

§ 493.55

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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.

[58 FR 5224, Jan. 19, 1993, as amended at 60 FR 20046, Apr. 24, 1995]

Subpart D—Certificate of Accreditation

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

§ 493.55 Application for registration certificate and certificate of accreditation.

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

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

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

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

(c) *Application format and contents.* The application must—(1) Be made to

HHS on a form or forms prescribed by HHS;

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

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

- (i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);
- (ii) The methodologies for each laboratory test procedure or examination performed, or both; and
- (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

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

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20046, Apr. 24, 1995]

§ 493.57 Requirements for a registration certificate.

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

(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.