

7. Tests involving radionuclides
 - (b) Examinations of water:
 1. Microbiology tests
 - (c) Examinations of milk, milk products, and milk containers:
 1. Tests for abnormal milk
 2. Tests for proper pasteurization
 3. Microbiology tests
 4. Chemical tests
 5. Physical tests
 6. Residual antibiotic tests
 - (d) Examinations of food products:
 1. Microbiology tests
 2. Chemical tests
 3. Physical tests
 4. Biological tests

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (a) 7. and r. (1) (b) 2. and 3., Register, October, 1980, No. 298, eff. 11-1-80; renun. from H 38.03, Register, April, 1982, No. 316, eff. 5-1-82.

HSS 165.04 Certification application. (1) APPLICATION AND EXCEPTIONS. All clinical laboratories, blood banks, and laboratories performing milk, water microbiology, and food products testing for the protection of the health of the public shall apply to the department for evaluation and certification, except:

- (a) Laboratories operated by the United States government and only serving patients under the auspices of that government;
- (b) Laboratories operated and maintained exclusively for teaching or research purposes and not involving patient or public health services;
- (c) Laboratories operated purely for internal quality control, or maintenance of the quality of their product, wherein compliance with governmental laws or codes is not required;
- (d) Physician office laboratories serving not more than 2 physicians and operated exclusively for the diagnosis and treatment of their patients.

(2) **APPLICATION FORM.** Applicants shall apply on forms prescribed by the department for evaluation and certification of those laboratory procedures or categories of procedures that the laboratory performs.

(3) **INFORMATION REQUIRED.** The application shall be accompanied by such information as the department may require.

(4) **SEPARATE LABORATORY LOCATIONS.** Separate applications shall be submitted for separate laboratory locations.

(5) **INITIAL APPLICATION.** Application for initial certification in a laboratory testing specialty may be submitted at any time.

(6) **RECERTIFICATION.** Application for recertification shall be submitted upon notification by the department.

(7) **ACTION BY THE DEPARTMENT.** Within 60 days after receiving a complete application for certification of a laboratory or blood bank, the department shall either approve the application and issue the certification or deny the application. If the application for certification is denied, the department shall give the applicant reasons, in writing, for the denial.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (intro.) and (6), Register, October, 1980, No. 298, eff. 11-1-80; renum. from H 38.04, Register, April, 1982, No. 316, eff. 5-1-82; cr. (7), Register, November, 1985, No. 359, eff. 12-1-85.

HSS 165.05 Certification of approval. (1) APPROVAL ACTIONS. The department shall issue a certificate of approval for the specialty(ies) upon determination of substantial compliance with the administrative code. This determination shall include a review of the application, the current yearly proficiency testing findings, and on-site inspection results. Inspections performed by the department or by an alternative inspection program approved by the department shall include at least a review of such factors as technical methods, procedures, physical facilities, staffing, and internal quality control practices. The department reserves the right to validate inspections and proficiency testing performed by other approved program providers, and to impose prorated fees for such proficiency testing validation activities in accordance with s. HSS 165.21 (1).

(2) **SPECIAL APPROVAL ACTIONS.** If the participating laboratory is in substantial compliance except that through no fault of its own or through participation for less than one year it has been unable to examine the required yearly number of proficiency specimens, but has demonstrated satisfactory proficiency on specimens totaling not less than 40% of the specialty number, the department may issue a certificate of approval to the laboratory.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; r. and recr. (1) and am. (2), Register, October, 1980, No. 298, eff. 11-1-80; am. (1), Register, December, 1981, No. 312, eff. 1-1-82; renum. from H 38.05, Register, April, 1982, No. 316, eff. 5-1-82.

HSS 165.06 Provisional certification of approval. (1) PROVISIONAL APPROVAL. The department may issue a certificate of provisional approval to a participating laboratory when the laboratory fails to meet the minimal performance testing standards or has other significant factor deficiencies, but past performance, testing experience, qualification of personnel, or efforts by the laboratory indicate that the deficiency has been corrected or is readily correctable.

(2) **LIMITATION OF PROVISIONAL APPROVAL.** Provisional certification of approval cannot be granted for more than 2 consecutive years.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1), Register, October, 1980, No. 298, eff. 11-1-80; renum. from H 38.06, Register, April, 1982, No. 316, eff. 5-1-82.

HSS 165.07 Interim certification of approval. Interim certification of approval may be granted for a newly participating laboratory for not more than 12 months. Thereafter, the laboratory shall meet the requirements for certification or provisional certification.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80; renum. from H 38.07, Register, April, 1982, No. 316, eff. 5-1-82.
Register, November, 1985, No. 359