practice medicine or osteopathy who is:

a) certified in clinical and/or anatomical pathology by the American Board of Pathology or possesses qualifications which are equivalent to those required for certification and may direct laboratory tests and procedures in all specialties and subspecialties, or

(3) Holds a baccalaureate degree from an accredited institution and is qualified as a medical technologist and subsequent to the date of qualifying as a medical laboratory technologist, has had at least three years of pertinent full-time clinical laboratory experience of which not less than one year has been spent working in the designated laboratory specialty in a licensed medical laboratory.

(4) Is an individual who is employed by a clinical laboratory within two years of the effective date of this Legislative Rule and qualifies under the "General Supervisor" Standard of CFR 493.1461 Subpart M (published February 28, 1992).

(5) With respect to the specialty of diagnostic cytology, is qualified as a cytotechnologist and has had three years of full-time experience as a cytotechnologist in a licensed medical laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding ten years.

(6) With respect to the speciality of diagnostic cytology, is an individual who has qualified as a "General Supervisor" by meeting requirements of 42 CFR 493.1469 (published February 28, 1992).

DUTIES OF MEDICAL LABORATORY SUPERVISOR

(1) The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and in the absence of the director, are held responsible for the proper performance of all laboratory procedures. The supervisor must be a full-time employee of the facility and be on the laboratory premises during the regular working day. He must be readily available for personal or telephone consultations during all other hours when tests are performed.

(2) He may arrange with another properly qualified person, at the technologist level or higher, to cover for him during vacation, illness or other unforeseen reasons he could not be available.

under this paragraph may direct laboratory tests and procedures only in the laboratory speciality in which they have demonstrated proficiency.

(4) An individual employed in a medical laboratory or an entity performing clinical laboratory testing who qualifies as a Laboratory Director of a laboratory involved in testing of moderate complexity as described under 42 CFR Subpart M 493.1405 published February 28, 1992.

DUTIES OF MEDICAL LABORATORY DIRECTOR

The director administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests. He shall serve the laboratory full time or on a regular part time basis. The director in conjunction with the owner shall be responsible for the employment of qualified laboratory personnel and their inservice training and shall be responsible for the proper performance of all tests made in the laboratory. He or his designated qualified supervisor shall be in the laboratory each working day for an adequate amount of time to direct and supervise the technical performance of the staff. If the director is a clinical pathologist and there is at least one licensed medical laboratory supervisor working full-time in the laboratory, the director shall be required to be in attendance at the laboratory during the working day at least once each month. If the director is to be continuously absent from the laboratory for more than six weeks, it shall be the responsibility of the director or owner to make arrangements for a qualified substitute director and to notify the Department in writing of the arrangements. A medical laboratory director shall not be responsible for more than five (5) laboratories at any one time.

QUALIFICATIONS OF MEDICAL LABORATORY SUPERVISOR

(1) Is a laboratory director;

(2) Hold's a master's degree from an accredited institution with a major in one of the chemical, physical or biological sciences and subsequent to graduation has had at least two years of pertinent full-time laboratory experience of which not less than one year has been spent working in the general laboratory setting;

DUTIES OF MEDICAL LABORATORY TECHNOLOGIST

The medical laboratory technologist shall perform tests and procedures which require the exercise of independent judgment and responsibility with minimal supervision by the medical laboratory director or the medical laboratory supervisor in only those specialties or subspecialties in which he is qualified by education, training, and experience. With respect to specialties in which the medical laboratory technologist is not qualified by education, training, and experience, he shall function only under direct supervision and perform only tests and procedures which require limited technical skill and responsibility. He shall supervise the work of subordinate personnel and medical laboratory trainees. The duties of a licensee shall be limited to the specialty(ies) for which he or she is licensed.

QUALIFICATIONS OF MEDICAL LABORATORY TECHNICIAN

(1) Every laboratory technician shall pass an examination by a national certifying organization recognized by the Department and meet at least one of the following qualifications:

a) an associate degree or equivalent (such as a 2 year technical certificate) in combination with either completion of an accredited medical laboratory technician program or a military medical laboratory specialist program; or

b) such other requirements in addition to passage of an examination recognized by the Department as are appropriate for a medical laboratory technician concentrating in an area such as histology.

c) is a high school graduate or equivalent and has 2 years of pertinent full-time laboratory experience as a technician trainee in a laboratory within two years of the effective date of this Legislative Rule.

d) is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the West Virginia Department of Health and Human Resources within two years of the effective date of this Legislative Rule.

QUALIFICATIONS OF MEDICAL LABORATORY TECHNOLOGIST

(1) Every medical laboratory technologist shall pass an examination administered by a national certifying organization recognized by the Department and have a bachelor's degree and at least one of the following qualifications:

a) completion of an accredited medical laboratory technologist program; or

b) certification by a national certifying organization acceptable to the Department as a medical laboratory technician and three years full-time work experience in a licensed medical laboratory; or

c) five years full-time work experience (or equivalent) in a licensed medical laboratory; or

d) such other requirements in addition to a baccalaureate degree and the passage of a national certification examination recognized by the Department as are appropriate for medical laboratory technologists concentrating in categories such as histology, blood banking, chemistry, hematology, immunology and microbiology.

e) an individual who is employed by a clinical laboratory within two years of the effective date of this Legislative Rule and qualifies under the "Technologist Qualifications" of 42 CFR 493.1433 (published March 14, 1990);

(2) Cytotechnologists shall pass an examination administered by a national certifying organization recognized by the Department and meet such other qualifications as promulgated by the Department including a baccalaureate degree and at least one of the following:

a) completion of an accredited cytotechnologist program; or

b) five-years of full-time work experience (or equivalent) in a licensed medical laboratory.

(3) With respect to the specialty of diagnostic cytology, an individual who has qualified as a cytotechnologist by meeting requirements of 42 CFR 493.1483 (published February 28, 1992) within two years of the effective date of this Legislative Rule.

appropriate media and stain slide preparations for microscopic examination.

(b) When mechanical and electronic instruments must be used in the performance of clinical laboratory tests licensed personnel must:

(1) Initially standardize or calibrate the instrument and periodically check its performance by monitoring results of appropriate standards and controls.

(2) Read and record tests results unless this is done mechanically by the instrument in the form of a digital read-out or a recording mechanism onto pre-calibrated charts.

(3) Quantitatively measure all samples and reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.

3. Other Motions Voted on by the Advisory Board:

Motions voted on and approved by the Board not directly part of the personnel qualifications and duties:

a. An administrative procedure recommendation to Dr. Wallace that a thirty (30) day temporary license be granted to people moving into the state and a two (2) year temporary license be granted to a new graduate. Approved: November 18, 1992.

b. An administrative procedure recommendation to Dr. Wallace that there be a requirement for ten (10) contact hours of continuing education per year. Approved: November 18, 1992.

c. Subject to the review and approval through a mechanism designated by the Secretary of the Department of Health and Human Resources the personnel standards shall not be applicable to tests commonly regarded as point-of-care testing, provided that federal regulations are observed. Approved: December 16, 1992.

e) is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician) within two years of the effective date of this Legislative Rule.

DUTIES OF MEDICAL LABORATORY TECHNICIAN

Medical laboratory technicians shall perform only those laboratory procedures which require technical skill and a minimum exercise of independent judgment. No medical laboratory technician shall perform tests and procedures unless a medical laboratory supervisor or the medical laboratory technologist is available in person or by electronic media. The duties of a licensee shall be limited to the specialty(ies) for which he or she is licensed.

UNLICENSED PERSONNEL, LABORATORY AIDES

A laboratory aide who is a high school graduate, or has equivalent education as determined by the department, is authorized to assist licensed personnel, in a clinical laboratory if he works under the direct and constant supervision of a licensed person, and has demonstrated satisfactorily to the director of the laboratory in which employed ability to engage in activities such as: labeling, centrifuging and transferring specimens, transcribing results which have been previously recorded either manually or mechanically, preparing equipment, culture media, and reagents, and provided that the following conditions exist:

(a) When manual methods are employed in the performance of clinical laboratory tests licensed personnel, must perform any test or part thereof which involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or validity of a test procedure, except that:

(1) In the case of qualitative and semi-quantitative "spot, table, or stick" tests, the aide may add the test reagent to the specimen or vice versa, as the case may be, but the results must be checked by the licensed person.

(2) In the case of microbiological tests the aide may make primary inoculations of test material to be cultured onto

CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: FRANK WELLMAN
SECTION SUPERVISOR, CHEMISTRY

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities?

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

d. Medical Laboratory Technicians can perform high complexity testing under the direct supervision of a Medical Technologist. In the absence of a Medical Technologist, the Medical Laboratory Technician can perform high complexity testing if it is reviewed at the beginning of the next regularly scheduled shift by a Medical Technologist or Director. Approved: December 16, 1992.

Respectfully Submitted,

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to provide documentation of "registry eligible".

8.2.1: The state law was intended to establish personnel standards higher than those implemented within CLIA. What happens if CLIA personnel standards change?

Under certification requirements I recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of two years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA, 493.1489 (5) needs to be deleted as qualifications for high complexity testing since it is contradictory to the original intent of the law as approved by the State of West Virginia.

Thank you.

3.3: A consultant should minimally meet the certification requirements of the Laboratory that the consultant is contracted to. Ideally the consultant would meet the requirements of the Supervisor.

3.5: Strike specimen processing as this is routinely a clerical position. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do not result in financial reimbursement.

I take exception to grouping laboratory technicians which are mostly 2 year Associate degree individuals with medical technologists which are mostly 4 year Baccalaureate degree personnel. Professional status was recently confirmed on the medical technologist by the National Labor Relations Board for unionization purposes which may not carry over to the laboratory technician. This grouping could have a profound effect on pay scales. Supervisors need to be included as testing personnel.

3.6: Define how long it will take to obtain a license, post graduation. Also insert the word "accredited" to the training program.

3.12: Define biophysical.

64-59-4: Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

6.1.12: Strike this completely. I am not sure of the intent of this line. If adopted as written, would that mean that laboratorians would become specialized and could not practice in a separate lab discipline? i.e. My job description is for a chemistry technologist, but occasionally it might be necessary to work in the hematology lab.

6.2: Won't apply if 6.1.2 is eliminated.

6.3.1: Eliminate "are exempt from such certification under this rule".

6.4 & 6.5: Additional clarification is needed to define what the secretary will approve and the process for approving. Additional clarification is needed to define the 10 hours. Are these contact hours, CME, or CEUs?

7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

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7.2.2: Delete "is" and replace with "has been" certified. This would better equalize the acceptable national registries.

CABELL HUNTINGTON HOSPITAL
1340 Hal Greer Boulevard, Huntington, West Virginia 25701

MEMORANDUM

TO: Kay Howard
Regulatory Department
Department of Health & Human Services
Room 265, Building 3, Capital Complex
Charleston, WV 25305

FROM: Edward J. Wiemuth
Microbiology Section Chief
Cabell Huntington Hospital

SUBJECT: Clinical Laboratory Technician and Technologist Licensure & Certification

DATE: July 21, 1995

I would like to offer the following comments concerning the rule"57".

Comment:

Fiscal Notes: The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of an 800 hundred number is not justified. Additionally I question the validity of cost for the investigators responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3: Does this exempt employees and facilities or just facilities?

2.2.4: The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

July 14, 1995

To: Regulatory Department
Department of Health and Human Services
Room 265, Building 3, Capitol Complex
Charleston, WV 25305
Attn: Kay Howard

Dear Kay,

The WVSSAMT would like to comment on the proposed rule titled Clinical Laboratory Technician and Technologist Licensure and Certification Series #57. Our specific comments are as follows:

1. In 64-59-3, the term "Clinical Laboratory Scientist" is defined to include both laboratory technologists and laboratory technicians. Similarly, the terms "Laboratory Technologist" and "Laboratory Technician" are both defined as "a clinical laboratory scientist". This seems contrary to the normal assumption that a CLS is equivilent to an MT, while a CLT is equivilent to an MLT.

2. The minimum standards for certification (and hence, licensure) as a clinical laboratory scientist seem lenient. Anyone who qualifies under the CLIA regs, including the moderate complexity standards (which require only a high school degree plus limited training) is eligible for certification and licensure as a CLS (see 7.2.4a). Why have licensure if the standards are not more stringent than CLIA already requires?

3. Under section 64-59-11.1, a licensed CLS can't perform tests in a waived lab unless a clinical laboratory supervisor or lab consultant has determined that the individual is qualified by education, experience, or training to perform the type of tests engaged in that lab. Since most waived labs don't have a supervisor

8.2.1, & 8.2.2. What is the intent of this? I think it is meant to allow testing personnel to acquire a license until certification can be verified. However, it would be more appropriate to include under 64-59-7 another line to provide documentation of "registry eligible".

8.2.1: The state law was intended to establish personnel standards higher than those implemented within CLIA. What happens if CLIA personnel standards change?

Under certification requirements I recommend not certifying those working in "waived laboratories" based on .42 CFR-494 with no further modifications.

Registry eligible individuals need a time period of two years to pass a registry. They could be awarded a two year non-renewable temporary license.

7.2.4a Again, since so much of this rule is referenced to CLIA, 493.1489 (5) needs to be deleted as qualifications for high complexity testing since it is contradictory to the original intent of the law as approved by the State of West Virginia.

Thank you.

West Virginia
SOCIETY FOR
CLINICAL
LABORATORY
SCIENCE

The WV Society For Clinical Laboratory Science Inc.

149 Bradley Street
Morgantown, WV 26505

July 17, 1995

Ms. Kay Howard
Regulatory Development
Department of Health and Human Resources
Room 265, Building 3, Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

As president of the West Virginia Society for Clinical Laboratory Science, Inc., formerly the West Virginia State Society for Medical Technology, Inc., I am writing to comment on the proposed rules to implement the Clinical Laboratories Quality Assurance Act.

It is my feeling that the economic impact statements included with the proposed rules are largely of a negative nature, and fail to recognize such positive outcomes as increased quality of laboratory testing as performed by individuals with documented competency, reduction of health care costs through elimination of duplicate and unnecessary testing, and decreased hospitalizations from physicians acting on erroneous results.

I would urge that different terminology be used to define the testing personnel licensed under this law. Clinical Laboratory Scientist is used as a title by myself and other registrants certified by the National Certifying Agency for Medical Laboratory Personnel (NCA). This certification is granted only to those practitioners who have completed a baccalaureate degree from an accredited program of medical technology, or an associate degree plus 4-6 years of advanced laboratory practice, and have successfully passed the CLS examination. Licensees who have not completed these steps will thus be able to use a professional title that they have not earned. I would encourage the use of clinical laboratory professional or practitioner, due to the recent ruling on professional status by the National Labor Relations Board.

It is imperative that Clinical Laboratory Supervisors be included in the group of testing personnel required to be licensed. Since they are not included in the general definition of those to be licensed, they would not be able to perform testing, nor be included in the grandfather clause. Inclusion of supervisors in the licensed group would allow these individuals to remain in positions that they currently hold, as allowed by CLIA '88.

or clinical consultant (they're not required to under CLIA), this requirement seems redundant. Just about anyone who qualifies for licensure as a CLS ought to be able to run waived tests.

4. *We are uncertain why the regulation would require the state to certify and license lab personnel. One or the other would seem sufficient.*

5. *The maximum license term is set at one year The state could probably save some money if licenses were valid for a two year period. (Note that the statute limits the license fee to $25, regardless of the state's costs of administering the program)*

We would like to thank you for allowing us to have the opportunity to comment on this rule. If you have any questions or need any further information about the WVSSAMT, feel free to contact me.

Sincerely,

Janet L. Crigler, MT(AMT)

Janet L. Crigler, MT(AMT)
President, WVSSAMT
29 Hollen Circle
Fairmont, WV 26554
Home 304-366-8743
Work 304-367-7137

Charleston Area Medical Center

Memorial Division

3200 MacCorkle Avenue, S.E.
Charleston, West Virginia 25304
(304)348-5432

July 24, 1995

Comment:

The cost impact presented in the proposed rules appears to be higher than needed. Could not a regular phone line suffice since the need and cost of a 1-800 number is not justified. Additionally I question the validity of cost for the investigator's responsibilities in the first year considering that an employee would not be hired in this capacity until year 2.

I think it is important to consider the positive financial impact of reliable test results as compared to unreliable ones provided by untrained, unqualified individuals i.e., elimination of inappropriate hospitalization and unnecessary medication.

Rules: 2.2.3 Does this exempt employees and facilities or just facilities.

2.2.4 The intent of the law is to provide quality. I believe that research can be compromised if the scientist performing the testing is not qualified.

3.3 A consultant should minimally meet the certification requirements of personnel certified to supervise high complexity lab testing.

3.5 Strike specimen processing as this is routinely a function of personnel who are also responsible for phlebotomy and other clerical duties. We assume that "test performance" means actual testing. Drop the word remuneration. Many labs participate in wellness events and health fairs that do no result in financial reimbursement.

I take exception to grouping Medical Laboratory Technicians which are Associate degreed (or equivalent) with Medical Technologists which are Baccalaureate (or equivalent) personnel. This grouping could have a profound effect on pay scales. Supervisors need to be included in testing personnel.

3.6 Define how long it will take to obtain a license, post graduation. Also, insert the word accredited to the training program.

3.12 Define biophysical.

64-59-4 Since so much of the language in this rule comes from CLIA, it is important that in the future that no subsequent revision be adopted without opportunity for public response. This response time should be a minimum of 90 days.

The pursuit of licensure for clinical laboratory personnel in West Virginia by our organization has always been directed to maintain higher standards than those established by CLIA '88. The recommendations of the West Virginia Clinical Laboratory Quality Assurance Advisory Board submitted to the Commissioner of Public Health maintains these standards. As president of WVSCLS and as a clinical laboratory professional practicing in the state, I must admit to my major disappointment that the work of this advisory board has apparently been ignored by adopting the minimum CLIA '88 regulations. The appearance that the Department of Health and Human Resources has decided to "take the easy way out" does a great disservice to each member of the advisory board, everyone who has worked many years to make this law a reality, not to mention the disservice to the citizens of the state, all of whom are deserving of competent delivery of quality health care. West Virginia has a golden opportunity to take the lead in this issue of health care, but, as is so often the case, has chosen to "play follow-the-leader."

Finally, I must take issue with the liberal interchange of the terms "certification" and "licensure". Certification, by definition, is an official endorsement or accreditation. Certification in our profession is granted by NCA, the American Society for Clinical Pathology, or by the American Medical Technologists. These agencies are approved by the federal government to grant certification upon successful completion of examination. A license is legal permission to engage in a business, occupation, or activity. Under this law, the State of West Virginia will grant licenses, not certification.

It has been a privilege to express my opinions, and I would urge the Department to rethink its stance on these issues.

Sincerely,

Kimberly S. Kline

Kimberly S. Kline, CLS(NCA), MT(ASCP)
President, WVSCLS (1994-95)