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Note: Chapters H 37 and H 38 were repealed, Register, September, 1976, and a new Chapter H 38 was created effective October 1, 1976.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., 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, 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 evaluate and certify by testing specialties and subspecialties being offered or performed by the laboratory,

and provide field 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 performance in evaluation and certification of facilities.

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

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 the purpose of laboratory screening and diagnostic examinations for the protection of the health of the public.

(2) COLLECTION STATION. Collection station means a place where specimens are 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 LABORATORY. A water laboratory means a laboratory that performs 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, AND FOOD LABORATORY. A milk, water, 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 national reputation and 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 of the evaluation and certification program 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 must meet the requirements of federal agencies for licensure or certification of clinical 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, 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 prupose 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 speciality. For purposes of these regulations, the department designates the following specialties and subspecialties to pertain under the law:

(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

(19) 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.

(20) 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.

(21) 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).

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

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

(24) 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.

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. Radioactive tests

(b) Examinations of water:

1. Microbiology tests
2. Chemical tests
3. Physical 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.

H 38.04 Certification application. (1) APPLICATION AND EXCEPTIONS. All clinical laboratories, blood banks, and laboratories performing milk, water, 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 no later than 6 weeks prior to the expiration date of current certification.

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

H 38.05 Certification of approval. (1) APPROVAL ACTIONS. The department after review of the application including the current yearly proficiency testing findings of the laboratory and such factors as technical methods, procedures, physical facilities, staffing experience, internal quality control practices, administrative and rule requirements of the department, shall issue a certificate of approval for the specialty (ies) or subspecialty (ies) if the laboratory is in substantial compliance.

(2) SPECIAL APPROVAL ACTIONS. If the 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 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.

H 38.06 Provisional certification of approval. (1) PROVISIONAL APPROVAL. The department may issue a certificate of provisional approval to a 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.

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

H 38.08 Deficiencies endangering the health of the public. (1) 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 for the specialty.

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

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

H 38.10 Denial, revocation, or suspension of certification. (1) DENIAL OR REVOCATION. If the department finds that the 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 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 owner with an opportunity for a hearing in accordance with the State Administrative Procedure and Review Act, chapter 227 of Wis. 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.

H 38.11 Change in owner. (1) Laboratories 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.

H 38.12 Change in director. (1) Laboratories 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.

H 38.13 Display of certificates. (1) 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.

H 38.14 Proficiency testing. (1) PROFICIENCY TESTING REQUIREMENTS. Laboratories shall be subject to proficiency testing as directed by

the department. The proficiency testing program shall be that conducted by the department or such other equivalent program approved by the department.

(2) SHIPMENT OF PROFICIENCY SPECIMENS. The department shall determine the number, type, and frequency of shipped proficiency specimens for specialties and shall notify laboratories annually or semi-annually of the shipping dates.

(3) USE OF REFERENCE LABORATORIES. The department may use reference laboratories, as defined, in determination of the acceptable values for proficiency specimens.

(4) REFEREE LABORATORIES. The department may select certain referee laboratories as defined from among the participants in each category of procedures to assist in confirming the validity of values assigned to proficiency test specimens.

(5) SPECIMEN SOURCES. The department shall prepare, or use other sources for reliable and suitable specimens for proficiency testing.

(6) TRANSPORTING OF SPECIMENS. Proficiency testing may be conducted by mail or hand carried specimens.

(7) EXAMINATION OF PROFICIENCY SPECIMENS. The department shall set standards of laboratory performance for the evaluation test procedures. Proficiency specimens shall be examined by the personnel of the laboratory who normally perform the specialty test and by the testing procedure commonly used by the laboratory and acceptable to the department. The proficiency testing specialty programs shall at least include microbiology or its subspecialties of enteric bacteriology, general bacteriology, parasitology, mycology; milk, water, and food bacteriology and chemistry; clinical chemistry including urinalysis; hematology, immunohematology; hepatitis associated antigen testing; serology, both syphilis and non-syphilis; screening tests for genetic defects; and alcohol tests for motor vehicle and snowmobile laws.

(8) REPORTING OF PROFICIENCY TEST RESULTS. Laboratories shall report to the evaluation and certification program their proficiency test results within the prescribed reporting time for each specialty and subspecialty and if scheduled specimens are not received on schedule or received in damaged condition.

(9) FAILURE TO REPORT RESULTS. If a laboratory fails to report proficiency testing results or unreceived or damaged specimens, grades for those specimens shall be recorded as zero.

(10) SPECIMEN PREPARATION AND MANAGEMENT. 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 will be included with each shipment of unknown specimens.

(11) LEVELS OF PERFORMANCE AND GRADING SYSTEMS. For proficiency testing for certification of laboratories the following levels of performance, and grading systems shall apply:

(a) *Alcohol testing.* 1. Satisfactory performance. a. A grade of 80% or higher is satisfactory performance.

2. Grading methods. a. The acceptable range of values is determined for each proficiency specimen from the mean value obtained by the reference laboratories and the median value for all participants. This may be given as an individual value in percent by weight or as a range of values.

(b) *Clinical chemistry.* 1. Satisfactory performance. a. A grade of 80% or higher is satisfactory performance.

2. Grading methods. a. The target ranges of acceptable values (relative to the standard value) for each constituent are expressed as ± number of milligrams per deciliter or ± percentage whichever is greater.

b. In certain instances, such as the Folin-Wu procedure for glucose, where a particular method gives a result which differs consistently from the mean of the reference laboratories using different procedures, the mean of that group of laboratories will be used as the standard value for evaluation of the group. This type of exception is necessary only in those cases where the normal range differs from that of the methods represented in the reference laboratory group.

(c) *Hematology.* 1. Satisfactory performance. a. A grade of 85% or higher is satisfactory performance.

2. Grading methods. a. Hemoglobin, hematocrit, and red cell count reports are scored by agreement with a ± percent of the mean value.

b. For white cell differential counts, the mean value is calculated from the reports of the reference laboratories and the 95% confidence limits are determined and recorded for grading.

c. Five points are deducted for each value which falls outside the 95% confidence limits. Additional points are deducted for failure to list significant abnormalities or incorrect listings or findings.

(d) *Immunohematology.* 1. Satisfactory performance a. A grade of 100% is required in ABO grouping and Rh typing. A grade of 85% or higher is satisfactory in all other areas of testing within this program.

2. Grading methods. a. Individual laboratory results are compared with the reference laboratory reports. Obviously deviant results or results outside the range are discarded. Each test procedure is graded separately and grades are averaged to obtain an overall and cumulative score.

(e) *Hepatitis associated antigen.* 1. Satisfactory performance. a. A grade of 80% or higher is satisfactory performance.

2. Grading methods. a. Results from reference laboratories are tabulated and obviously deviant findings are discarded. Individual laboratory results and grades are compared with this tabulation.

(f) *Microbiology.* 1. Satisfactory performance. a. A grade of 80% or higher is satisfactory performance.

2. Grading methods. a. Results submitted by participating laboratories are graded by comparison with the organism identification reported by the reference laboratories and/or referee laboratories.

b. For assurance of a valid evaluation, some of the results submitted by a reference laboratory may be discarded when obviously deviant from results submitted by the majority of reference laboratories.

(g) *Milk, water, and food.* 1. Satisfactory performance. a. A grade of 75% or higher is satisfactory performance.

2. Grading methods. a. For milk, results within ± designated standard deviations of the geometric mean are acceptable. The designated standard deviation limits depend on the type of test and its specificity and sensitivity.

b. For water, 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 and/or shall be able to detect amounts of inorganic and organic chemicals, physical characteristics, and radioactivity in 75% of water samples when these constituents or conditions are present in normal or abnormal amounts if these testing services are offered.

(h) *Phenylketonuria.* 1. Satisfactory performance. a. A grade of 90% or higher is satisfactory performance.

2. Grading methods. a. Participating laboratory results must fall within the acceptable range of values.

b. The acceptable range includes the standard disc value nearest the mean value for the participants and the adjacent values. Standard test discs for phenylketonuria are used.

c. Individual laboratory results must fall within ± designated standard deviations of the mean.

(i) *Syphilis and non-syphilis serology.* 1. Satisfactory performance. a. A grade of 90% or higher in non-syphilis serology is satisfactory performance.

b. A grade of 90% in reproducibility and 90% in agreement in syphilis serology is satisfactory performance.

2. Grading methods. a. Results of the individual laboratories are compared with the results of the reference laboratories.

b. Percent achievement in syphilis serology is calculated in 2 categories. Percent of reproducibility is 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 is 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.

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

H 38.15 Proficiency testing manual. (1) PROVISION OF MANUAL. For informational purposes, the department shall prepare and maintain a current proficiency testing manual titled: *Current Methods of Proficiency Testing Applicable to section 143.15 of Wisconsin Statutes.*

(2) MANUAL CONTENTS, REVIEW, AND APPLICATION. The manual will provide information by specialties of nationally and other recommended testing methods and procedures; proficiency specimen types, numbers,

and shipping dates; proficiency grading procedures; acceptable proficiency performance levels; and, on the management and reporting of proficiency specimen findings. The manual shall be reviewed yearly and technically and procedurally updated to assure inclusion of new and nationally recommended procedures and methods for meeting service needs and for meeting compliance with state and federal programs.

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

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 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.

(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) PLACE OF TESTING. 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.

(5) 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.

H 38.17 Specimen records. (1) Laboratories shall maintain daily specimen records including:

(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 received.

(e) Reason if specimen unsatisfactory.

(f) Test performed, date, results.

(g) Identification of examiner.

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

(i) Date test results were reported.

(j) Specimen records shall be maintained for not less than one year.

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

H 38.18 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. The equipment, inspections, calibrations, monitoring controls, procedures, proficiency testing results, policies, and other quality control records shall be maintained for at least 2 years.

(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 section 143.15, Wis. 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.

H 38.19 Facilities and equipment. (1) GENERAL REQUIREMENTS. Laboratories shall have adequate facilities, equipment, instruments, supplies, 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.

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

(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 operational procedural 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, solutions, glassware, instruments, and supplies shall be available. 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.

(i) The premises shall conform to the requirements of applicable federal, state, and local codes pertaining to plumbing, heating, electricity,

fire, and safety. Electrical equipment shall be maintained and used under safe conditions for the prevention of fire and shock hazards.

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

H 38.20 Standards of directors. (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 such person may direct 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 specialties 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 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 ongoing qualified consultation; or

(g) In small hospital 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.

(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) For a water treatment plant laboratory a person is a qualified director who has at least a high school diploma or equivalency, and has had at least 6 months' experience in an approved water laboratory, 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, in lieu of the required experience the person successfully passes oral and written examinations conducted by the department.

(g) A person who on July 31, 1975, was serving as a laboratory director of one of the aforementioned types of laboratories described in section H 38.20 (2) and who has demonstrated knowledge of and satisfactory performance proficiency using the appropriate prescribed standard methods 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 section 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 section 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 section 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.

H 38.21 Fees. (1) DETERMINATION OF FEES. The fee for certification or recertification of a laboratory shall be determined by the number of testing specialties for which a laboratory offers services and requires certification, as follows:

(a) One specialty	$ 75
(b) Two specialties	$ 200
(c) Three specialties	$ 375
(d) Four specialties	$ 600
(e) Five specialties	$ 875
(f) Six specialties	$1,200

(2) ADDED SPECIALTIES. A fee of $250 shall be charged for each specialty added during the year.

(3) REFUNDS. Certification fees are not refundable.

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

(5) USE OF CERTIFICATION FEES. Certification fees shall be used to offset the cost of the 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.

H 38.22 Injunctions. (1) The operation or maintenance of a laboratory in violation of section 143.15, Wis. 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.

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

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) A medical technologist

(f) A public health officer or laboratory director

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

(h) Department of natural resources water laboratory director

(i) Public consumers

(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 semiannually 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.