Monitoring Blood Glucose Levels By Indiana Basic Life Support Personnel

Guidelines and Curriculum

Adopted by the

Indiana Emergency Medical Services Commission

December 18, 2015

Developed by the Connecticut Emergency Medical Advisory Board
For the Connecticut Office of Emergency Medical Services

Guidance

The State of Indiana has given authority for the Emergency Medical Services Commission to approve the utilization of glucometers for testing and monitoring as basic life support under Indiana code 16-18-2-33.5. The utilization is only under the auspices of the local services' medical director and is not intended to be construed as being set forth as protocol for all EMTs and EMR's. Programs utilizing blood glucose monitoring must have written policies and protocols for their services and providers as well as a quality assurance program in place. The services will need to follow the policy as set forth by the Indiana EMS Commisson for approval, which includes, but not limited to, updated applications and appropriate training.

The use of any laboratory testing is subject to review by the FDA and other agencies. All services who intend to utilize glucose monitoring must meet all federal and state guidelines and show documentation for obtaining the necessary waivers and certifications as so directed. See Appendix A for additional information

Curriculum

Suggested Time Frames
(Assuming less than 13 students and proper instructor to student ratio)

Lecture portion of course 1 to 1.5 hours
Lab portion of course 1 hour
Evaluation portion of course 1 to 1.5 hours

Reference materials for course development

Browner, Bruce D., Pollak, Andrew N., and Gupton, Carol L. Emergency Care and Transportation of the Sick and Injured: 8th Edition. Jones and Bartlett Publishers: Boston, 2002.

Willis, Mark G., Goold, Grant B., and Watson, K. Lee. MedEMT: A Learning System for Prehospital Care. Prentice Hall: Upper Saddle River, NJ, 2000.

Pagana, Kathleen D. and Pagana, Timothy J. Diagnostic and Laboratory Test Reference, 3rd Edition. Mosby: St. Louis, 1977.

User Guide: Ascensia Elite Diabetes Care System. Bayer Corporation: Mishawaka, IN, 2002
Developed for the Kansas Board of Emergency Medical Services

Legend for Objectives			
C= Cognitive		P= Psychomotor	A= Application
1	Knowledge		
2	Application		
3	Problem Solving Level		

Objectives

Terminal Objective

Upon completion of this course, the EMT/EMR will demonstrate the ability to perform a blood glucose test on a patient and act appropriately to the findings without compromising the patient's care or safety.

Cognitive Objectives

At the end of this lesson, the EMT/EMR student will be able to:
1.1 Given case study descriptions, the EMT will be able to correctly identify those patients in need of blood glucose evaluation. (C-1)
1.2 Given information regarding normal blood glucose levels and the role of glucose in the body, the EMT/EMR will be able to identify reasons for measuring a patient's glucose levels. (C-1)
1.3 Given information regarding diabetes, the EMT/EMR will be able to define and explain diabetes as to the cause and general effect on the human body. (C-1)
1.4 Given information regarding diabetes, the EMTEMR will be able to explain the role of insulin in the body and how it affects glucose utilization. (C-1)
1.5 Given class information, the EMT/EMR will be able to identify and describe the glucometer and its function. (C-1)

1.6 Given the process of blood glucose assessment with a glucometer, the EMT/EMR will be able to identify correctly those body substance isolation procedures and equipment that are required to be used. (C-1)
1.7 Given glucometer information, the EMTEMR will accurately describe the proper use of the glucometer and the equipment needed for blood glucose testing. (C-1)
1.8 Demonstrate an understanding of the significance of blood glucose test results. (C-1)
1.9 Explain possible critical values for blood glucose in different patients, as defined in the lesson material. (C-3)
1.10 Define Type I and Type II Diabetes, as explained in the course. (C-1)
1.11 Given a patient with high or low blood sugar values, explain the course of treatment appropriate to each patient. (C-3)
1.12 Given information in the course, the EMTEMR will explain the contraindications of administering glucose to the patient. (C-3)
1.13 Given course information, the EMT/EMR will highlight the complications associated with use of a glucometer as related to patient care. (C-1)
1.14 Given course information, the EMT/EMR will describe possible sources of glucose test errors. (C-3)
1.15 The EMT/EMR will be able to state the consequence of and the need to recognize a patient with critically high or critically low panic values. (C-3)
1.16 Given course information, the EMT/EMR will describe accurately the proper disposal of materials used in blood glucose testing. (C-1)

MATERIALS

AV Equipment Instructors should have available in the classroom all materials needed for blood glucose testing, as well as for testing accuracy of the blood glucometer. Additionally, AV equipment for projecting PowerPoint slides should be accessible, as well as a marker board, flipchart, or black board as available.

Instructors may choose to develop handouts using the PowerPoint media or from other sources of information relative to the topic.

EMS Equipment Exam gloves and other BSI equipment as determined by local infection control plans, glucometer, regent strips, alcohol wipes, cotton balls, bandages, sharps containers, and other disposal containers.

Whenever possible, use the brand of glucometer that the EMT/EMR-students will be using.

PERSONNEL

Primary Instructor: One EMT, RN, MD, Advanced EMT, or Paramedic with knowledge in basic and advanced blood glucose monitoring techniques.

Assistant Instructor: The instructor to student ratio should be no greater than 1:6 for psychomotor skill practice. Individuals used as assistant instructors should be knowledgeable in basic and advanced blood glucose monitoring techniques.

Time to Complete 3 to 4 hours

PRESENTATION

Declarative (What)

I. Anatomy and Physiology Review

A. Cellular Metabolism

1. Glucose is the fuel for all cellular basic energy needs.
2. Other cells can use fats, too, for energy; but they are less efficient. Metabolized fat gives off more waste products than does glucose. In order for MOST cells to utilize glucose, there needs to be insulin present in the blood stream. Insulin changes the permeability of the cell when it attaches, thus allowing certain substances "in" that previously would not have been allowed in the cell. Insulin allows for a change in cell membrane permeability to allow glucose to enter the cell and be used as energy.

B. Brain Cell Metabolism

1. Brain cells do not need Insulin in order to utilize glucose.
2. For this reason, the brain will continue to function without adequate insulin levels.
3. Brain cells do need adequate levels of glucose for proper function.
4. When glucose levels become too low, the brain cells cease to function normally and the patient will exhibit a change in behavior that may be subtle or extreme.

5. There is no “set” blood sugar level at which the brain will begin to malfunction, as it is inherently different for each person.

C. Blood sugar levels

1. There are “normal” ranges for blood sugars in humans.
2. Whether a person is fasting or has eaten will determine the level of glucose in the blood (serum).
3. Normal blood glucose findings are reflective of milligrams per deciliter (US standard) and are reflected as follows:
    a. Infant (40 – 90 mg/dl)
    b. Child <2 Years (60 – 100 mg/dl)
    c. Child >2 years to Adult (70 – 105 mg/dl)
    d. Elderly may see an increase in normal range after age 50 years of age. The American Diabetes Association generally accepts this up to 126 mg/dl.

4. These values represent “normal” findings for blood serum testing; such is done with a blood glucometer or by venous blood testing in a lab.
5. Serum glucose testing is helpful in diagnosing many metabolic diseases. EMT personnel will use this to determine if the patient has a condition related to either a low or high blood sugar. This will mostly be done on known diabetic patients, although the test can be used to determine if diabetes or altered blood sugar is the cause of an unconscious – unknown situation.

6. Increased levels of blood glucose can indicate a variety of situations:
    a. Diabetes mellitus
    b. Acute stress response
    c. Cushing's disease
    d. Diuretic therapy
    e. Corticosteroid therapy.
    f. Pancreatic cancer
    g. Pancreatitis (chronic alcoholics)
    h. Grave's disease
7. Early mornings can often bring higher glucose levels due to several "overnight" factors including fasting, hormone/endocrine levels that typically change after midnight, etc.
8. Decreased levels can indicate a variety of situations, as well:

    a. Insulinoma
    b. Hypothyroidism
    c. Addison's disease
    d. Extensive liver disease
    e. Hypopituitarism

9. The role of the EMT is to monitor the blood glucose levels and to treat hypoglycemia and hyperglycemia appropriately.
10. Blood glucose testing can identify situations for the EMT to treat in the pre-hospital setting, as well as provide valuable information for hospital personnel.

D. Types of Diabetes

1. Type I diabetes is a result of little or no insulin production by the pancreas
   a. These patients are most likely insulin dependent.
   b. Often called juvenile diabetes, however it can develop later in life as well.
   c. Patients with Type I diabetes are likely to have complications such as blindness, heart disease, high blood pressure, postural hypotension, kidney failure and nerve disorders.
2. Type II diabetes occurs when the amount of insulin produced by the pancreas is insufficient, or the insulin produced is in sufficient quantity, but is ineffective.
   a. These patients may often be controlled by diet or oral medications.
   b. Less likely to have insulin injections daily.
   c. Less likely to experience hypoglycemia
   d. Often referred to as adult onset diabetes.
   e. Patients with Type II diabetes are likely to have complications such as blindness, heart disease, high blood pressure, postural hypotension, kidney failure and nerve disorders.

E. Clinical Presentation of Altered Blood Glucose Levels

1. Hypoglycemia (Low Blood Sugar) BS < Normal
   a. Normal or rapid respirations
   b. Pale, moist (clammy) skin
   c. Diaphoresis (sweating)

d. Dizziness, headache
e. Rapid pulse
f. Normal to low blood pressure
g. Altered mental status, aggressive, confused, lethargic, or unusual behavior
h. Anxious or combative behavior
i. Hunger
j. Seizure, fainting, or coma
k. Weakness on one side of the body (may mimic stroke)

2. Hyperglycemia (High Blood Sugar) BS > 200
a. Kussmaul respirations
b. Dehydration as indicated by dry, warm skin and sunken eyes.
c. A sweet or fruity (acetone) odor on the breath, caused by the unusual waste products in the blood (ketones)
d. A rapid, weak ("thready") pulse
e. A normal or slightly low blood pressure
f. Varying degrees of unresponsiveness.

II. Emergency Treatment of Altered Blood Glucose Levels

A. Some assessment to consider when dealing with the diabetic patient.

1. Assess insulin delivery: Are they currently injecting insulin? Are they taking oral medication? Are they using an insulin pump? (This last device may be implanted and not immediately apparent to the provider.) Any emergency department would want to know about an insulin pump.
2. Assess potential for low/high blood sugars: When did they last eat? Have they experienced vomiting? Do they have an

illness like influenza or a cold? (Even acute conditions like influenza, colds, etc. can significantly impact glucose control.) One episode of vomiting and "losing" a meal can trigger low blood glucose levels. This information should be relayed to the emergency department during transport.

B. Emergency Care

1. Hypoglycemia

a. Scene Size Up and Body Substance Isolation as needed

b. Initial assessment

c. Determine need for rapid transport

d. Focused History and Physical Assessment with vitals

Blood Glucose Check

e. If Blood Glucose is < 80, the patient is responsive and in control of their airway and one or more S/S of hypoglycemia are present, administer oral glucose in accordance with local protocol.

If Blood Glucose is < 80 and the patient has a lowered LOC and no control over their airway, give supportive care and get the patient to advanced life support care for intravenous dextrose or glucagon.

g. Monitor LOC and blood glucose levels.

h. Supportive care in transport

i. Detailed and On-going assessments as indicated.

2. Hyperglycemia

a. Scene Size Up and Body Substance Isolation as needed

b. Initial assessment

* Administer oxygen

c. Determine need for rapid transport

d. Focused History and Physical Assessment with vitals

* Blood Glucose Check

e. If blood glucose is > 200, transport to emergency department for appropriate treatment which may include rehydration and/or insulin administration.

f. Consider advanced life support if vital signs are abnormal for the patient.

C. Indication for Blood Glucose Monitoring

1. Altered level of consciousness in any patient.
2. Shakiness, weakness
3. Rapid pulse and respiratory rate
4. Neurological deficit
5. Seizures
6. Known diabetic

III. Body Substance Isolation Procedures

A. EMT personnel should refer to their departmental infection control plan for specific needs regarding body substance isolation.

B. As a rule, EMT personnel will need to wear exam gloves for the blood glucometer procedures.
   1. Spurting blood is not reasonable to anticipate.
   2. Eyewear, mask, and gown are not indicated for this procedure in most circumstances.

IV. Use of the Blood Glucometer

A. Equipment needed for blood sugar testing with the glucometer.
   1. Exam gloves
   2. Alcohol prep pads
   3. Glucometer
   4. Test strips
   5. Cotton balls and band-aid
   6. Lancets
   7. Sharps container and proper waste disposal container

B. Identify the appropriate puncture site
   1. Adult and children over 1 year
      a. Fingers, 3rd or 4th on the palmar side
      b. Central fleshy areas
   2. Contraindications for the typical puncture site
      a. Old puncture sites
      b. Epidermal damage, scarring
      c. Desire of the patient

C. Preparation of the site.
   1. Cleanse with 70% isopropyl alcohol, using a scrubbing/circular motion.
      a. Do NOT use povidone – iodine as specimen contamination may elevate some test results.
   2. Allow alcohol to dry.
      a. Failure to allow alcohol to dry may:
         i) Cause a stinging sensation
         ii) Contaminate the specimen
         iii) Destroy red blood cells

D. Prepare blood glucometer.
   1. Load test strip into the blood glucometer as directed by the

manufacturer.

2. Glucometer must be set for the test strip code to ensure an accurate test. This is done PRIOR to the call.

E. Acquire blood specimen.

1. Use lancet to stick the site prepared and form a small drop of blood.
2. Apply blood drop to the test strip as directed by the manufacturer.
3. Allow blood glucometer to process information and return the test result.

F. After test care and procedure.

1. Use cotton ball to hold pressure on puncture site and place band-aid on site
2. Record blood glucometer reading.

V. Maintenance and Use of Blood Glucometers

A. Set up

1. Blood glucometers come with specific test strips, which are identified by batch number. The number of the test strip must match the number that the glucometer is set for. This is to be done anytime you place a new set of test strips into service. Look at the specific manufacturer's instructions. Note that test strips expire. Only non-expired strips should be used.
2. Blood glucometers must be routinely tested to ensure that they are properly calibrated and returning accurate results. Follow the specific manufacturer's directions.

B. Specifics of Blood Glucometers

1. There are numerous types and brands of blood glucometers.

2. Each one will have specific instructions for:
    a. The type of test strips to be used.
    b. The process for setting the glucometer up for use.
    c. Instructions for testing the glucometer
    d. Actions that may lead to a false test result
    e. Cleaning the glucometer
    f. Memory storage for previous test results
    g. Battery maintenance

C. Care of the Blood Glucometer
    1. Handle with care! Dropping may damage internal components.
    2. Do NOT expose the meter, test strips, code strips or check strips to excessive humidity, heat, cold, dust, or dirt.
    3. Clean with damp cloth. Do NOT immerse or use large amounts of water or cleaner.
    4. Use only those chemicals recommended by the manufacturer.
    5. Store the meter in the case/carrier provided by the Manufacturer.

D. Meter and Test Strip Problems
    1. Each meter will have specific display numbers that indicate a malfunction. Consult the manual.
    2. If the display goes blank during the test, you most likely have a battery failure. Replace batteries often to avoid this possibility.
    3. If the function number is different from the number on the test strip, you need to reset the meter. Avoid this by ensuring that when changing batches of test strips, you set the meter correctly.

4.Result of test is “Out of Range”. You may have a bad or damaged test strip or a meter failure. Retry with new test strip. (Another thing that may cause “Out of Range” is if the blood glucose level is out of the meter’s measuring range. (Consult the manual.)

5. Meter fails to begin counting down after blood is applied. The blood may have been applied wrong, the test strip inserted incorrectly, or the sample has been applied to the test strip before the meter was “ready” for it. (This can also happen if you do not obtain enough blood for the sample.)

6. Some display segments do not appear. This indicates a faulty LCD screen or an electronics or battery failure.

7. Meter reads “Lo” after blood is applied to the test strip. This may well indicate that the blood sugar is under 20 mg/dl. Ensure that you know what this means on the glucometer you are using. Generally indicates a VERY LOW blood sugar. May also indicate a faulty test strip or a wrong function number (does not match test strip number).

8. Meter reads “Hi” after blood is applied to the test strip. This generally indicates that the blood sugar is above 500 or 600, depending upon the glucometer. Ensure that you know what this means on the glucometer you are using. Generally indicates a VERY HIGH blood sugar. May also in indicate a faulty test strip or a wrong function number (does not match test strip number).

9. Blood glucose or control test results are inconsistent, or control test results are not within the specified range. This may be caused by not enough blood or control solution on the test strip, expired test strips or test solution, deterioration from heat or humidity, or extreme temperatures.

VI. Glucose Administration

A. Names

1. Generic Name is Oral Glucose
2. Trade names include Glutose® and Insta-Glucose®

B. Indications

1. Patients with altered mental status and a known history of diabetes that is normally controlled by medication.
2. Patients in whom the blood glucometer reading shows below normal.
3. In rare cases, direct physician contact may order glucose to patients with a blood glucose reading that is “normal”, but in whom higher levels are normal.

C. Contraindications

1. Unresponsive patient.
2. Responsive patient who is becoming unresponsive and who will lose airway control should encourage caution in administration.
3. Patients who cannot swallow or maintain their airway

D. Technical

1. Increases blood sugar level

2. Is dependent upon adequate levels of insulin for all cells except brain cells.

E. Dosage

1. One tube per protocol is normal dose
2. Physician may order second dose, depending upon post administration blood glucose test levels.

F. Route

1. Oral
2. Between cheek and gum for buccal absorption

G. Side Effects

1. None when given correctly
2. May be aspirated in patients with no gag reflex
3. Can drive blood sugar to high levels. Consider this when administering, but do NOT fail to treat hypoglycemia.

VII. Case Studies

A. Your unit receives a call for an insulin reaction. You find, upon arrival, a 44 year old female patient who presents giddy and nervous. The family states that she is an insulin dependent diabetic who had her insulin today and has not eaten. What are the treatment steps for this patient?

Blood glucometer shows a reading of 40 mg/dl.

B. Your unit receives a call for an unconscious subject. Upon arrival at the business, you find a 22 year old male patient who is supine on the floor and unresponsive. He has vomitus on the floor beside him and around his mouth. He is breathing and has a strong pulse. He has no identification or medic alert tags on him. What are your treatment steps for this patient?

Blood glucometer shows a reading of "Lo".

C. Your unit receives a call for a traffic crash. Upon arrival you find an elderly patient behind the wheel of a car that has gone off of the road and is up against a tree by a creek. The patient presents unresponsive, but with no specific signs of injury.

Vitals are stable except for the decreased LOC, which is found to be responsive to painful stimuli. What are your treatment steps for this patient?

Blood glucometer shows a reading of 22 mg/dl.

D. Your unit responds to a home for the report of a diabetic who is found unresponsive. You find the patient unresponsive and breathing shallow. Skin is warm and dry. Vitals are within normal limits. The patient, a 77 year old female is an insulin dependent diabetic who has eaten today, but it is unknown if she had her insulin. What are your treatment steps for this patient?

Blood glucometer shows a reading of "Hi".

APPLICATION (LAB)

Procedural (How)

I. Students will experience the following in a lab setting with instructor guidance:

A. Identify proper sites for blood sampling.

B. Locate proper sites for blood sampling.

C. Demonstrate the skill of preparing the glucometer and puncture testing for this site.

D. Assemble the glucometer.

E. Perform a blood glucose test

F. Interpret and troubleshoot the glucometer and its readings.

G. Properly dispose of waste material.

H. Identify proper treatment for the patient based on findings.

Guidance for the lab portion of the course will be the objectives

CONTEXTUAL

Basic life support personnel in Indiana have not been given the opportunity to monitor blood glucose levels in the past. With the establishment of legislation and regulations, basic personnel may now be trained to use a blood glucometer and do so in the performance of care when approved by the local medical director.

STUDENT ACTIVITIES

Auditory (Hear)

The student should be able to hear the beep of the glucometer as results are ready to be read.

Visual (See)

The student should see the glucometer and all necessary

1. Equipment.

2. The student should see audio-visual aids or materials of glucose testing.
3. The preparation of the glucometer.
4. The preparation of the puncture site.
5. The student should se the instructor perform a blood glucose stick.
6. The student should see the results of a glucose stick.
7. The student should see how to record the results in the patient report.
8. The student should see how to dispose of contaminated equipment and supplies.
9. The student should see how to clean equipment.

Kinesthetic (Do)

1. The student should practice the preparation of the glucometer.
2. The student should practice the identification and preparation of puncture site.
3. The student should practice using the glucometer.
4. The student should practice disposing of contaminated equipment and supplies.

5. The student should practice documenting the results of blood glucose testing.

LAB OUTLINE

I. Demonstration
- A. Instructor demonstrates changing batteries in the blood glucometer.
- B. Instructor demonstrates use of a check strip to check blood glucometer performance.
- C. Instructor calibrates the glucometer to match the test strips.
- D. Instructor performs a control test with the blood glucometer.
- E. Instructor demonstrates a blood glucose test on a volunteer patient and records findings appropriately.
- F. Instructor demonstrates proper disposal of waste materials.

II. Practice
- A. Student demonstrates changing batteries in the blood glucometer.
- B. Student demonstrates use of a check strip to check blood glucometer performance.
- C. Student calibrates the glucometer to match the test strips.
- D. Student performs a control test with the blood glucometer.
- E. Student demonstrates a blood glucose test on a volunteer patient and records findings appropriately.
- F. Student demonstrates proper disposal of waste materials.

EVALUATION

Practical Evaluation

A. The student must demonstrate the proper use of the blood glucometer to analyze a patient's blood glucose.
   1. Must obtain valid reading.
   2. Must prepare site without contamination.
   3. Must dispose of waste properly.
   4. Must show proper BSI.
   5. Must properly document findings.
   6. No critical errors.
   7. A minimum of 11 points awarded.

B. The student must demonstrate the proper testing of the blood glucometer to for calibration and control testing as specified in blood glucometer manual.

Glucose Testing
Skill/Test Sheet

Skill	Possible Points	Points Awarded
Body Substance Isolation	1 – Critical	
Identify and prepare the site	1	
Gently squeeze the site area	1	
At the same time, use the lancet to pierce the skin	1	
Gently squeeze to express a drop of blood	1	
Operate the glucometer according to the manufacturer's recommendation	1 -Critical	
Place the drop of blood on the test Strip	1	
Place gauze or cotton ball on puncture site and apply pressure	1	
Apply bandage	1	
Document glucose results, time of test, and who performed the test	1	
Dispose of equipment and supplies properly	1	
Clean equipment according to Manufacturers directions	1	
Verbalize treatment according to Results (instructor can alter result to vary appropriate answer)/	1	
Follow protocols/Contact medical Control	1	

Total Points _____ Pass / Fail
Instructor/Evaluator: _____
Date: _____

Appendix A.

The Law (Public Law 100-578)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law specified that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute. The section of the statute specifying the criteria for categorizing a test as waived was excerpted without elaboration in the regulations at 42 CFR *493.15(b)* and 493.15(c) contained a list of these waived tests as described below.

The Regulations (42 **CFR part 493)**

On February 28, 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

The specified tests that are listed in the regulation are:

1. Dipstick or Tablet reagent urinalysis (non automated) for the following:
    - Bilirubin
    - Glucose
    - Hemoglobin
    - Ketone
    - Leukocytes
    - Nitrite
    - pH
    - Protein
    - Specific gravity
    - Urobilinogen
2. Fecal occult blood
3. Ovulation tests - visual color comparison tests for luteinizing hormone
4. Urine pregnancy tests - visual color comparison tests

5. Erythrocyte sedimentation rate-non-automated
6. Hemoglobin-copper sulfate - non-automated
7. Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
8. Spun microhematocrit
9. (added 1/19/93) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout

In November 1997, the CLIA waiver provisions were revised by Congress to make it clear that tests approved by the FDA for home use automatically qualify for CLIA waiver. Professional use versions of home use tests are not automatically waived. However, such professional versions do qualify for expedited waiver review since only the differences between the home use and professional use versions need to be examined to determine whether the professional version qualifies for waiver.

To summarize, under the current process, waiver may be granted to: 1) any test listed in the regulation, 2) any test system for which the manufacturer or producer applies for waiver if that test meets the statutory criteria and the manufacturer provides scientifically valid data verifying that the waiver criteria have been met, and 3) test systems cleared by the FDA for home use.

FR Announcement: Public Health Service; CLIA Program; Categorization of Waived Tests 09/13/95; HSQ-225-P; 60 FR 47534

Selected Sections of 42CFR493 are below.
[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2004]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR493.1]
[Page 967-971]
TITLE 42--PUBLIC HEALTH
CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)
PART 493_LABORATORY REQUIREMENTS--Table of Contents
Subpart A_General Provisions
Sec. 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 Sec. 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.
Subpart A_General Provisions
Sec. 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 CMS in accordance with this part;
Adverse action means the imposition of a principal or alternative sanction by CMS.
ALJ stands for Administrative Law Judge.
[[Page 972]]
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 CMS'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 CMS 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.
Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.
Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.
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 CMS 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 Sec. 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 Sec. 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 Sec.

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 CMS (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with Sec. 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 Sec. 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 CMS or its agent; or in accordance with Sec. 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 Sec. 493.37, to a laboratory to perform only the waived tests listed at Sec. 493.15(c).
CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where CMS 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 CMS in accordance with subpart E of this part.
Condition level deficiency means noncompliance with one or more condition level requirements.
[[Page 973]]
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.
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.
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 CMS, 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.
CMS agent means an entity with which CMS 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 CMS 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 CMS agent.
FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.
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.
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.
Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory
[[Page 974]]
criteria specified at section 353(d)(3) of the Public Health Service Act.
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 CMS 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, 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.
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 CMS, the State survey agency or other CMS 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, CMS or other CMS 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. CMS 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).
Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.
Sample in proficiency testing means the material contained in a vial, on a
[[Page 975]]
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 licensure program means a State laboratory licensure or approval program.
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 CMS 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.
Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

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 Sec. 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 CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.
Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under
[[Page 976]]
section 353(d)(3) of the Public Health Service Act.
[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; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]
Sec. 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
(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 Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-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; 60 FR 20043, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]
Sec. 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 Sec. 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.
[60 FR 20043, Apr. 24, 1995]
Sec. 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
[[Page 977]]
(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--non-automated;
(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]
Sec. 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.
[[Page 978]]
(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 Sec. 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 CMS 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, CMS, 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
[[Page 979]]
Subpart B_Certificate of Waiver
Sec. 493.35 Application for a certificate of waiver.

Source: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.
(a) Filing of application. Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in Sec. 493.15 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
[[Page 981]]
listed in Sec. 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 Sec. 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 Sec. 493.15.
(iv) To collect information regarding the appropriateness of waiver of tests listed in Sec. 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; 60 FR 20044, Apr. 24, 1995]
Sec. 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 Sec. 493.35.
(b) Laboratories issued a certificate of waiver--
(1) Are subject to the requirements of this subpart and Sec. 493.15(e) of subpart A of this part; and
(2) Must permit announced or 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 non-compliance 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 Sec. Sec. 493.35 and 493.37.
[[Page 982]]
(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.
[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995]
Sec. 493.39 Notification requirements for laboratories issued a certificate of waiver.
Laboratories performing one or more tests listed in Sec. 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 Sec. 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
(b) Within 30 days of any change(s) in--
(1) Ownership;
(2) Name;
(3) Location; or
(4) Director.
[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]
PART 493_LABORATORY REQUIREMENTS--Table of Contents
Subpart E_Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program
Sec. 493.551 General requirements for laboratories.
Source: 63 FR 26732, May 14, 1998, unless otherwise noted.
(a) Applicability. CMS may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:
(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.
[[Page 989

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by CMS.
(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to CMS all records and information required and permits inspections as outlined in this part.
(b) Meeting CLIA requirements by accreditation. A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:
(1) Obtain a certificate of accreditation as required in subpart D of this part.
(2) Pay the applicable fees as required in subpart F of this part.
(3) Meet the proficiency testing (PT) requirements in subpart H of this part.
(4) 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 the 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. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by CMS, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under Sec. 493.1840.
(5) Authorize its accreditation organization to release to CMS or a CMS agent the laboratory's 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 Sec. 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.
(6) Authorize its accreditation organization to release to CMS 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 the action. Based on this notification, CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.
(c) Withdrawal of laboratory accreditation. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by CMS, whichever is earlier.
Sec. 493.559 Publication of approval of deeming authority or CLIA exemption.
(a) Notice of deeming authority or exemption. CMS publishes a notice in the Federal Register when it grants deeming authority to an accreditation organization or exemption to a State licensure program.
(b) Contents of notice. The notice includes the following:
(1) The name of the accreditation organization or State licensure program.
(2) For an accreditation organization:
(i) The specific specialty or subspecialty areas for which it is granted deeming authority.
(ii) A description of how the accreditation organization

reasonable assurance to CMS that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.
(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.
(4) The basis for granting deeming authority or exemption.
(5) The term of approval, not to exceed 6 years.
Sec. 493.575 Removal of deeming authority or CLIA exemption and final determination review.
(a) CMS review. CMS conducts a review of the following:
(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at Sec. 493.573. CMS reviews, as appropriate, the criteria described in Sec. Sec. 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.
(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at Sec. 493.573. CMS reviews, as appropriate, the criteria described in Sec. Sec. 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.
(3) A review of an accreditation organization or State licensure program, at CMS's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.
(4) A review of the accreditation organization or State licensure program
[[Page 996]]
whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of CMS or a CMS agent for the following periods:
(i) One year for accreditation organizations.
(ii) Two years for State licensure programs.
(b) CMS action after review. Following the review, CMS may take the following action:
(1) If CMS determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, CMS may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of CMS's determination, or exempt status to a State within 30 days of CMS's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.
(2) If CMS determines that there are widespread or systematic problems in the organization's or State's inspection process, CMS may give conditional approval during a probationary period, not to exceed 1

year, effective 30 days following the date of the determination.
(c) Final determination. CMS makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:
(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.
(2) Facility-specific data, as well as other related information.
(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.
(4) The organization's accreditation requirements, or the State's licensure or approval requirements.
(d) Date of withdrawal of approval. CMS may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to CMS have not been made during the probationary period.
(e) Continuation of validation inspections. The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by CMS does not affect or limit the conduct of any validation inspection.
(f) Federal Register notice. CMS publishes a notice in the Federal Register containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.
(g) Withdrawal of approval-effect on laboratory status--(1) Accredited laboratory. After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.
(2) CLIA-exempt laboratory. After CMS withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of CMS's approval of the program.
(3) Extension. After CMS withdraws approval of an accreditation organization or State licensure program, CMS may extend the 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 for the appropriate certificate to CMS or a CMS agent before the initial 60-day period ends.
(h) Immediate jeopardy to patients. (1) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited
[[Page 997]]
by the organization, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time CMS determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of that State licensure program.
(i) Failure to pay fees. CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in Sec. Sec. 493.645(a) and 493.646(b).
(j) State refusal to take enforcement action. (1) CMS may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when CMS determines it to be necessary.
(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.
(k) Request for reconsideration. Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488.
Subpart K_Quality System for Nonwaived Testing
Sec. 493.1231 Standard: Confidentiality of patient information.
The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.
Sec. 493.1235 Standard: Personnel competency assessment policies.
As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.
Sec. 493.1236 Standard: Evaluation of proficiency testing performance.
(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.
(b) The laboratory must verify the accuracy of the following:
(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.
(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).
(c) At least twice annually, the laboratory must verify the accuracy of the following:
(1) Any test or procedure it performs that is not included in subpart I of this part.

[[Page 1034]]
(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.
(d) All proficiency testing evaluation and verification activities must be documented.
Sec. 493.1254 Standard: Maintenance and function checks.
(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following:
(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.
(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:
(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.
(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
(ii) Perform and document the 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.
Sec. 493.1255 Standard: Calibration and calibration verification procedures.
Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:
(a) Perform and document calibration procedures--
(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;
(2) Using the criteria verified or established by the laboratory as specified in Sec. 493.1253(b)(3)--
(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and
(ii) Including the number, type, and concentration of

materials, as well as acceptable limits for and the frequency of calibration; and
(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.
(b) Perform and document calibration verification procedures--
(1) Following the manufacturer's calibration verification instructions;
(2) Using the criteria verified or established by the laboratory under Sec. 493.1253(b)(3)--
(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and
(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of
[[Page 1038]]
the range to verify the laboratory's reportable range of test results for the test system; and
(3) At least once every 6 months and whenever any of the following occur:
(i) 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.
(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.
(iii) Control materials 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 fail to identify and correct the problem.
(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.
Sec. 493.1256 Standard: Control procedures.
(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.
(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in Sec. 493.1253(b)(3).
(c) The control procedures must--
(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.
(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.
(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty

requirements at Sec. Sec. 493.1261 through 493.1278.
(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.
(3) At least once each day patient specimens are assayed or examined perform the following for--
(i) Each quantitative procedure, include two control materials of different concentrations;
(ii) Each qualitative procedure, include a negative and positive control material;
(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;
(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and
(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.
(4) For thin layer chromatography--
(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and
(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.
(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.
(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced;
[[Page 1039]]
major preventive maintenance is performed; or any critical part that may influence test performance is replaced.
(7) Over time, rotate control material testing among all operators who perform the test.
(8) Test control materials in the same manner as patient specimens.
(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.
(10) Establish or verify the criteria for acceptability of all control materials.
(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.
(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is

verified by the laboratory.
(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.
(e) For reagent, media, and supply checks, the laboratory must do the following:
(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in Sec. 493.1261(a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) 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), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.
(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.
(4) Before, or concurrent with the initial use--
(i) Check each batch of media for sterility if sterility is required for testing;
(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and
(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.
(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.
(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.
(g) The laboratory must document all control procedures performed.
(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.
[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]
Subpart Q_Inspection
Sec. 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
Source: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.
(a) Each laboratory issued a CLIA certificate must meet the requirements in Sec. 493.1773 and the specific requirements for its certificate type, as specified in Sec. Sec. 493.1775 through 493.1780.
(b) All CLIA-exempt laboratories must comply with the inspection requirements in Sec. Sec. 493.1773 and 493.1780, when applicable.
[63 FR 26737, May 14, 1998]

[[Page 1074]]
Sec. 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.
(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.
(b) General requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:
(1) Test samples, including proficiency testing samples, or perform procedures.
(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.
(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).
(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:
(i) Specimen procurement and processing areas.
(ii) Storage facilities for specimens, reagents, supplies, records, and reports.
(iii) Testing and reporting areas.
(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.
(c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.
(d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.
(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.
(f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.
(g) Failure to permit an inspection or reinspection. Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.
[63 FR 26737, May 14, 1998; 63 FR 32699, June 15, 1998]
Sec. 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.
(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:
(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.
(2) Evaluate a complaint from the public.
(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.
(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.
(c) The laboratory must comply with the basic inspection requirements of Sec. 493.1773.
[63 FR 26737, May 14, 1998]