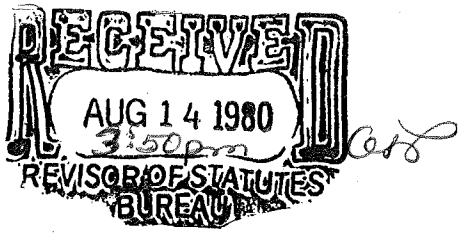
H 38

CERTIFICATE



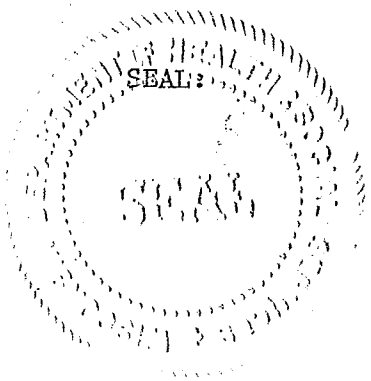
STATE OF WISCONSIN)
) SS
DEPARTMENT OF HEALTH AND SOCIAL SERVICES)

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 August 14, 1980.

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 St., in the city of Madison, this 14th day of August A.D., 1980.



D. E. P.

Donald E. Percy, Secretary
DEPARTMENT OF HEALTH AND SOCIAL SERVICES

11-1-80

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

Relating to rules concerning laboratory certification.

Analysis prepared by the Department of Health and Social Services

Pursuant to the 1979-81 budget bill, section 972c, this rule establishes minimum uniform standards for the evaluation and certification of clinical, milk, and water laboratories, and establishes the standards to be met by equivalent evaluation programs that a laboratory may use in place of Department evaluation, with attendant changes in specialty designation and the fee schedule.

Pursuant to authority vested in the Department of Health and Social Services by s. 143.15, Stats., the Department of Health and Social Services hereby adopts, amends, repeals, and renumbers rules interpreting s. 143.15, stats., as follows;

Sections H 38.01(1), (2), and (3) of the Wisconsin Administrative Code are amended to read:

H 38.01 Introduction. (1) STATUTORY REQUIREMENT. Section 143.15, Laboratories, approval of, Wis. Stats., ~~was modified by chapter 39, section 633, laws of 1975, effective July 31, 1975, chapter 198, section 42, effective April 14, 1976, chapter 224, section 112, effective May 5, 1976. Section 143.15 now~~ requires in part: that laboratories, except physician office laboratories serving not more than 2 physicians, performing clinical laboratory tests or examinations of milk, water, and food products for the purpose of protecting the health of the public shall apply to the department of health and social services for an evaluation of the examinations and appropriate certification; that the certification normally will be valid for 12 months and subject to revocation, denial, or suspension for cause; that the department of health and social services shall establish certification standards; and that laboratories shall not operate without a certificate.

(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, ~~the PKU screening 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.

(3) METHOD. The program ~~is to~~ shall evaluate and certify ~~by testing specialties and subspecialties being offered or performed by the laboratory,~~ laboratories by specialty services offered and provide ~~field~~ on-site surveys, technical consultation, ~~bench and~~ other training assistance, ~~proficiency testing,~~ and facility certification. The program applies nationally accepted testing procedures and standards to the extent that they exist and are appropriate and special standards as determined or required by other programs such as Medicare, and stresses satisfactory proficiency testing performance ~~in evaluation and certification of facilities~~ in programs approved by the department.

Sections H 38.02(1), (2), (7), (8), (14), (16), (17), and (18) of the Wisconsin Administrative Code are amended to read:

H 38.02 Definitions. (1) LABORATORY OR CLINICAL LABORATORY. 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 ~~the purpose of~~ laboratory screening, ~~and~~ diagnostic, and treatment ~~examinations for the protection of the health of the public~~ purposes.

(2) COLLECTION STATION. Collection station means a place where specimens are obtained, deposited or temporarily stored but not examined. If specimens are examined at a collection station, the station will be considered a laboratory.

(7) WATER MICROBIOLOGY LABORATORY. A water microbiology laboratory means a laboratory that performs microbiological tests on water to assure the safety and potability of private or public waters. Water laboratories that peform such tests for others are deemed to be commercial water laboratories.

(8) MILK, WATER MICROBIOLOGY, AND FOOD LABORATORY. A milk, water microbiology, and food laboratory means a laboratory that performs tests on milk, water, and food, or any combinations, to assure purity and safety and/or compliance with city, county, state, or federal laws. Laboratories that perform such tests for others are deemed to be commercial milk, water, and food laboratories.

(14) REFERENCE LABORATORY. Reference laboratory means a laboratory of ~~national reputation and~~ known expertise and reliability.

(16) PROFICIENCY TESTING PROGRAM. Proficiency testing program means those activities ~~of the evaluation and certification program~~ which are required by the department to define, monitor, and measure the accuracy of testing by a laboratory ~~or a comparable proficiency testing program approved by the department~~. Such ~~comparable~~ proficiency testing programs approved by the department must meet the applicable requirements of federal agencies for licensure or certification of clinical and milk, water and food laboratories.

(17) LABORATORY EVALUATION. Laboratory evaluation means a system of determining and testing laboratory methods, procedures, and proficiency by inspection of the facility and equipment, review of personnel qualifications, review of practices, records, and controls and the use of proficiency testing performance by the department.

(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 ~~including microbiology, biology, serology, chemistry, immunology, hematology, radioassay, cytology, and microscopy. Laboratory subspecialty means the natural subdivisions of a specialty.~~ For purposes of these regulations, the department designates ~~the following~~ specialties ~~and subspecialties to pertain under the law~~ which include, but are not limited to the following:

~~(a) Microbiology~~
~~1. General bacteriology~~
~~2. Enteric bacteriology~~
~~3. Mycology~~
~~4. Parasitology~~
~~5. Virology~~
~~(b) Serology~~
~~1. Syphilis~~
~~2. Non-syphilis~~
~~(c) Chemistry~~
~~1. Alcohol Testing~~
~~2. Phenylketonuria~~
~~3. Urinalysis~~
~~4. Other chemical tests~~
~~(d) Hematology, including coagulation~~
~~(e) Immunohematology~~
~~1. Blood group and Rh typing~~
~~2. Antibody identifications~~
~~3. Cross matching~~
~~4. Hepatitis associated antigen~~
~~(f) Cytology~~

(a) Alcohol Testing
(b) Bacteriology, General or Enteric or Both
(c) Clinic Microbiology (Includes Clinic Bacteriology, Clinic Mycology, Clinic Parasitology)
(d) Mycobacteriology
(e) Mycology
(f) Parasitology
(g) Clinical Chemistry
(h) HAA Testing
(i) Hematology
(j) Immunohematology
(k) Milk Testing & Water Microbiology Testing
(l) Non-syphilis Serology
(m) Phenylketonuria Testing
(n) Syphilis Serology
(o) Cytology*

* No proficiency testing program, see H 38.21(1)(a)

Section H 38.02(19) of the Wisconsin Administrative Code is renumbered H 38.02(20).

Section H 38.02(19) of the Wisconsin Administrative Code is adopted to read:

(19) PARTICIPATING LABORATORY. Participating laboratory means a laboratory that participates in a proficiency testing program approved by the department.

Section H 38.02(20) of the Wisconsin Administrative Code is renumbered H 38.02(21) and amended to read:

(21) DIRECTOR OF THE LABORATORY. Director of the laboratory means the person who plans, organizes, directs, and participates in the operations of the laboratory, including but not limited to training and supervision of laboratory personnel, and the reviewing of laboratory procedures and approval of test results. The director is responsible for the proper performance of all laboratory procedures.

Sections H 38.02(21) to (24) of the Wisconsin Administrative Code are renumbered H 38.02(22) to (25).

Section H 38.03(1)(a)7 of the Wisconsin Administrative Code is amended to read:

7. ~~Radioactive tests~~ Tests involving radionuclides

Sections H 38.02(1)(b)2 and 3 of the Wisconsin Administrative Code are repealed.

Section H 38.04(1) (intro.) of the Wisconsin Administrative Code is amended to read:

H 38.04 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:

Section H 38.04(1)(c) of the Wisconsin Administrative Code is amended to read:

(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;

Section H 38.04(6) of the Wisconsin Administrative Code is amended to read:

(6) RECERTIFICATION. Application for recertification shall be submitted ~~no later than 6 weeks prior to the expiration date of current certification~~ upon notification by the department.

Section H 38.05(1) of the Wisconsin Administrative Code is repealed and recreated 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 performed by other approved programs.

Section H 38.05(2) of the Wisconsin Administrative Code is amended to read:

(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 ~~in the evaluation and certification program~~ it has been unable to examine the required yearly number of proficiency specimens, but has demonstrated satisfactorily proficiency on specimens totaling not less than 40% of the specialty number, the department may issue a certificate of approval to the laboratory.

Section H 38.06(1) of the Wisconsin Administrative Code is amended to read:

H 38.06 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.

Section H 38.07 of the Wisconsin Administrative Code is amended to read:

H 38.07 Interim certification of approval. (1) INTERIM APPROVAL. Interim certification of approval may be granted for a newly participating ~~specialty laboratories~~ laboratory for not more than 12 months. Thereafter, ~~laboratories~~ the laboratory shall meet the requirements for certification or provisional certification.

Section H 38.09(1) of the Wisconsin Administrative Code is amended to read:

H 38.09 Certification period. (1) INITIAL CERTIFICATION. ~~I~~nitial certification, unless suspended or revoked, shall be valid for the remainder of the established certification period ~~for the specialty~~.

Section 38.10(1) of the Wisconsin Administrative Code is amended to read:

H 38.10 Denial, revocation, or suspension of certification. (1) DENIAL OR REVOCATION. If the department finds that the participating laboratory is not in substantial compliance with chapter H 38, certification shall be denied or revoked for the designated laboratory testing specialty(ies). The department shall notify the director and the owner of the laboratory, list the reason(s) for the intended denial or revocation, and designate at least 10 days for correction of deficiencies or for submission of an appeal request in writing to the department. On appeal, the department shall provide the laboratory director and the owner with an opportunity for a hearing in accordance with the State Administrative Procedure and Review Act, chapter 227 of Wis. Stats.

Section H 38.11(1) of the Wisconsin Administrative Code is amended to read:

H 38.11 Change in owner. (1) ~~Laboratories~~ A laboratory having a change in owner shall promptly inform the department and apply for recertification.

Section H 38.12(1) of the Wisconsin Administrative Code is amended to read:

H 38.12 Change in director. (1) ~~Laboratories~~ A laboratory having a change in laboratory director shall promptly inform the department of the change and provide the name, address, educational degrees, specialty certification, and experience of the director.

Section H 38.14 of the Wisconsin Administrative Code is repealed and recreated to read:

H 38.14 Proficiency testing. (1) REQUIREMENTS FOR PARTICIPATING LABORATORIES. All laboratories requiring certification shall participate satisfactorily in a proficiency testing program or a combination of programs which have been approved by the department. Participation shall be in those specialties for which the laboratory offers services and for which an approved proficiency testing program is available.

(a) Proficiency test specimens shall be examined on the laboratory premises by the personnel of the laboratory who normally perform the specialty test and by the testing procedure commonly used by the laboratory.

(b) Laboratories shall report their proficiency test results within the prescribed reporting time. Participating laboratories that fail to report proficiency testing results or unreceived or damaged specimens, or do not have a valid reason for failure to report shall receive a grade of zero for that shipment.

(2) REQUIREMENTS FOR PROVIDERS OF PROFICIENCY TESTING PROGRAMS. The department shall approve proficiency testing programs by specialty as listed in H 38.02(18).

(a) The minimum annual number of proficiency testing specimens required for each specialty shall be as follows:

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

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

(b) Proficiency specimens shall be prepared in such manner as to be representative of the types of specimens encountered in routine testing. Complete instructions for handling, reconstituting, testing, and reporting shall be included with each shipment of unknown specimens.

(c) Providers of approved proficiency testing programs shall promptly report to the department. These reports shall include at least a determination of satisfactory and unsatisfactory performance for each participating laboratory and such data and criteria as deemed necessary by the department to determine performance level.

(d) Providers of proficiency testing programs seeking equivalence shall apply to the department providing information as to specialty programs; numbers, types and frequency of specialty specimens; grading methods; and any other information required by the department to determine the acceptability of the program. The department shall use the results from approved programs for purposes of certification or decertification of laboratories.

(3) LEVELS OF PERFORMANCE AND GRADING SYSTEMS. The department shall determine if the grading systems and levels of performance used by proficiency testing programs are acceptable, reasonable and valid. The department shall set standards for satisfactory performance in the proficiency testing programs where the standards applied by the provider of the program are deemed inappropriate by the department. For the purposes of proficiency testing for certification of laboratories, satisfactory performance standards provided by the approved programs shall be equivalent to the following:

(a) Alcohol testing. A grade of 80% or higher 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.

(b) General and Enteric Bacteriology, Clinic Microbiology, Mycobacteriology, Mycology, and Parasitology. A grade of 80% or higher shall be satisfactory performance. The department may establish a score for each shipment by determining the percent of the test results which are acceptable. The consensus of reference, referee or participating laboratories shall determine acceptable performance.

(c) Clinical Chemistry. An overall grade of 80% or higher shall be satisfactory performance. The target ranges of acceptable values (relative to the standard value) for each constituent shall be expressed as $\pm$ number of standard units per unit volume or $\pm$ percentage of standard value whichever is greater.

(d) HAA testing. A grade of 80% or higher shall be satisfactory performance. Results from reference laboratories shall be tabulated by method used. Individual laboratory results shall be compared with this tabulation. The consensus of reference, referee or participant laboratories shall determine acceptable performance.

(e) Hematology. A grade of 85% or higher shall be satisfactory performance. For hemoglobin, hematocrit, and cell counting, individual laboratory results shall fall within a designated $\pm$ percent or standard deviation of the mean based on reference, referee or participating laboratory results. For white cell differential counts and 35mm transparencies the consensus of reference, referee or participating laboratories shall determine acceptable performance.

(f) Immunohematology. 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 reference, referee or participant laboratories shall determine acceptable results.

(g) Milk and water microbiology testing. A grade of 80% or higher shall be satisfactory performance.

1. For milk, acceptable test results shall fall within a $\pm$ designated standard deviation of the logarithmic mean. The designated standard deviation limits shall be determined by the department and depend on the type of test and its specificity and sensitivity. Analysts certified to perform inhibitor or phosphatase tests or both shall be able to detect positive samples by the appropriate official test methods.

2. For water microbiology, participating laboratories shall be able to detect coliforms in 75% of water samples when the coliform count is between 2 and 5 microorganisms per 100 milliliters.

(h) Non-syphilis Serology. A grade of 90% or higher 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 and participating laboratories.

(i) Phenylketonuria. A grade of 80% or higher 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. For the Guthrie bacterial inhibition assay, the acceptable range shall be in terms of the standard disk values in common use.

(j) Syphilis Serology. A grade of 90% in reproducibility and 90% 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.

Sections H 38.15(1) and (2) of the Wisconsin Administrative Code are repealed.

Section H 38.18(1) and (2) of the Wisconsin Administrative Code are renumbered H 38.15(1) and (2) and subsection (1) is amended to read:

H 38.15 General records and reports. (1) MAINTAINING RECORDS. The employer shall maintain for at least 2 years and make available at the facility for examination by the department, laboratory records pertaining to personnel health ~~records,~~ training, and experience~~.~~, and records pertaining to ~~The~~ equipment, inspections, calibrations, monitoring controls, procedures, proficiency testing results, policies, and other quality control ~~records shall be maintained at least 2 years~~ measures.

Section H 38.16(2) of the Wisconsin Administrative Code is amended to read:

(2) REPORTING SPECIMEN TEST RESULTS. Laboratories shall report specimen findings to persons authorized or allowed by law to receive such reports. The report shall include the name and address of the examining laboratory ~~and where applicable the name of the director, and the name and address of the examining laboratory if the specimen was forwarded to another laboratory~~. All service, product quality control, or monitoring specimens accepted by the laboratory shall be tested on the premises, unless forwarded to another laboratory certified by or acceptable to the department.

Section H 38.16(4) of the Wisconsin Administrative Code is repealed.

Section H 38.16(5) of the Wisconsin Administrative Code is renumbered H 38.16(4).

Sections H 38.17(1)(d), (f), and (h) of the Wisconsin Administrative Code are amended to read:

H 38.17 Specimen records. (1) ~~Laboratories shall maintain daily specimen records including~~ Specimen records shall be maintained for not less than one year and shall include the following:

(d) Date specimen collected, date specimen received, and date specimen result reported.

(f) Test performed~~, date,~~ and results.

(h) If examined by other certified laboratory, name and address of examining laboratory.

Section H 38.17(1)(i) of the Wisconsin Administrative Code is repealed.

Sections H 38.19(1)(a) through (i) of the Wisconsin Administrative Code are renumbered H 38.18(1) through (i) and subsections (1)(a), (b), (d), (e), (h), and (i) are amended to read:

H 38.18 Facilities and equipment. (1) GENERAL REQUIREMENTS. Laboratories shall have adequate facilities, equipment, instruments, supplies, and testing methods, ~~and internal quality control~~ for performing the procedure or categories of procedures for which certification is required:

(a) Working space shall be adequate, well lighted, well ventilated, ~~and convenient to the location of essential utilities~~ environmentally controlled, and with essential utilities for accurate test performance.

(b) Temperature controlled spaces and equipment including incubators, water baths, refrigerators, freezers, and sterilizers shall be properly maintained, ~~with reliable monitoring devices in proper working order~~ monitored and the results recorded.

(d) Appropriate authoritative manuals, including a current ~~operational procedural~~ procedure manual, texts, and printed material on maintenance, methods, controls, calibrations, records, and policies shall be available for use by laboratory personnel.

(e) ~~Proper storage space for reagents~~ Reagents, solutions, glassware, instruments, and supplies shall be ~~available~~ properly stored. Reagents and solutions shall be clearly labeled to show identification, proper storage, titer or concentration, expiration or preparation date, and other pertinent information.

(h) Premises shall be kept clean and free from unnecessary biological, chemical, and physical hazards and have available autoclave, chemical, or other methods satisfactory to the department, for disposing of hazardous materials. All infectious waste material shall be decontaminated before leaving the premises or marked in a manner that will alert sanitation personnel as to the nature of the waste material.

(i) The premises shall conform to the requirements of applicable ~~federal, state, and local codes pertaining to~~ mechanical, plumbing, ~~heating, electricity,~~ electrical, fire, and safety codes of federal, state, and local governments. Electrical equipment shall be maintained and used under safe conditions for the prevention of fire and shock hazards.

Section H 38.18(1)(j) of the Wisconsin Administrative Code is adopted to read:

(j) Laboratories performing procedures in mycobacteriology and mycology culturing shall use a biological safety cabinet which shall be inspected and its proper function verified at least annually.

Section H 38.19 of the Wisconsin Administrative Code is adopted to read:

H 38.19 Internal Quality Control. (1) The laboratory shall have a complete and on-going quality control program for all laboratory specialties for which the laboratory offers service.

(a) All test methods and results shall be continuously monitored for accuracy by simultaneous validation, where applicable, with reference specimens whose qualitative and quantitative reactions under the conditions of the testing are known.

(b) Results of such monitoring and remedial actions taken shall be recorded as generated and maintained in accessible form in the laboratory.

(c) All components, stock cultures, antigens, antiserums, cells, controls, media, reagents, solutions and standards used in performing a test shall be periodically checked as to identity, growth properties, potency, reactivity, sensitivity, specificity, sterility, titer, expiration date, and stability where applicable. Complete records of these checks shall be retained.

(d) Specimens shall be collected, handled, and tested in a manner to assure identity and stability and to give accurate and precise results.

(e) Correct reporting methods, appropriate units or nomenclatures shall be used. All abnormal results shall be reviewed or rechecked.

Sections H 38.20(1)(a), (e), (f), and (g) of the Wisconsin Administrative Code are amended to read:

(a) The person is a physician licensed in Wisconsin and certified in anatomical or clinical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or, board eligible, and ~~such person may direct~~ directs up to but not more than 3 laboratories; or

(e) The person holds at least a bachelor degree and was director of a Wisconsin clinical laboratory on July 31, 1975, and for the previous 5 years, and ~~the~~ person directs only one laboratory; or

(f) The person is a Wisconsin licensed physician of a group of ~~3 or more~~ physicians performing laboratory tests only for their patients and designated by the group as laboratory director, provided that the laboratory has at least a medical technologist,

or has ~~ongoing-qualified~~ consultation provided by a pathologist or medical technologist; or

(g) In ~~small~~ hospitals ~~areas~~ where the services of a qualified director are not ~~normally~~ available for the specialties provided, the person in (b), (c), and (d) above may qualify as an administrative laboratory director for that laboratory if it has a ~~qualified~~ consultant pathologist.

Section H 38.20(2)(f) of the Wisconsin Administrative Code is repealed and recreated to read:

(f) A person who on July 31, 1975, was serving as a laboratory director of one of the aforementioned types of laboratories as described in section H 38.20(2) and who has demonstrated knowledge of and satisfactory performance proficiency using the Standard Methods as described in H 38.20(2)(a), (b), (c), or (d) or other methods acceptable to the department qualifies to serve as director of that kind of laboratory.

Section H 38.21(1) of the Wisconsin Administrative Code is repealed and recreated to read:

H 38.21. (1) DETERMINATION OF FEES. Fees shall be determined as follows: Each specialty, $100; Inspection, $100; Certification fee, $25.

(a) Laboratories participating in the Department's proficiency testing program shall pay a specialty fee to the department for each specialty in which they are certified. Laboratories participating in an alternative program approved by the department shall not be charged a specialty fee by the department. Specialty fees shall not be charged for any specialty for which proficiency testing programs are not available.

(b) Laboratories which are inspected by department personnel shall pay an inspection fee to the department. Laboratories inspected by an alternative program approved by the department shall not be charged an inspection fee by the department.

(c) All laboratories shall pay the annual certification fee to the department.

Section H 38.21(2) of the Wisconsin Administrative Code is repealed.

Sections H 38.21(3), (4), and (5) of the Wisconsin Administrative Code are renumbered H 38.21(2), (3), and (4) respectively, and are amended to read:

(2) REFUNDS. ~~Certification fees~~ Fees ~~are~~ shall not be refundable.

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

(4) USE OF ~~CERTIFICATION~~ FEES. ~~Certification fees~~ Fees shall be used to offset the cost ~~of the~~ to the department for certification of laboratories and the collection of fees.

Section H 38.22(1) of the Wisconsin Administrative Code is amended to read:

H 38.22 Injunctions. (1) The operation or maintenance of a laboratory in violation of s. 143.15, Stats., or rules created thereunder, is prohibited. The department may in addition to other remedies, prosecute an action for an injunction to restrain such violations or to enjoin the future operation of the laboratory until compliance with the section and rules has been obtained. Any lab which operates without a certificate of approval shall be fined not less than $100 nor more than $1,000. Each day such violation continues shall constitute a separate offense (s. 143.15(6), Stats.).

Sections H 38.23(1)(b), (c), (d), (e), (h), and (i) of the Wisconsin Administrative Code are amended to read:

(b) The Wisconsin ~~society~~ Society ~~of pathologists~~ Pathologists, ~~inc~~ Inc.

(c) The Wisconsin ~~hospital association~~ Hospital Association

(d) The ~~state medical society~~ State Medical Society of Wisconsin

(e) ~~A medical technologist~~ The Wisconsin Association for Medical Technology

(h) ~~Department of natural resources water laboratory director~~ The Wisconsin Department of Natural Resources

(i) ~~Public consumers~~ A public consumer

Section H 38.23(3) of the Wisconsin Administrative Code is amended to read:

H 38.23(3) MEETINGS. The advisory council shall elect a chairperson and meet ~~semiannually~~ at least annually or more often at the discretion of the chairperson or petition of any 4 members.

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

Dated: August 14, 1980

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

SEAL:

Donald E. Percy, Secretary

State of Wisconsin \ DEPARTMENT OF HEALTH & SOCIAL SERVICES

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

August 14, 1980

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

Dear Mr. Prestegard:

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

This rule is being submitted to the Secretary of State as required by section 227.023, Wis. Stats.

Sincerely,

D.E.P.

Donald E. Percy
SECRETARY

Enclosure