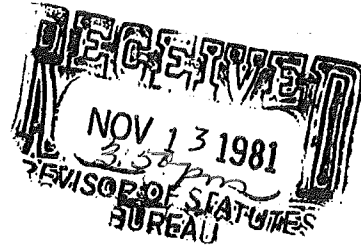


CERTIFICATE



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

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

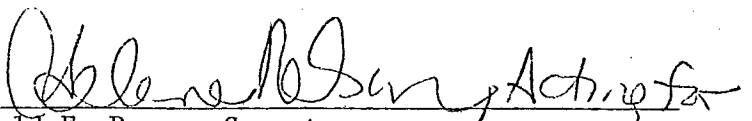
I, Donald E. Percy, Secretary of the Department of Health and Social Services and custodian of the official records of said department, do hereby certify that the annexed rules relating to laboratory certification were duly approved and adopted by this department on November 13, 1981.

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 13 day of November, A.D. 1981.



SEAL:


Donald E. Percy, Secretary
Department of Health and Social Services

ORDER OF THE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
REPEALING, AMENDING AND ADOPTING RULES

To repeal H 38.17(1)(j) and H 38.20(2)(g); to amend H 38.01(2), H 38.02(18), H 38.05(1), H 38.14(2)(a), H 38.21(1), and H 38.21(3); and to adopt H 38.20 (intro.), relating to laboratory certification.

Analysis prepared by the Department of Health and Social Services:

These rules reduce the number of specimens that a clinical or milk/water laboratory is expected to analyze each year to demonstrate to the Department that it is proficient in performing tests on specimens. The change will enable laboratories to select from a wider variety of approved alternate testing programs. The rules also remove the fee exempt status for state hospitals and institutions.

Pursuant to 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, amends and adopts rules interpreting s. 143.15, Stats., as follows:

SECTION 1. H.38.01(2) of the Wisconsin Administrative Code is amended to read:

(2) OTHER PROGRAM RELATIONSHIPS. In addition to functioning for the attainment of reliable clinical, water, milk, and food product testing, the certification program endeavors to assure the development of clinical and disease control laboratory services to meet the needs and requirements of a number of federal and state health related programs and to achieve better laboratory morbidity reporting systems for disease detection and management. The health related laws or programs receiving input from the laboratory evaluation and certification program include the ~~premarital syphilis-serology-law~~; infant metabolic disorder testing law, alcohol analyses for implied consent and coroner motor vehicle and snowmobile death laws, codes for controlling enteric disease cases and carriers, the Wisconsin Hospital Approval Act, federal Medicare, Medicaid certification, interstate laboratory licensure law, and appropriate municipal, state, and federal laws controlling the quality of laboratory testing services for water, milk, and food products.

SECTION 2. H 38.02 (18) of the Wisconsin Administrative Code is amended to read:

(18) LABORATORY SPECIALTY. Laboratory 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 these regulations this chapter, the department designates specialties which include, but are not limited to the following:

- (a) Clinical laboratory specialties.
- {a} 1. Alcohol Testing.
 - {b} 2. Bacteriology, General or Enteric or both.
 - {c} 3. Clinic Microbiology (includes Clinic Bacteriology, Clinic Mycology, Clinic Parasitology).
 - {d} 4. Mycobacteriology.
 - {e} 5. Mycology.
 - {f} 6. Parasitology.
 - {g} 7. Clinical Chemistry.
 - {h} 8. HAA Hepatitis Testing.
 - {i} 9. Hematology.
 - {j} 10. Immunohematology.
 - ~~{k}~~ 10m. Milk Testing & Water Microbiology Testing.
 - {t} 11. Non-syphilis Serology.
 - {m} 12. Phenylketonuria Testing.
 - {n} 13. Syphilis Serology.
 - {o} 14. Cytology*.

Note: No proficiency testing program is available for cytology.
Therefore, the department does not charge a fee for this specialty.
See H 38.21(1)(a).

~~*No-proficiency-testing-program;-see-H-38:21(t)(a)~~

SECTION 3. H 38.05 (1) of the Wisconsin Administrative Code is amended to read:

H 38.05 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 programs program providers, and to impose prorated fees for such proficiency testing validation activities in accordance with s.
H 38.21(1).

SECTION 4. H 38.14 (2)(a) of the Wisconsin Administrative Code is amended to read:

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

1. Alcohol	25
2. Bacteriology, General or Enteric or both	20 <u>8</u>
3. Microbiology, Clinic (clinic bacteriology, clinic mycology, clinic parasitology)	20
4. Mycobacteriology	15 <u>8</u>
5. Mycology	20 <u>8</u>
6. Parasitology	20 <u>8</u>
7. Clinical Chemistry	24 (or 192 tests)
8. HAA Hepatitis	20
9. Hematology	16
10. Immunohematology	18
11. Milk	34
12. Non-syphilis Serology	20 (or 48 tests) <u>12</u>
13. Phenylketonuria	12
14. Syphilis Serology	40 <u>20</u>

~~Shipments for all programs shall cover the entire test year and shall be sent at appropriate intervals.~~

SECTION 5. H 38.17 (1)(j) of the Wisconsin Administrative Code is repealed.

SECTION 6. H 38.20 (intro.) of the Wisconsin Administrative Code is adopted to read:

H 38.20 (intro.) Each laboratory shall be under the direction of a qualified laboratory director.

SECTION 7. H 38.20 (2)(g) of the Wisconsin Administrative Code is repealed.

SECTION 8. H 38.21 (3) of the Wisconsin Administrative Code is amended to read:

(3) EXCEPTION. ~~State hospitals and state institutions, and all~~ All official public health agency laboratories shall be exempt from fees.

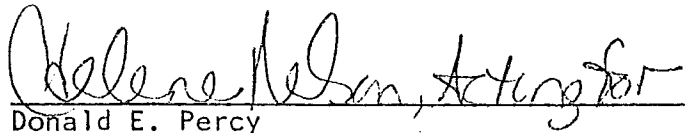
CSP
11/17/81
per call
with
Paul Menger.

The rules, amendments, and repeals 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

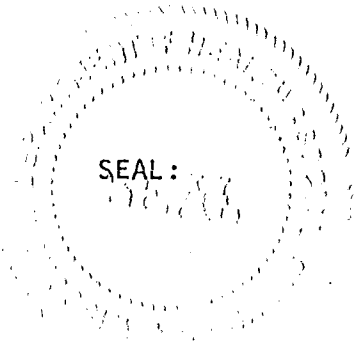
Dated: 11-13-81

By:


Donald E. Percy

Secretary

SEAL:



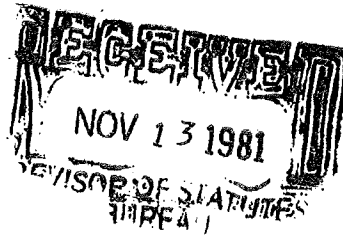


State of Wisconsin \

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

OFFICE OF THE SECRETARY
1 WEST WILSON STREET
MADISON, WISCONSIN 53702

November 13, 1981



Mr. Orlan Prestegard
Revisor of Statutes
411 West, State Capitol
Madison, Wisconsin 53702

Dear Mr. Prestegard:

As provided in section 227.023, Stats., there is hereby submitted a certified copy of H 38, administrative rules relating to laboratory certification.

These rules are being submitted to the Secretary of State as required by section 227.023, Stats.

Sincerely,

Donald E. Percy, Acting for

Donald E. Percy
SECRETARY