CHAPTER 4740 DEPARTMENT OF HEALTH LABORATORIES; ACCREDITATION REQUIREMENTS

4740 2020 ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION REQUIREMENTS FOR BASE CERTIFICATION 4740 2040 CERTIFIED TEST CATEGORIES

4740.2020 ADMINISTRATIVE PROCEDURES REGARDING CERTIFICATION.

[For text of subps 1 and 2, see MR]

Subp 3 Issuance of provisional certification. The commissioner shall issue a provisional certification to a laboratory that

[For text of items A to C, see MR]

D provides written assurance that the laboratory adheres to base certification and analyte specific certification requirements of parts 4740 2010 to 4740.2040

The provisional certification is valid until the commissioner, after an inspection, approves or denies certification. If, two years after the date of issuance of the provisional certification, the commissioner has not inspected the laboratory, the commissioner shall renew a provisional certification if the laboratory files a renewal application according to subpart 6

[For text of subp 4, see M R.]

Subp 5 **Certification approved.** The commissioner shall approve base certification and analyte certification for a laboratory when the commissioner determines, after an inspection, that the laboratory complies with the applicable provisions of parts 4740 2010 to 4740 2040 The certification approval is valid for two years from the date of issuance of the provisional certification

Subp 6 Certification renewal. The commissioner shall renew a base certification and analyte certification if the commissioner receives the following from the laboratory at least 30 days before the expiration date of the certificate (1) an application meeting the standards of subpart 1, items A, B, C, subitems (1) to (3), and D, and part 4740 2030, subpart 2, and (2) appropriate fees. With the renewal application the laboratory shall submit any changes to the quality assurance plan or laboratory manual or a statement that the plan and manual continue to accurately describe current practices. The revised manual and plan must continue to meet the standards of part 4740 2030, subparts 4 and 6. The renewal certification is valid for two years. The commissioner shall inspect a laboratory certified by renewal at least once every three years.

[For text of subp 7, see M R]

Subp 8 **Revocation of certification.** The following are grounds to revoke a base certification or analyte certification of the laboratory

[For text of items A to F, see M R]

G failure to cooperate with an inspector designated by the commissioner

Withm 30 days after the revocation, the laboratory must notify all existing and new clients whose analytical work requires a certified laboratory that it is not certified. The laboratory shall provide verification of this notice to the commissioner. The laboratory shall not advertise itself as certified and shall remove or replace any advertisements that indicate that it is certified.

A laboratory that has had its certification revoked may not reapply for certification until it has corrected all deficiencies. It may reapply according to subpart 1 and, with the application, must provide documentation of the steps taken to correct the deficiencies

[For text of subps 9 to 11, see MR]

Statutory Authority: MS s 144 98

History: 22 SR 1712

4740.2030 REQUIREMENTS FOR BASE CERTIFICATION.

Subpart 1 **Methodology.** The laboratory shall specify the analytical methodology, sample collection, and preservation procedures used for each analyte for which it seeks certi-

fication The analytical methodology, sample collection, and preservation procedures used for samples required to be analyzed under a permit, program, or rule administered by a state agency must meet the requirements specified by that permit, program, or rule The analytical methodology, sample collection, and preservation procedures used to analyze samples for the Safe Drinking Water Program must comply with Code of Federal Regulations, title 40, sections 141 21 to 141 24, and Minnesota Rules, chapter 4720 The analytical methodology, sample collection, and preservation procedures used to analyze samples under the Clean Water Program must comply with Code of Federal Regulations, title 40, section 136 3 The analytical methodology, sample collection, and preservation procedures used to analyze samples for the Resource Conservation and Recovery Program must comply with Code of Federal Regulations, title 40, part 261 The analytical methodology, sample collection, and preservation procedures used to analyze samples for the Underground Storage Tank Program must comply with Wisconsin Department of Natural Resources PUBL-SW-141, "Modified DRO Method for Determining Diesel Range Organics" (September 1995), and PUB-SW-140, "Modified GRO Method for Determining Gasoline Range Organics" (September 1995), which are incorporated by reference The Wisconsin modified methods are available through the Minitex mterlibrary loan system, and are not subject to frequent change

When a client collects a sample, the laboratory must inform the client of the appropriate procedures. The laboratory may delegate responsibility for proper sample collection and submission under parts 4740 2010 to 4740 2040 to a client. The laboratory must report any deviations as noted in subpart 9, item A.

Alternative methodology may be used if the EPA approves the methodology and the laboratory submits a copy of the EPA approval to the commissioner

Subp 2 **Performance evaluations.** The laboratory shall analyze a performance evaluation sample for each certified analyte at least once annually during the term of certification. The laboratory shall handle and analyze the performance evaluation samples with its usual analysts, equipment, and methods. The laboratory shall obtain the performance evaluation samples from an approved provider. The commissioner shall make available a list of approved providers of performance evaluation samples. If the commissioner determines performance evaluation samples are not available for an analyte, the commissioner may review the laboratory's quality control data to evaluate precision and accuracy for that analyte.

The laboratory must show acceptable performance as determined by the approved provider on each performance evaluation sample

The laboratory shall provide the commissioner with the results of performance from the approved provider within 30 days after the laboratory receives them. When a provider notifies the laboratory that a performance evaluation sample result falls outside acceptable results, the laboratory must promptly take corrective action. Within 30 days after receiving notice of the unacceptable results, the laboratory must submit to the commissioner documentation of the corrective action planned and taken. Within 30 days after receiving notice of unacceptable results, the laboratory must request a follow—up performance evaluation sample from an approved provider. The laboratory shall provide the commissioner with the results of the follow—up performance evaluation within 30 days after receiving them

The commissioner may supply blind performance evaluation samples to certified laboratories on a randomly chosen basis and to a specific laboratory if the commissioner receives a complaint about the laboratory's performance or suspects fraud in the generation or reporting of test results. A blind performance evaluation sample is one that is not distinguishable as a performance evaluation sample

[For text of subps 3 to 5, see M R]

Subp 6 **Laboratory procedures manual.** The laboratory shall possess a written document—controlled manual of procedures used by laboratory personnel to analyze samples Actual practice must conform to the written procedures. The manual must have a table of contents and numbered pages. The manual must be reviewed annually and changes must be initialed by the laboratory director or the director's designee. The description of each test procedure must include sections describing the following.

A the sample used for the analysis,

B the sample acceptance and rejection criteria,

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- C the reagents, supplies, and materials and equipment used,
- D step-by-step analysis procedures,
- E methods of calculation,
- F detection and reporting limits,
- G safety precautions, and
- H limitations of the procedure

[For text of subps 7 to 10, see M.R.]

Statutory Authority: MS s 144 98

History: 22 SR 1712

4740.2040 CERTIFIED TEST CATEGORIES.

Subpart 1 **Scope.** The commissioner shall certify the analytes m subparts 2 to 6 for a specific program. The programs for which the commissioner shall certify an analysis are

- A the Clean Water Program, Code of Federal Regulations, title 40, part 136,
- B the Safe Drinking Water Program, Code of Federal Regulations, title 40, part 141.
- C. the Resource Conservation and Recovery Program, Code of Federal Regulations, title 40, part 261, and
- D. the Underground Storage Tanks Program, Code of Federal Regulations, title 40, part 280

To be certified for a specific program, the laboratory shall use the sample collection, preservation, and handling techniques required in the methodology meeting the conditions of the specific program

Subp 2. Inorganic analytes.

A Inorganic analytes eligible for certification under the Clean Water Program are

- (1) acidity,
- (2) alkalinity,
- (3) biochemical oxygen demand, 5 day,
- (4) biochemical oxygen demand, carbonaceous,
- (5) chemical oxygen demand,
- (6) chloride,
- (7) color;
- (8) cyanide,
- (9) nitrogen, ammonia,
- (10) nitrogen, total kjeldahl,
- (11) nitrogen, nitrate,
- (12) nitrogen, nitrate + nitrite,
- (13) nitrogen, mtrite,
- (14) oil and grease,
- (15) organic carbon, total,
- (16) phenol, total compounds,
- (17) phosphorus, ortho,
- (18) phosphorus, total,
- (19) residue (solids), total,
- (20) residue (solids), filterable (dissolved),
- (21) residue (solids), nonfilterable (TSS),
- (22) residue (solids), volatile;
- (23) specific conductance;
- (24) sulfate,
- (25) sulfide, and
- (26) surfactant

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Total residual chlorine, pH, and turbidity analyses under the Clean Water Program need not be done by a certified laboratory as long as the analyses are performed as soon as practicable but not later than one hour after collection and the methodology used is that specified under Code of Federal Regulations, title 40, section 136 3

[For text of item B, see M R.] [For text of subp 3, see M R.]

Subp. 4 Metal chemistry.

[For text of items A and B, see MR]

- C Metals analytes eligible for certification under the Resource Conservation and Recovery Program are
 - (1) arsenic,
 - (2) barrum;
 - (3) cadmium;
 - (4) chromium;
 - (5) copper,
 - (6) lead,
 - (7) mercury,
 - (8) molybdenum,
 - (9) nickel,
 - (10) selenium,
 - (11) silver,
 - (12) zinc; and
 - (13) toxicity characteristic leaching procedure (TCLP) extraction

Subp 5 Volatile organic compounds (VOCs).

A. Analytes eligible for certification under the Clean Water Program are

[For text of subitems (1) to (56), see MR]

- (57) n-butylbenzene.
- (58) naphthalene,
- (59) acetone;
- (60) p-dioxane,
- (61) ethyl ether,
- (62) 2-chloroethylvinyl ether, and
- (63) methyl ethyl ketone

[For text of item B, see M R]

- C. Analytes eligible for certification under the Resource Conservation and Recovery Program are
 - (1) acetone,
 - (2) carbon disulfide.
 - (3) p-dioxane,
 - (4) ethyl ether,
 - (5) methyl ethyl ketone, and
 - (6) methyl isobutyl ketone
- $\,\,$ D $\,$ Analytes eligible for certification under the Underground Storage Tanks Program are
 - (1) diesel range organics (DROs);
 - (2) gasoline range organics (GROs), and
 - (3) petroleum volatile organic compounds (PVOCs)

Subp 6 Synthetic organic compounds (SOCs).

- A Analytes eligible for certification under the Clean Water Program are
 - (1) acrolem,
 - (2) acrylonitrile,

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- (3) aldrin.
- (4) benzidine,
- (5) delta-BHC,
- (6) beta-BHC,
- (7) alpha-BHC,
- (8) gamma-BHC (lindane),
- (9) bis(2-chloroethoxy) methane,
- (10) bis(2-chloroethyl) ether,
- (11) 1,1'-biphenyl,
- (12) 4-bromophenylphenyl ether,
- (13) chlordane,
- (14) 4-chloro-3-methylphenol,
- (15) 2-chloronaphthalene,
- (16) 2-chlorophenol;
- (17) 4-chlorophenylphenyl ether,
- (18) 4,4'-DDD,
- (19) 4,4'-DDE,
- (20) 4,4'-DDT,
- (21) 3,3'-dichlorobenzidine,
- (22) 2,4-dichlorophenol,
- (23) dieldrin,
- (24) 2,4—dimethylphenol,
- (25) 2,4-dinitrophenol,
- (26) 2,6-dinitrotoluene,
- (27) 2,4—dinitrotoluene,
- (28) 1,2-diphenylhydrazine,
- (29) endosulfan I,
- (30) endosulfan Π ,
- (31) endosulfan sulfate,
- (32) endrin,
- (33) endrın aldehyde,
- (34) heptachlor,
- (35) heptachlor epoxide,
- (36) hexachlorobenzene,
- (37) hexachlorobutadiene,
- (38) hexachlorocyclopentadiene,
- (39) hexachloroethane;
- (40) isophorone;
- (41) 2-Methyl-4,6-dimtrophenol,
- (42) nitrobenzene;
- (43) 2-nitrophenol,
- (44) 4-nitrophenol,
- (45) N-nitrosodi-n-propylamine,
- (46) N-nitrosodimethylamine,
- (47) N-nitrosodiphenylamine,
- (48) polyaromatic hydrocarbons (PAHs):
 - (a) acenaphthene;
 - (b) acenaphthylene,
 - (c) anthracene,

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- (d) benzo(a)anthracene,
- (e) benzo(a)pyrene,
- (f) benzo(b)fluoranthene,
- (g) benzo(g,h,1)perylene,
 - (h) benzo(k)fluoranthene,
- (1) chrysene,
- (1) dibenzo(a,h)anthracene,
- (k) fluoranthene,
- (1) fluorene.
- (m) indeno(1,2,3-cd)pyrene,
- (n) naphthalene,
- (o) phenanthrene, and
- (p) pyrene,
- (49) PCB-1016,
- (50) PCB-1221,
- (51) PCB-1232,
- (52) PCB-1242,
- (53) PCB-1248;
- (54) PCB-1254;
- (55) PCB-1260,
- (56) pentachlorophenol,
- (57) phenol;
- (58) phthalates
 - (a) benzylbutyl phthalate,
 - (b) dı(2-ethylhexyl) phthalate,
 - (c) di-n-butyl phthalate,
 - (d) di-n-octyl phthalate,
 - (e) diethyl phthalate, and
 - (f) dimethyl phthalate,
- (59) toxaphene:
- (60) 1,2,4-trichlorobenzene; and
- (61) 2,4,6-trichlorophenol

[For text of item B, see M R]

 $\label{eq:coverage} C.\ Analytes\ eligible\ for\ certification\ under\ the\ Resource\ Conservation\ and\ Recovery\ Program\ are$

- (1) acrylamide,
- (2) benzidine,
- (3) benzoic acid,
- (4) beta-BHC,
- (5) gamma-BHC (lındane),
- (6) 1,1'-biphenyl,
- (7) bis(2-chloroisopropyl) ether;
- (8) chlorpyrifos,
- (9) dalapon,
- (10) 2,4–D (2,4–dichlorophenoxyacetic acid);
- (11) 4,4'-DDT,
- (12) dinoseb,
- (13) 1,2-diphenylhydrazine,
- (14) endrin,

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- (15) MCPA,
- (16) methyl parathion,
- (17) 2-methyl phenol,
- (18) 3-methyl phenol,
- (19) PCB,
- (20) PCB in oil,
- (21) n-nitrosodi-n-butylamine,
- (22) polyaromatic hydrocarbons (PAHs)
 - (a) benzo(a)anthracene,
 - (b) benzo(a)pyrene,
 - (c) benzo(b)fluoranthene,
 - (d) benzo(1)fluoranthene,
 - (e) benzo(k)fluoranthene,
 - (f) dibenzo(a,h)anthracene,
 - (g) fluoranthene;
 - (h) indeno(1,2,3-cd)pyrene, and
 - (1) pyrene,
- (23) pentachlorobenzene,
- (24) toxicity characteristic leaching procedure (TCLP) extraction,
- (25) phthalates
 - (a) benzylbutyl phthalate;
 - (b) dı-n-butyl phthalate;
 - (c) di(2-ethylhexyl) phthalate, and
 - (d) dimethyl phthalate,
- (26) pronamide,
- (27) 1,2,4,5-tetrachlorobenzene,
- (28) 2,3,4,6-tetrachlorophenol,
- (29) toxaphene;
- (30) 2,4,5-T, and
- (31) 2,4,5-TP

[For text of item D, see M R.]

Statutory Authority: MS s 144 98

History: 22 SR 1712