D1001

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.15(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.

Interpretive Guidelines §493.15(e)

Tests listed on the waiver list in §493.15(c) **are not** subject to routine survey. A survey of waived tests may be conducted **only** when authorized by the RO in the following instances:

- Determine if a laboratory is testing outside its certificate;
- Collect information regarding the appropriateness of tests specified as waived tests
- Investigate a complaint from the public; and/or
- Determine if the laboratory is operated and if testing is performed in a manner that does not constitute an imminent and serious risk to public health.

Refer to §§493.1773 and 493.1775 for additional guidelines for inspecting laboratories issued a certificate of waiver.

Laboratories holding a Certificate of Waiver must follow the current manufacturer's instructions for the waived test systems they are using for patient testing. To meet the waived testing regulatory requirements, these laboratories must comply with the manufacturer's requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing. These laboratories may only use the specimen types that were approved by the Food and Drug Administration (FDA) with the waived test system they are using, and they must follow the manufacturer's quality control (QC) and test performance requirements. We encourage laboratories to also comply with manufacturer's recommendations for the waived test system. Some manufacturers produce tests that can be run as a waived test or a moderate complexity test. Any laboratory with a Certificate of Waiver that uses the nonwaived test system instructions from a manufacturer should be advised that they must use the manufacturer's instructions for waived testing. If the situation remains uncorrected, the laboratory may be cited for performing tests beyond the scope of the certificate held by the laboratory, as well as failing to follow manufacturer's instructions. See S&C-04-05.

NOTE: It is never acceptable for a laboratory operating under a Certificate of Waiver to modify the manufacturer's instructions for the waived test system. Any such changes will result in a test that is **no longer waived** (i.e., the waived test is uncategorized for

CLIA and therefore a high complexity test). For example, if a test specifies urine as the waived specimen type and the laboratory tests a different body fluid, then the laboratory is no longer performing a waived test and the lab is then subject to routine inspections and the CLIA requirements for high complexity testing. Waived laboratory testing personnel must follow the manufacturer's instructions in their entirety and without variation. Great care should be taken to add the proper reagents in the order and amount specified by the manufacturer's instructions to ensure compliance with the CLIA regulations and reliable test results.

§493.17 Test categorization

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(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 description 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 l. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

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

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

(i) Score 1.

(A) Calibration materials are stable and readily available;

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

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

(ii) Score 3.

(A) Calibration materials, if available, may be labile;

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

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

(6) Test system troubleshooting and equipment maintenance.

(i) Score l.

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

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

(ii) Score 3.

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

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

(7) Interpretation and judgment.

(i) Score 1.

(A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

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

(ii) Score 3.

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

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

(b) Revisions to the criteria for categorization

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

(c) Process for device/test categorization utilizing the scoring system under §493.17(a)

(1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both 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 REGISTER in a notice with opportunity for comment.

Interpretive Guidelines §493.17(c)(5)

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the following web link for the FDA categorization database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays, and examinations not yet classified are considered high complexity.

Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

NOTE: A modified waived or moderate complexity test (including modifications in its intended use) is considered uncategorized for CLIA purposes and therefore becomes a high complexity test.

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§493.19 Provider-*p*erformed *m*icroscopy (PPM) *p*rocedures

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

(a) Requirement. To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

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

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

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

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

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

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

(6) Limited specimen handling or processing is required.

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

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

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

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.
(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) Revision to criteria and the list of PPM procedures

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(e) Laboratory requirements

Laboratories eligible to perform PPM examinations must--

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

§493.20 Laboratories performing tests of moderate complexity

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

Interpretive Guidelines §493.20

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

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of

compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§493.1773 and 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.1773, and 493.1775.

§493.25 Laboratories performing tests of high complexity

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

Interpretive Guidelines §493.25

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

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements in §§493.1773 and 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.1773 and 493.1775.

Subpart B--Certificate of Waiver

§493.35 Application for a certificate of waiver

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(a) Filing of application.

Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in §493.15 must file a separate application for each laboratory location.

Interpretive Guidelines §493.35 (a)

See §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(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.

Interpretive Guidelines §493.35(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection. See §6034 of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See §6036.3 of the SOM for further guidance.

See §6008 of the SOM for guidance for Home Health Agencies with multiple sites.

(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.

Interpretive Guidelines §493.35(b)(2)

See §6036.2 of the SOM for the definition for limited public health testing. Note that laboratories operating under a certificate of waiver may not perform moderate or high complexity testing.

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can 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.

Interpretive Guidelines §493.35(b)(3)

Common direction means that all testing sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

The application must--

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

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

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

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

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

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

(d) Access requirements

Laboratories that perform one or more waived tests listed in §493.15(c) and no other tests must meet the following conditions:

Interpretive Guidelines §493.35(d)

Cite deficiencies for not following manufacturer's instructions at §493.15(e). (Use D1001)

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

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

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

Interpretive Guidelines §493.35(d)(2)(i)

Consult with your RO for assistance in determining when there is substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

An example of a substantive reason to inspect waived testing is if testing personnel are observed cutting urine dipsticks in half. (This violates both the manufacturer's instructions and causes questionable results to be reported.)

(ii) To evaluate complaints from the public.

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

Interpretive Guidelines §493.35(d)(2)(ii)-(iii)

See Chapter 5 of the SOM for specific procedures regarding complaint investigations.

(iv) To collect information regarding the appropriateness of waiver of tests listed in §493.15.

(e) Denial of application

If HHS determines that the application for a certificate of waiver is to be denied, HHS will--

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

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

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

§493.37 Requirements for a certificate of waiver

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

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

(b) Laboratories issued a certificate of waiver--

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

Interpretive Guidelines §493.37(b)(1)

Cite the laboratory's failure to follow manufacturer's instructions at §493.15(e). (Use D1001.)

(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.
Interpretive Guidelines §493.37(d)

See the Adverse Action section of the SOM beginning at §6250 for enforcement procedures.

(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 §§493.35 and 493.37.

§493.37(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.

§493.39 Notification requirements for laboratories issued a certificate of waiver

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

(a) Before performing and reporting results for any test or examination that is not specified under §493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

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

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

Interpretive Guidelines §493.39(a) and (b)

See §§6006 and 6030 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.

See §6032 of the SOM for applicable instructions on handling changes in ownership, name, location or director.

Subpart C--Registration Certificate, Certificate for Provider-Performed Microscopy Procedures, and Certificate of Compliance

§493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(a) Filing of application

Except as specified in paragraph (b) of this section, all laboratories performing nonwaived testing must file a separate application for each laboratory location.

Interpretive Guidelines §493.43(a)

See §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(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.

Interpretive Guidelines §493.43(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate certificate for each State, contact the RO to determine which State conducts the inspection. See §6034 of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See §6036.3 of the SOM for further guidance.

See §6008 of the SOM for guidance for home health agencies with multiple sites.

(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.

Interpretive Guidelines §493.43(b)(2)

See §6036.2 of the SOM for information on limited public health testing.

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can 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.

Interpretive Guidelines §493.43(b)(3)

In instances where the main laboratory is certified to perform waived, moderate and/or high complexity tests, the alternate sites may perform testing in all complexities covered by the certificate provided that all other applicable requirements are met (e.g., quality control, personnel).

Common direction means that all sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

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

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

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

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

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

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

(d) Access and reporting requirements

All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§493.45 Requirements for a registration certificate

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—

(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in §493.15 (c) or specified as PPM procedures.

Interpretive Guidelines §493.45(a)

All facilities performing laboratory testing must have a registration, compliance or accreditation certificate or a certificate of waiver prior to performing patient testing.

See §§6006 and 6030 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.

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

(1) Complies with the requirements of §493.43;

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

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

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

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

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

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

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

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

(e) A registration certificate is--

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

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

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

Interpretive Guidelines §493.45(f)

See the Appeals section of the SOM beginning at §6300 for instructions on denial of a certificate application.

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

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

§493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

(a) A certificate for PPM procedures is required--

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

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

(b) HHS will issue a certificate for PPM procedures if the laboratory--

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

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

(c) Laboratories issued a certificate for PPM procedures are subject to--

(1) The notification requirements of §493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

(3) Inspection only under the circumstances specified under §§493.1773 and 493.1775, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c) (1) and (2) of this section.

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

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

§493.49 Requirements for a certificate of compliance

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in §493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory--

(1) Meets the requirements of §§493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and
(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance--

(1) Are subject to the notification requirements of §493.51; and

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

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

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

(iv) To collect information regarding the appropriateness of tests listed in §493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

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

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

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

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

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

(1) Provide the laboratory with a statement of grounds on which the determination

of noncompliance is based; and

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

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

(g) A laboratory seeking to renew its certificate of compliance must--

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

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

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

(1) Basis for denial of the application; and

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

Interpretive Guidelines §493.49(h)(2)

See the Appeals section of the SOM beginning at §6300 for instructions on denial of a certificate application.

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

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

§493.51 Notification requirements for laboratories issued a certificate of compliance

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

Laboratories issued a certificate of compliance must meet the following conditions:

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

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

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

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

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

Interpretive Guidelines §493.51(a)-(c)

See the section of the SOM beginning at §6016 and §6032 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the Adverse Action section of the SOM beginning at §6256 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

§493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

Laboratories issued a certificate for PPM procedures must notify HHS or its designee--

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under §493.15(c), for which it does not have a

registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in--

(1) Ownership;
(2) Name;

(3) Location; or

(4) Director

Interpretive Guidelines §493.53(b)

See the section of the SOM beginning at §6016 and §6032 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the Adverse Action section of the SOM beginning at §6256 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

Subpart D--Certificate of Accreditation

§493.55 Application for registration certificate and certificate of accreditation

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(a) Filing of application

A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory--

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

Interpretive Guidelines §493.55(a)(1)

When HHS approves accreditation organizations and State licensure programs, the ROs are notified and the approved organizations and programs are published as a notice in the FEDERAL REGISTER.

See §§6150-6151 of the SOM.

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

Interpretive Guidelines §493.55(a)(2)

See §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(b) Exceptions

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

Interpretive Guidelines §493.55(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the

inspection. See §6034 of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See §6036.3 of the SOM for further guidance.

See §6008 of the SOM for guidance for home health agencies with multiple sites.

(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.

Interpretive Guidelines §493.55(b)(2)

See §6036.2 of the SOM for the definition of limited public health testing.

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can 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.

Interpretive Guidelines §493.55(b)(3)

Common direction means that all sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

The application must--

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

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the

requirements established by the Secretary under section 353 of the Public Health Service Act; and

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

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

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

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

(d) Access and reporting requirements

All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§493.57 Requirements for a registration certificate

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

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

Interpretive Guidelines §493.57

See §§6006 and 6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

§493.57(a) HHS will issue a registration certificate if the laboratory--

(1) Complies with the requirements of §493.55;

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

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

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

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

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

(ii) Prior to the expiration of the certificate of compliance.

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

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

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

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

Interpretive Guidelines §493.57

See the Appeals section of the SOM beginning at §6300 for instructions on denial of a certificate of accreditation application.

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

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

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

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

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

§493.61 Requirements for a certificate of accreditation

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

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

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

(b) Laboratories issued a certificate of accreditation must--

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

(2) Meet the requirements of §493.63;

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

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

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

Interpretive Guidelines §493.61(b)(5)

See the section of the SOM regarding Special Procedures for Accredited and CLIA-exempt laboratories beginning at §§6152 and 6200 for procedures on follow-up of correction of deficiencies cited during validation inspections.

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

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

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

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

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

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

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

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

Interpretive Guidelines §493.61(d)

42 CFR §488.11 lists State survey agency functions.

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

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

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

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

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

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

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

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

Interpretive Guidelines §493.61(g)

Accrediting organizations which lose deemed status are required to notify their participating laboratories. These laboratories must re-apply for accreditation with another CMS-approved accrediting organization or apply for the appropriate CLIA certificate with CMS.

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

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

(2) Meet the requirements of this subpart; and

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

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

(1) The basis for denial of the application;

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

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

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

§493.63 Notification requirements for laboratories issued a certificate of accreditation

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

Laboratories issued a certificate of accreditation must:

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

changes in--

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

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

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

Interpretive Guidelines §493.63(a)-(c)

See the section of the SOM beginning at §6016 and §6032 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the Adverse Action section of the SOM beginning at §6256 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

Subpart H – General Guidelines

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

By law, proficiency testing (PT) programs are evaluated initially for CMS approval and annually thereafter for re-approval. After review, Central Office (CO) will issue PT program approvals and/or re-approvals provided they meet the requirements of Subpart I, Proficiency Testing Programs for Nonwaived Testing. A listing of these programs with the specialties, subspecialties, and specific analytes for which they are approved is available on the CMS CLIA web site at http://www.cms.gov/clia. The RO is responsible for ensuring that their SAs are aware of the approved program listing for the current year. Address questions related to the currently approved PT programs to the RO.

A CMS-approved PT program has been evaluated and found to be in compliance with the requirements of Subpart I and the applicable sections of Subpart H. When a laboratory experiences problems with PT samples, it resolves them with the PT program. When the SA experiences problems with an approved program, report all available information to the RO, who discusses the findings with CO. CO renders a decision on the termination or continued approval of the PT program, as appropriate. The Centers for Disease Control and Prevention may be requested by CO to provide technical advice.