

CR 83-34

CERTIFICATE

STATE OF WISCONSIN)
) SS
DEPARTMENT OF HEALTH AND SOCIAL SERVICES)

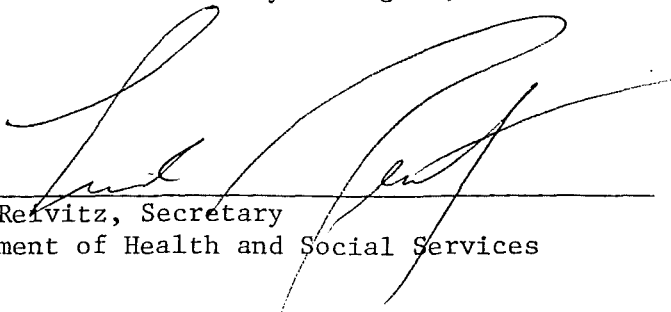
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TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

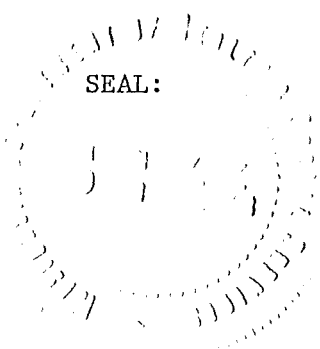
I, Linda Reivitz, Secretary of the Department of Health and Social Services and custodian of the official records of said Department, do hereby certify that the annexed rules relating to laboratory certification were duly approved and adopted by this Department on August 30, 1983.

I further certify that said copy has been compared by me with the original on file in this Department and that the same is a true copy thereof, and of the whole of such original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the State Office Building, 1 W. Wilson Street, in the city of Madison this 30th day of August, A.D. 1983.



Linda Reivitz, Secretary
Department of Health and Social Services



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ORDER OF THE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
REPEALING, RENUMBERING AND AMENDING, AMENDING, REPEALING
AND RECREATING, AND CREATING RULES

To repeal HSS 165.14(3)(i); to renumber and amend HSS 165.14(3)(j); to amend HSS 165.14(2) (intro.) and (a) and (3)(f) and 165.21(1) and (3); to repeal and recreate HSS 165.02; and to create HSS 165.21(5), relating to laboratory certification.

Analysis Prepared by the Department of Health and Social Services:

These revisions update, clarify and place in proper form and order the list of definitions, correct spelling and wording errors and remove unneeded language. References to Phenylketonuria testing have been removed because the Department under s. 146.02(2), Stats., has elected to approve only the State Laboratory of Hygiene for neonatal screening procedures, thus eliminating the need for certification in this specialty for other laboratories. The required grade for satisfactory syphilis serology performance has been lowered to accommodate the decrease in the number of annual proficiency testing specimens which was accomplished in a previous code revision. The fee exemption statement has been revised, which in conjunction with the revised definition of a public health laboratory, removes any ambiguity concerning the intent of the Department to exempt only city, county, combined city-county, and multiple county health departments from payment of fees. Since the program is totally fee-funded and thus self-supporting, creation of the fee revision statement is needed in order to provide a mechanism for increasing revenue if additional funds are required for program support. This eliminates the need for annual revision of the rules to obtain sufficient funds for program support and requires a demonstration of the need for the increased revenue as well as providing for a review of the increase by the program's Advisory Council.

Pursuant to the authority vested in the Department of Health and Social Services by s. 143.15(5) and (7), Stats., the Department of Health and Social Services hereby repeals, renumbers and amends, amends, repeals and recreates, and creates rules interpreting s. 143.15, Stats., as follows:

SECTION 1. HSS 165.02 of the Wisconsin Administrative Code is repealed and recreated to read:

HSS 165.02 DEFINITIONS. In this chapter: (1) "Administrative laboratory director" means a person who meets the requirements of s. HSS 165.20(1)(g) or the requirements of s. HSS 165.20(3)(b).

(2) "Blood bank" means any facility where activities are conducted involving the drawing, processing, or storage of human blood or blood derivatives, preliminary to transfusion or human use.

(3) "Certification of approval" means a finding by the department that a laboratory is in substantial compliance with the requirements of s. 143.15, Stats., and this chapter.

(4) "Commercial milk laboratory" means a laboratory that offers milk testing services to others for monitoring product quality or for meeting city, county, state, or federal code requirements.

- (5) "Department" means the Wisconsin department of health and social services.
- (6) "Director" means the person who plans, organizes and directs the operations of the laboratory, including but not limited to training and supervising laboratory personnel, reviewing laboratory procedures and approving test results, and who is responsible for the proper performance of all laboratory procedures.
- (7) "Evaluation and certification program" or "certification program" means the laboratory evaluation and certification program of the department.
- (8) "Facility" means a clinical laboratory, a blood bank laboratory, or a laboratory engaged in the testing of milk, water, or food products.
- (9) "Laboratory" or "clinical laboratory" means a facility where microbiological, biological, physical, serological, chemical, hematological, immunological, cytological, or microscopic examinations of specimens taken from the human body, milk, water, food products, or other matter, are performed for screening, diagnostic, and treatment purposes.
- (10) "Laboratory certification advisory council" means the council appointed under s. HSS 165.23.
- (11) "Laboratory evaluation" mean a system of determining and testing laboratory methods, procedures, and proficiency by inspection of the facility and equipment, review of personnel qualifications, practices, records, and controls, and the use of proficiency testing performance by the department.
- (12) "Laboratory specialty" or "specialty" means the science discipline used for the examination of materials derived from the human body or other matter, for the purpose of disease prevention, laboratory screening, diagnosis, or treatment of patients, or the examination of milk, water, or food products for the purpose of determining purity, potability, or freedom from harmful substances. For purposes of this chapter, the department designates laboratory specialties which include but are not limited to the following:
- (a) Clinical laboratory specialties.
1. Alcohol testing for implied consent.
 2. Bacteriology, general or enteric or both.
 3. Clinic microbiology (includes clinic bacteriology, clinic mycology, clinic parasitology).
 4. Mycobacteriology.
 5. Mycology.
 6. Parasitology.
 7. Clinical chemistry.
 8. Hepatitis testing.
 9. Hematology.
 10. Immunohematology.
 11. Non-syphilis serology.
 12. Syphilis serology.
 13. Cytology.

Note: No proficiency testing program is available for cytology. Therefore, the department does not charge a fee for this specialty. See s. HSS 165.21(1)(a).

(b) Milk, water, and food laboratory specialties.

1. Standard plate count.
2. Inhibitors.
3. Plate loop count.
4. Coliform plate count.
5. Phosphatase testing.
6. Somatic cell count.
7. Mastitis screening.
8. MPN procedure.
9. MF technique.

(13) "Local public health agency laboratory" means a laboratory operated by a single city or county health department, a multiple county health department, or a city-county health department which performs clinical, milk, water, or food tests for the prevention, detection, diagnosis, and control of disease.

(14) "Milk plant laboratory" means a laboratory of a milk plant that functions solely for the purpose of maintaining quality control of the milk plant's products for compliance with city, county, state, and federal statutes, ordinances, rules and regulations.

(15) "Owner" means the person who owns the laboratory facility, the institution operating a laboratory facility, or the state, county, or city agency operating a laboratory facility.

(16) "Participating laboratory" means a laboratory that participates in a proficiency testing program approved by the department.

(17) "Proficiency testing program" means those activities which are required by the department to define, monitor, and measure the accuracy of testing by a laboratory and which meet the applicable requirements of federal agencies for licensure or certification of clinical and milk, water and food laboratories.

(18) "Referee laboratory" means a laboratory that has participated in a proficiency testing program and has shown agreement, reproducibility, and reliability in testing procedures or methods.

(19) "Reference laboratory" means a laboratory of known expertise and reliability.

(20) "Revocation of certification" means the withdrawal of the certification of the laboratory by specialty discipline.

(21) "Suspension of certification" means the temporary withdrawal of the certification of the laboratory by specialty discipline until the cause for suspension is corrected.

SECTION 2. HSS 165.14(2)(a) and (3)(f) of the Wisconsin Administrative Code are amended to read:

(2) REQUIREMENTS FOR PROVIDERS OF PROFICIENCY TESTING PROGRAMS. The department shall approve proficiency testing programs by laboratory specialty as listed in s. HSS 165.02 (~~18~~ 12).

(a) The minimum annual number of proficiency testing specimens required for each laboratory specialty, covering the entire test year and sent at appropriate intervals, shall be as follows:

1. <u>Alcohol testing for implied consent</u>	25
2. <u>Bacteriology, General general or Enteric enteric or both</u>	8
3. <u>Microbiology, Clinic microbiology (includes clinic bacteriology, clinic mycology, clinic parasitology)</u>	20
4. <u>Mycobacteriology</u>	8
5. <u>Mycology</u>	8
6. <u>Parasitology</u>	8
7. <u>Clinical Chemistry chemistry</u>	24 (or 192 tests)
8. <u>Hepatitis Hepatitis testing</u>	20
9. <u>Hematology</u>	16
10. <u>Immunoematology</u>	18
11. <u>Milk</u>	34
12. <u>Non-syphilis Serology serology</u>	12
13. Phenylketonuria	12
14. 13. Syphilis Serology serology	20

(3) (f) Immunoematology. A grade of 100% shall be required in ABO grouping and Rh typing. A grade of 85% or higher shall be satisfactory performance in all other areas of testing within this program. Individual laboratory results shall be compared with reference laboratory results. The consensus ~~of~~ of reference, referee or participant laboratories shall determine acceptable results.

SECTION 3. HSS 165.14(3)(i) of the Wisconsin Administrative Code is repealed.

SECTION 4. HSS 165.14(3)(j) of the Wisconsin Administrative Code is renumbered HSS 165.14(3)(i) and amended to read:

~~(j)~~ (i) Syphilis serology. A grade of ~~90~~ 85% in reproducibility and ~~90~~ 85% in agreement shall be satisfactory performance. Individual participant values shall be compared to an acceptable range which shall be determined for each proficiency test specimen from the consensus of reference, referee or participating laboratories. Percent achievement in syphilis serology shall be calculated in 2 categories. Percent of reproducibility shall be equal to the number of correctly matched split samples divided by the total number of split samples submitted and multiplied by 100. Percent of agreement shall be equal to one-half the number of partial agreements plus the number of complete agreements divided by the total number of reports compared and multiplied by 100.

SECTION 5. HSS 165.21 (1) and (3) of the Wisconsin Administrative Code are amended to read:

(1) DETERMINATION OF FEES. Except when increased under sub. (5), Fees fees shall be determined as follows: each laboratory specialty, \$100; inspection, \$200; certification \$75.

(3) EXCEPTIONS. All ~~official~~ local public health agency laboratories shall be exempt from fees.

SECTION 6. HSS 165.21 (5) of the Wisconsin Administrative Code is created to read:

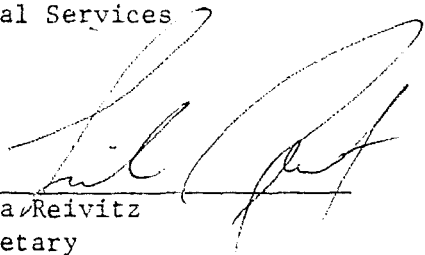
(5) FEE REVISION. Fees under this section may be increased up to a maximum of 8% a year if necessary to support the program. Any fee increase shall be based on a demonstrated need for increased funds to support the level of effort and objects of expenditure in effect on January 1, 1983, and shall be reviewed by the laboratory certification advisory council before taking effect.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register as provided in s. 227.026(1), Stats.

Department of Health and
Social Services

Date: 4-30-83

By:


Linda Reivitz
Secretary

SEAL:

