Chapter H 38

LABORATORY CERTIFICATION

Note: Chapters H 37 and H 38 were repealed, Register, September, 1976, and a new Chapter H 38 was created effective October 1, 1976.

H 38.01 Introduction. (1) STATUTORY REQUIREMENT. Section 143.15, Laboratories, approval of, Wis. Stats., 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 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 shall evaluate and certify laboratories by specialty services offered and provide on-site surveys, technical consultation, other training assistance, and facility certification. The program applies nationally accepted testing procedures and standards to the ex-

tent 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 programs approved by the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80; am. (2), Register, December, 1981, No. 312, eff. 1-1-82.

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 miscroscopic examinations of specimens taken from the human body, milk, water, food products, or other matter, are performed for laboratory screening, diagnostic, and treatment 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.

(3) BLOOD BANK. 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.

(4) COMMERCIAL MILK LABORATORY. A 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) MILK PLANT LABORATORY. A milk plant laboratory means a laboratory that functions solely for the purpose of maintaining quality control of its products for compliance with city, county, state, or federal codes.

(6) FOOD LABORATORY. A food laboratory means a laboratory that performs tests on foods for adulterants, contaminants, or additives. Food laboratories that perform such tests for others are deemed to be commercial food laboratories.

(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 perform 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.

(9) PUBLIC HEALTH LABORATORY. A public health laboratory means a laboratory operated by an official public health agency performing tests for the prevention, detection, diagnosis, and control of disease. Such laboratories may perform clinical, milk, water, and food tests.

(10) FACILITY. A facility means a clinical laboratory, a blood bank laboratory, or a public or private laboratory engaging in the testing of milk, water, or food products.

(11) PERSON. Person means an individual, firm, partnership, association, corporation, municipality, or other entity whether organized for profit or not, performing clinical or milk, water, or food product laboratory tests for the protection of the health of the public.

(12) DEPARTMENT. Department means the Wisconsin department of health and social services.

(13) THE EVALUATION AND CERTIFICATION PROGRAM OR CERTIFICATION PROGRAM. The evaluation and certification program or certification program means the evaluation and certification program of the department.

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

(15) REFEREE LABORATORY. Referee laboratory means a laboratory that has participated in the proficiency testing program and has shown agreement, reproducibility, and reliability in special testing procedures or methods.

(16) PROFICIENCY TESTING PROGRAM. Proficiency testing program means those activities which are required by the department to define, monitor, and measure the accuracy of testing by a laboratory. Such 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 evalution means a sytem 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. For purposes of this chapter, the department designates specialties which include, but are not limited to the following:

(a) Clinical laboratory specialties.

1. Alcohol Testing.

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. HAA Hepatitis Testing.

9. Hematology.

10. Immunohematology.

11. Non-syphilis Serology.

12. Phenylketonuria Testing.

13. Syphilis Serology.

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).

(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.

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

(20) OWNER OF THE LABORATORY. Owner of the laboratory means the person or persons who own the laboratory facility, the owner of an institution operating a laboratory facility or a governmental state, county, or city agency operating a laboratory facility.

(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.

(22) ADMINISTRATIVE LABORATORY DIRECTOR. Administrative laboratory director means a person who meets the requirements of H 38.20 (1) (g) or the requirements of H 38.20 (3) (b).

(23) CERTIFICATION OF APPROVAL. Certification of approval means that the laboratory is in substantial compliance with the requirements of s. 143.15, Stats., and the rules promulgated thereunder and with the physical, technical, procedural, staffing, proficiency testing, and administrative requirements of the department.

(24) REVOCATION OF CERTIFICATION. Revocation of certification means to annul or invalidate the certification of the laboratory by specialty discipline.

(25) SUSPENSION OF CERTIFICATION. Suspension of certification means to temporarily invalidate the certification of the laboratory by specialty discipline until the cause for suspension is corrected.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; cr. (18) (f), Register, January, 1978, No. 265, eff. 2-1-78; am. (1), (2), (7), (8), (14), (16), (17) and (18), renum. (19) to (24) to be (20) to (25), cr. (19), and as renum., am. (21), Register, October, 1980, No. 298, eff. 11-1-80; am. (18) and cr. (18) (h), Register, December, 1981, No. 312, eff. 1-1-82.

H 38.03 Examinations necessary for the protection of the health of the public. (1) EXAMINATIONS. The department designates the following clinical, water, milk, or food examinations as necessary for the protection of the health of the public.

(a) Examinations of body fluids, tissues, discharges, respiratory and environmental air:

1. Microbiology tests
2. Serology tests
3. Chemical tests
4. Hematology tests
5. Immunohematology tests
6. Cytology tests
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.

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:

(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.

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.

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

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.

(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.

H 38.07 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.

H 38.08 Deficiencies endangering the health of the public. No level of certification shall be granted if any deficiency endangers the health of the public.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76.

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

(2) RECERTIFICATION. Recertification, unless suspended or revoked, shall be valid for 12 months.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1), Register, October, 1980, No. 298, eff. 11-1-80.

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 ch. 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, ch. 227, Stats.

(2) SUSPENSION. If the department finds that any deficiency in a laboratory presents a hazard to the health of the public or to laboratory workers, it may suspend certification, provisional certification, or interim certification of approval of a laboratory until the deficiency is corrected in a manner satisfactory to the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1), Register, October, 1980, No. 298, eff. 11-1-80.

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

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80.

H 38.12 Change in director. 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.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80.

H 38.13 Display of certificates. The owner or director of the laboratory shall display the current certificate (s) of approval, provisional approval, or interim approval.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. Register, October, 1980, No. 298, eff. 11-1-80.

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, covering the entire test year and sent at appropriate intervals, shall be as follows:

1. Alcohol	25
2. Bacteriology, General or Enteric or both	8
3. Microbiology, Clinic (clinic bacteriology, clinic mycology, clinic parasitology)	20
4. Mycobacteriology	8
5. Mycology	8
6. Parasitology	8
7. Clinical Chemistry	24 (or 192 tests)
8. Hepatitus	20

9. Hematology	16
10. Immunohematology	18
11. Milk	34
12. Non-syphilis Serology	12
13. Phenylketonuria	12
14. Syphilis Serology	20

(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 detemined 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 ± 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 or 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 ± 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 agree-

ments plus the number of complete agreements divided by the total number of reports compared and multiplied by 100.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; r. and recr. Register, October, 1980, No. 298, eff. 11-1-80; am. (2) (a), Register, December, 1981, No. 312, eff. 1-1-82.

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, training, and experience, and records pertaining to equipment, inspections, calibrations, monitoring controls, procedures, proficiency testing results, policies, and other quality control measures.

(2) REPORTING OF SPECIMEN RESULTS. Laboratories shall report as prescribed by the department those specimen results which the department finds necessary for the administration of s. 143.15, Stats., for the prevention, diagnosis, or control of disease, or for compliance with other laws of functional concern to the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; r. (1) and (2), renum. from H 38.18 and am. (1), Register, October, 1980, No. 298, eff. 11-1-80.

H 38.16 Specimen procurement and reporting. (1) ACCEPTANCE OF SPECIMENS. Clinical laboratories shall examine specimens only at the request of persons or agencies authorized or allowed by law to submit specimens.

(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. 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.

(3) EXCEPTIONS. Subsections (1) and (2) hereof, shall not apply to the taking, testing, or reporting of nonclinical laboratory specimens by a laboratory or its personnel solely for the determination of the accuracy or sufficiency of its procedures, supplies, equipment, or operations.

(4) SPECIMEN STABILITY REQUIRED. The department may require laboratories to show evidence that specimens shipped through the mail or other delivery systems and accepted by them for analysis are sufficiently stable for determinations requested, and to establish criteria for suitability of specimens.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (2), r. (4) and renum. (5) to be (4), Register, October, 1980, No. 298, eff. 11-1-80.

H 38.17 Specimen records. (1) Specimen records shall be maintained for not less than one year and shall include the following:

(a) Laboratory number or other identification information of specimens.

(b) Name of the person, facility, agency, or source of specimen.

(c) Name of the person, facility, or agency authorized or allowed by law to submit the specimen.

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

(e) Reason if specimen unsatisfactory.

(f) Test performed and results.

(g) Identification of examiner.

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

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (intro.), (d), (f) and (h), r. (1) (i), Register, October, 1980, No. 298, eff. 11-1-80; r. (1) (j), Register, December, 1981, No. 312, eff. 1-1-82.

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

(a) Working space shall be adequate, well lighted, well ventilated, 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, monitored and the results recorded.

(c) Analytical measuring instruments and equipment shall be kept in good working order, checked routinely, and precisely calibrated.

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

(e) Reagents, solutions, glassware, instruments, and supplies shall be 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.

(f) Glassware and pipettes shall be adequate for the purpose they are used, free of excessive scratches or cloudiness, and have clear graduations.

(g) When sterile needles, syringes, and lancets are required for testing procedures, they shall be cleaned and sterilized by standard or acceptable methods prior to use.

(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 mechanical, plumbing, 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.

(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.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; renum. from H 38.19 and am. (1) (a), (b), (d), (e), (h) and (i) and cr. (1) (j), Register, October, 1980, No. 298, eff. 11-1-80.

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.

History: Cr. Register, October, 1980, No. 298, eff. 11-1-80.

H 38.20 Standards of directors. Each laboratory shall be under the direction of a qualified laboratory director.

(1) CLINICAL LABORATORY DIRECTOR. The clinical laboratory director is qualified if:

(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 directs up to but not more than 3 laboratories; or

(b) The person holds an earned doctoral degree from an accredited institution with a chemical, physical, biological, or medical science as the major subject and has had 3 or more years of general clinical laboratory training and experience of which at least 2 years were spent in one of the laboratory specialites of a clinical laboratory having a director at the doctoral level, except that the directorship shall be limited to that specialty and the person shall direct only one laboratory; or

(c) The person holds a master degree with a chemical, physical, biological, or medical science as the major subject and has had 4 or more years of general clinical laboratory training and experience in a specialty of a clinical laboratory having a director at the doctoral level, except that

the directorship is limited to that specialty and the person shall direct only one laboratory; or

(d) The person holds a bachelor degree with a chemical, physical, biological, or medical science as the major subject, and has had 6 or more years of general clinical laboratory training and experience in a specialty of a clinical laboratory having a director at the doctoral level, except the directorship is limited to that specialty and the person shall direct only one laboratory; 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 directs only one laboratory; or

(f) The person is a Wisconsin licensed physician of a group of 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 consultation provided by a pathologist or medical technologist; or

(g) In hospitals where the services of a qualified director are not 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 consultant pathologist.

(2) MILK, WATER, FOOD LABORATORY DIRECTOR. (a) For a commercial milk laboratory a person is a qualified director who has a bachelor degree with a biological or microbiological science as the major subject, and has had one or more year's experience in an approved milk laboratory, and has demonstrated knowledge of and performance proficiency using the *Standard Methods for the Examination of Dairy Products* of the American public health association or other methods acceptable to the department, and meets existing state and federal requirements for commercial milk laboratory directors; or, in lieu of the year of experience the person successfully passes oral and written examinations conducted by the department.

(b) For a milk plant laboratory a person is a qualified director who has a high school diploma or equivalency, and has had at least 6 months' experience in an approved milk laboratory, and has demonstrated knowledge of and performance proficiency using the *Standard Methods for the Examination of Dairy Products* of the American public health association or other methods acceptable to the department; or, in lieu of 6 months' experience the person successfully passes oral and written examinations conducted by the department.

(c) For a food laboratory a person is a qualified director who has a bachelor degree with a microbiology or food science major including the isolation and identification of pathogenic bacteria, and meets existing state and federal requirements for food laboratory directors, and has demonstrated knowledge of and performance proficiency using the current methods of *Evaluation of Milk Laboratories* of the United States public health service, *Bacteriological Analytical Manual for Foods* of the food and drug administration, *Official Methods of Analysis* of the association of official analytical chemists, *Compendium of Methods for Microbiological Examination of Foods* of the American public health association, or other methods acceptable to the department.

(d) For a water laboratory a person is a qualified director who has a bachelor degree with a major in chemistry or microbiology, and has had 2 years' experience in a water laboratory, and meets existing state and federal requirements for water laboratory directors, and has demonstrated knowledge of and performance proficiency using the *Standard Methods for the Examination of Water and Waste Water* of the American public health association or other methods acceptable to the department.

(e) For a milk, water, and food laboratory a person is a qualified director who has a bachelor degree with a major in chemistry or microbiology, and has had 2 years' experience in an acceptable milk, water, and food laboratory, or applicable combination, and has demonstrated knowledge of and performance proficiency using standard methods prescribed for commercial milk, water, or food laboratory directors under (a), (c), and (d) or other methods acceptable to the department, and meets existing state and federal requirements for such directors.

(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.

(3) PUBLIC HEALTH LABORATORY DIRECTOR. The public health laboratory director is qualified if:

(a) For laboratories performing clinical tests, the person holds a bachelor degree with a chemical, physical, biological, or medical science as the major subject, and has had 3 years' general clinical laboratory training and experience either in a clinical laboratory or a public health laboratory performing clinical tests, and has demonstrated knowledge of and performance proficiency using standard methods prescribed for commercial milk, water, and food laboratory directors under s. H 38.20 (2) (a), (c), or (d), or other methods acceptable to the department, and meets existing state and federal requirements for such directors; or

(b) In a public health laboratory doing clinical testing where the services of an otherwise qualified director as defined in s. H 38.20 (1) or (3) (a) are not available, he is a duly licensed physician designated as administrative laboratory director by the public health agency; or

(c) For laboratories not performing clinical tests, the person holds a bachelor degree with a major in chemistry or microbiology, and has had 2 years' experience in a public health laboratory or other laboratory performing similar milk, water, and food analyses, and has demonstrated knowledge of and performance proficiency using standard methods prescribed for commercial milk, water, food laboratory directors under s. H 38.20 (2) (a), (c), (d), and (e), or other methods acceptable to the department, and meets existing state and federal requirements for such directors; or

(d) The person was director of an official public health laboratory on July 31, 1975, limits his directorship to those specialties he directed before July 31, 1975, and provided he is approved by the department.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (f), Register, January, 1978, No. 265, eff. 2-1-78; am. (1) (a), (e), (f) and (g), r. and recr. (2) (f), Register,

October, 1980, No. 298, eff. 11-1-80; cr. (intro.) and r. (2) (g), Register, December, 1981, No. 312, eff. 1-1-82.

H 38.21 Fees. (1) DETERMINATION OF FEES. Fees shall be determined as follows: each specialty, $100; inspection, $200; certification $75.

(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.

(2) REFUNDS. Fees shall not be refundable.

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

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

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; r. and recr. Register, January, 1978, No. 265, eff. 2-1-78; r. and recr. (1), r. (2), renum. (3) to (5) to be (4) to (6) and am., Register, October, 1980, No. 298, eff. 11-1-80; am. (1) and (3), Register, December, 1981, No. 312, eff. 1-1-82.

H 38.22 Injunctions. 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.).

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am., Register, October, 1980, No. 298, eff. 11-1-80.

H 38.23 Advisory council. (1) LABORATORY CERTIFICATION ADVISORY COUNCIL. The department shall establish an advisory council of not more than 9 members, who shall serve for staggered 3 year terms and represent or be the following:

(a) A physician directed clinical laboratory

(b) The Wisconsin society of pathologists, inc.

(c) The Wisconsin hospital association

(d) The state medical society of Wisconsin

(e) The Wisconsin association for medical technology

(f) A public health officer or laboratory director

(g) A milk, water, or food laboratory director

(h) The Wisconsin department of natural resources

(i) A public consumer

(2) RESPONSIBILITIES. The council shall study laboratory certification matters, advise, make recommendations to, and consult with the department.

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

(4) REIMBURSEMENT FOR EXPENSES. Council members shall be reimbursed for their actual and necessary expenses incurred in the performance of their duties.

History: Cr. Register, September, 1976, No. 249, eff. 10-1-76; am. (1) (e), (h) and (i) and (3), Register, October, 1980, No. 298, eff. 11-1-80.