

CR 91-181

RECEIVED

JUL 9 1992
9:20
Revisor of Statutes
Bureau

CERTIFICATE

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

I, Gerald Whitburn, Secretary of the Department of Health and Social Services and custodian of the official records of the Department, do hereby certify that the annexed rules relating to laboratory certification were duly approved and adopted by this Department on July 7, 1992.

I further certify that this copy has been compared by me with the original on file in the Department and that this copy is a true copy of the original, and of the whole of the 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 7th day of July, 1992.



SEAL:

Gerald Whitburn, Secretary
Department of Health and Social Services

RECEIVED

JUL 9 1992

Revisor of Statutes
Bureau

Order of the
Department of Health and Social Services
Repealing, Renumbering and Amending Rules

To repeal HSS 165.21(1)(a) to(c); to renumber and amend HSS 165.21 (1)(intro.); and to amend HSS 165.02(12), relating to laboratory certification.

Analysis Prepared by the Department of Health and Social Services

The Department certifies all clinical and milk-water laboratories in the state, except physician office laboratories serving not more than 2 physicians. The principal activities involved in certification of laboratories are: 1) administration and processing of applications, bills, licenses and other documentation related to participating laboratories; 2) on-site inspection and evaluation of regulated laboratories; and 3) periodic proficiency testing (PT) to assess the accuracy of laboratory performance in certified specialties. From the inception of the program in 1951 until 1979, the Division of Health had the responsibility for all three of these functions. In that year, by legislative mandate, the proficiency testing portion of the program was transferred to the State Laboratory of Hygiene. At that time, the Department designated the State Laboratory as the official state PT program and, under contract, the State Laboratory has provided this service to the Department up to the present time. Laboratories may also choose from three additional national PT programs approved by the Department.

Under the current contractual arrangement, the Department charges laboratories three separate fees: 1) a specialty fee for those laboratories participating in the Department-designated State Laboratory PT program, 2) an inspection fee, and 3) a certification fee. Approximately 60% of the total revenue collected is paid to the State Laboratory for the PT program. For the past several years, the State Laboratory has contended that the PT contract revenue it receives from the Department is not sufficient to fund the services it provides and that the State Laboratory must subsidize these activities in part from its GPR budget. Both parties agree that this regulatory program should fully support itself from the fees collected, but the present administrative rules restrict the ability of the Department to increase fees to the level of support needed for the PT portion of the program.

These proposed rule changes would allow the State Laboratory's PT program to separate from the Department's certification program, to independently vend its PT services to regulated laboratories nationwide, and to collect fees for PT directly from the participating laboratories. The specialty fees to be charged by the Department in the amended rules are only those required to support the administrative processing and inspection costs incurred by the Department in the certification process. The separate inspection and certification fees would be eliminated. Regulated laboratories would be free to choose the State Laboratory program or one of several Department-approved national programs and would pay the PT program provider directly.

The proposed change in specialty designations conforms more accurately to current laboratory practice and terminology. The specialty list also corresponds more closely to federally designated specialties. Since more than half of the state-certified laboratories are also required to meet federal regulations, the modifications will avoid confusion for laboratories which must meet both sets of requirements.

The Department's authority to repeal, renumber and amend these rules is found in s. 143.15(5) and (7), Stats. The rules interpret s. 143.15 Stats.

SECTION 1. HSS 165.02 (12) is amended to read:

HSS 165.02 DEFINITIONS. (12) "Laboratory specialty" or "specialty" means ~~the~~ a 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, consisting of:
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~~ Virology;
 8. ~~Hepatitis testing~~ Routine chemistry;

9. ~~Hematology~~ Endocrinology;
10. ~~Immunohematology~~ Toxicology;
11. ~~Non-syphilis serology~~ Urinalysis;
12. ~~Syphilis serology~~ Hematology;
13. Cytology;
14. Immunohematology;
15. General immunology; and
16. Syphilis serology; and

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-, consisting of:

1. Standard plate count;
2. Inhibitors;
3. Plate loop count;
4. Coliform plate count;
5. Phosphatase testing;
6. ~~Somatic cell count~~ Direct microscopic somatic cell count;
7. ~~Mastitis screening~~ Optical or electronic somatic cell count;
8. MPN procedure;
9. MF technique;
10. ONPG-MUG (colilert); and
11. Presence-absence.

SECTION 2. HSS 165.21 (1)(intro.) is renumbered 165.21(1), and HSS 165.21(1), as renumbered, is amended to read:

HSS 165.21 FEES. (1) DETERMINATION OF FEES. Except when increased under sub. (5), fees shall be determined as follows: each laboratory specialty, \$100; inspection, \$200; certification \$75 shall pay an annual fee of \$85 to the department for each specialty in which the laboratory requests certification. This fee does not include costs for proficiency testing, which shall be paid by each laboratory directly to the proficiency testing program provider.

SECTION 3. HSS 165.21 (1)(a) to (c) are repealed.

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. 227.22(2), Stats.

Wisconsin Department of Health
and Social Services

DATED: July 7, 1992

By:



Gerald Whitburn
Secretary

SEAL:

RECEIVED

JUL 9 1992

Revisor of Statutes
Bureau

Tommy G. Thompson
Governor
Gerald Whitburn
Secretary



Mailing Address
1 West Wilson Street
Post Office Box 7850
Madison, WI 54707-7850
Telephone (608) 266-9622

State of Wisconsin
Department of Health and Social Services

July 9, 1992

RECEIVED

JUL 9 1992

Revisor of Statutes
Bureau

Mr. Bruce E. Munson
Revisor of Statutes
119 Martin Luther King, Jr., Blvd.
Madison, WI 53703

Dear Mr. Munson:

As provided in s. 227.20, Stats., there is hereby submitted a certified copy of HSS 165, administrative rules relating to laboratory certification.

These rules are also being submitted to the Secretary of State as required by s. 227.20, Stats.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gerald Whitburn".

Gerald Whitburn
Secretary

Enclosure