Chapter ATCP 77

LABORATORY CERTIFICATION

Note: Chapter ATCP 77 as it existed on September 30, 1999, was repealed and a new chapter ATCP 77 was created, Register, September, 1999, No. 525, eff. 10–1–99.

Subchapter I — General Requirements

ATCP 77.01 Definitions. In this chapter:

(1) "Analyst" means an individual who performs a test under s. ATCP 77.02.

(2) "Certified analyst" means an analyst that is certified by the department to perform tests under s. ATCP 77.02 (1) or (2).

(3) "Certified laboratory" means a laboratory at which an operator is certified to perform tests under s. ATCP 77.02.

(4) "Department" means the state of Wisconsin department of agriculture, trade and consumer protection.

(4m) "Drug residue screening test" means any test under s. ATCP 77.02 (1) (k) to (1) (zc) or (1) (zq), other than a confirmatory test, that a person uses to comply with drug residue testing requirements under s. ATCP 65.72.

(5) "FDA" means the United States department of health and human services, public health service, food and drug administration.

(6) "Food" has the meaning given in s. 97.01 (6), Stats.

(7) "Food and recreational safety administrator" means the administrator of the department's division of food and recreational safety.

(8) "Individual" means a natural person.

(9) "Laboratory" means a facility at which an operator performs tests.

(10) "Laboratory administrator" means an individual who supervises a laboratory under s. ATCP 77.12.

(11) "Milk" means the lacteal secretion of cows, sheep, goats, water buffalo, or camelids and includes dairy products made from milk.

(12) "Operator" means a person who owns or controls a laboratory.

(13) "Person" means an individual, corporation, partnership, cooperative association, limited liability company, trust, or other organization or entity. "Person" includes counties, municipalities, the state of Wisconsin and agencies of the state.

(14) "Public health standard" means a federal, state or local statute, rule or ordinance which specifies a standard for the safety or wholesomeness of milk, water or food for human consumption.

(15) "Public water system laboratory" means a laboratory that tests water for a public water system as defined in s. NR 108.02 (12).

(16) "Test" means a laboratory examination of milk, water or food.

(17) "Visual read test" means a drug residue screening test performed by an individual who interprets the result without the aid of a mechanical reader.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; emerg. cr. (4m) and (17), eff. 11–15–01; CR 01–124: cr. (4m) and (17) Register December 2002 No. 564, eff. 1–1–03; CR 07–006: am. (4m), Register January 2008 No. 625, eff. 2–1–08; CR 14–073: am. (4m) Register August 2016 No. 728, eff. 9–1–16; **CR 19–076: am. (4m), (7), (11) Register May 2020 No. 773, eff. 6–1–20.**

ATCP 77.02 Laboratory tests to protect public health. For purposes of s. 93.12, Stats., the department declares that the following milk, food, water, wastewater and recreational water tests are necessary to protect public health:

(1) MILK. Any of the following tests related to milk and dairy products:

(a) Standard plate count.
(b) Plate loop count (raw milk only).
(c) Spiral Plate Count (raw milk only).
(d) Petrifilm Aerobic Count.
(e) Petrifilm Rapid Aerobic Count.
(f) TEMPO Aerobic Count.
(g) Peel Plate Aerobic Count.
(h) BactoScan FC.
(i) BactoCount IBC.
(j) BacSomatic Bacteria Count.
(k) Charm BSDA.
(L) Charm II Competitive.
(m) Charm II Sequential.
(n) Charm II Quantitative.
(o) Charm II Sulfa.
(p) Charm II Chloramphenicol.
(q) Charm II Tetracycline.
(r) Charm SL (Safe Level).
(s) Charm 3 SL–3.
(t) Charm FLUSLBL.
(u) Charm ROSA SULF.
(v) Charm ROSA Tetracycline SL.
(w) Charm ROSA TRIO.
(x) Delvotest P.
(y) Delvotest P 5 Pack.
(z) New SNAP Beta Lactam.
(za) SNAP Tetracycline.
(zb) BetaStar Advanced Test for Beta Lactams.
(zc) BetaStar Advanced Test for Tetracyclines.
(zd) Direct Microscopic Somatic Cell Count.
(ze) Electronic Somatic Cell Count.

(zf) Petrifilm Coliform Count/High Sensitivity Coliform Count.

(zg) Coliform Plate Count.

(zh) TEMPO Coliform Count.

(zi) Peel Plate Coliform Count.

(zj) Pasteurized Milk Containers.

(zk) Disintegration Test.

(zL) Flat Lid or Pour Contact Tests.

(zm) Phosphatase Test–Fluorophos.

(zn) Phosphatase Test–Charm PasLite.

(zo) Phosphatase Test – Charm FAP.

(zp) Accupoint Advanced Alkaline Phosphatase.

(zq) Tests performed to comply with ch. ATCP 65, other than milk component tests which are not related to public health.

(2) FOOD. Any of the following tests related to food:

(a) Standard plate count.

(b) Plate loop count.

(c) Petrifilm aerobic count.

(d) Coliform plate count.

(e) Petrifilm coliform count.

(f) Other tests under ch. ATCP 75 to detect pathogens in food.

(3) WATER, WASTEWATER OR RECREATIONAL WATER. Any of the following tests related to water, wastewater or recreational water:

(a) LTB or P–A broth, followed by BGLB and either EC or EC–MUG.

(b) A–1 broth (fecal coliform, SWTR only).

(c) Colilert or Colilert 18.

(d) Colisure.

(e) Readycult.

(f) E*Colite.

(g) Modified Colitag.

(h) M–Endo or LES Endo, followed by BGLB and either EC, EC–MUG, or NA–MUG.

(i) MI Medium.

(j) Coliscan.

(k) m–ColiBlue24.

(L) Chromocult.

(m) mFC agar (fecal coliform, SWTR only).

(n) HPC or R2A.

(o) SimPlate.

(p) m–TEC (fecal coliform).

(q) Pseudalert.

(r) Enterolert.

(s) Cryptosporidium and Giardia.

(t) Other tests under ch. NR 809 or 812 to detect microbiological contamination in drinking water.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (intro.), r. and recr. (1) and (3), Register January 2008, No. 625, eff. 2–1–08; renumbering of (1) (aa) to (dd) to be (1) (za) to (zd) made under s. 13.92 (4) (b) 1., Stats., Register January 2008 No. 625; CR 14–073: am. (1) (zd) Register August 2016 No. 728, eff. 9–1–16; **CR 19–076: am. (1) (e) to (zd), cr. (1) (ze), (zf), (zq), am. (3) (e), (g), (n), (q), renum. (3) (q) to (3) (t) and am., cr. (3) (q) to (s) Register May 2020 No. 773, eff. 6–1–20.**

ATCP 77.03 Laboratory certification; general. **(1)** ANNUAL CERTIFICATION REQUIRED. (a) Except as provided in par. (b), no person may perform any laboratory test listed under s. ATCP 77.02 to determine whether milk, food or water complies with public health standards required under federal or state law unless the department annually certifies the laboratory operator to perform that test at the laboratory where the test is performed. An annual certificate expires on December 31 of each year.

Note: A laboratory operator certified under sub. (1) (a) to perform a specified drug residue test may perform both the confirmatory drug residue test for which that operator is certified, as well as the corresponding drug residue screening test.

(b) An operator may perform a drug residue test as a screening test under s. ATCP 77.23 at the operator's laboratory, even though the operator is not certified under par. (a) to perform that drug residue test as a confirmatory test, if the department annually approves the operator to perform that drug residue screening test at that laboratory. An annual certificate of approval expires on December 31 of each year.

(2) SCOPE OF CERTIFICATION. (a) A person who operates 2 or more laboratories shall obtain a separate certification under sub. (1) for each laboratory. A certification may not be transferred between operators or laboratories.

(b) The department shall identify, in each certification under sub. (1), the tests which the operator is certified to perform at that laboratory.

(c) An operator approved under sub. (1) (b) to perform a drug residue test as a screening test may not perform that test as a confirmatory test unless the operator is certified to do so under sub. (1) (a).

Note: The department may approve a laboratory operator, under s. ATCP 77.23, to perform a drug residue screening test on milk even though the department has not certified that laboratory operator under this section to perform that test as a confirmatory test. See also s. ATCP65.76.

(3) CERTIFICATE DISPLAYED. An operator shall display, at a prominent location in each certified laboratory, the current certification issued for that laboratory under sub. (1).

(4) EXEMPTIONS. Subsection (1) does not apply to any of the following:

(a) The United States government.

(b) Milk testing by the department.

(c) An educational institution that operates a laboratory solely for teaching or academic research purposes, and does not test milk, water or food for human consumption.

(d) A person who operates a laboratory solely to conduct quality control tests on food or water sold by that person, provided that the tests are not required by statute, rule or ordinance.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; emerg. renum. (2) (c) to be (2) (b), cr. (2) (c), eff. 11–15–01; CR 01–124: renum. (2) (c) to be (2) (b), cr. (2) (c) Register December 2002 No. 564, eff. 1–1–03; CR 07–003: r. and recr. (1) and (2) (c), Register January 2008 No. 625, eff. 2–1–08.

ATCP 77.04 Applying for certification. **(1)** INITIAL APPLICATION. An operator shall apply for initial certification under s. ATCP 77.03 on a form provided by the department. The operator shall submit a separate application for each laboratory. An application shall include all of the following:

(a) The operator's correct legal name and address, and any trade names used by the operator. The application shall indicate whether the operator is an individual, corporation, partnership, cooperative association, limited liability company, trust, or other organization or entity.

(b) The name, address, telephone number, and e–mail address of the laboratory.

(c) The name of the laboratory administrator under s. ATCP 77.12.

(d) The tests under s. ATCP 77.02 for which the operator seeks certification.

(e) Documentation that the laboratory is qualified to perform each test which the operator identifies under par. (d). Documentation shall include all of the following:

1. Proof that the laboratory has all of the equipment needed to perform each test.

2. Written test procedures used for each test, or an identification of the standard test methods used for each test.

3. Proof of analytical proficiency in each test. Proof may consist of quality assurance test results from comparison studies, split samples or proficiency tests which meet the proficiency evaluation requirements under s. ATCP 77.24 or 77.34. The operator of a water laboratory shall also provide documentation required under s. ATCP 77.32.

Note: An operator may obtain application forms and submit applications to the department at the following address:

Wisconsin department of agriculture, trade and consumer protection
Division of food and recreational safety, bureau of food and recreational businesses
Laboratory Certification Program
P.O. Box 8911
Madison, WI 53708–8911
(608) 224–4712

(2) ANNUAL RENEWAL. To renew an annual certification, the operator of a certified laboratory shall file a renewal application with the department by December 31 of each year. The operator shall file the renewal application on a form provided by the department. The renewal application shall include all of the following:

(a) The information required under sub. (1) (a) to (d). The application shall identify any changes since the last annual renewal.

(b) The information required under sub. (1) (e) if the operator requests certification to perform a test which the department has not yet certified the operator to perform.

(c) The certification fees required under s. ATCP 77.06.

Note: The department will send renewal application forms to certified laboratories approximately 6 weeks before their current annual certifications expire.

(3) FALSE INFORMATION. No person may misrepresent or falsify any information contained in a certification application under this section.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; **CR 19–076: am. (1) (b) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.06 Certification fees. (1) FEE AMOUNTS. Except as provided under sub. (2) or (3), an operator shall pay the following certification fees:

(a) *Milk or food tests.* An annual certification fee of $492 for each test under s. ATCP 77.02 (1) or (2) at each laboratory for which the operator is certified. This fee does not apply to a laboratory that is approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

(b) *Certified analysts; milk or food tests.* An annual certification fee of $36 for each analyst who performs one or more tests under s. ATCP 77.02 (1) or (2). This fee does not apply to an individual approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

(c) *Discretionary inspection or additional analyst certification; milk or food tests.* A supplemental fee of $180 for each discretionary inspection or requested certification of one or more analysts to conduct any test under s. ATCP 77.02 (1) or (2), if the certification occurs at any time other than during a mandatory inspection under s. ATCP 77.14 (1). This fee does not apply to an individual approved under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

(d) *Water tests.* An annual certification fee of $408 for each test under s. ATCP 77.02 (3) for which the operator is certified.

(e) *Drug residues in milk; screening tests.* The fees provided in s. ATCP 77.23 (3) if the laboratory performs drug residue screening tests on milk samples.

(2) PARTIAL FEES. An operator of a milk or food laboratory shall pay the fee as provided in par. (a) and the operator of a water laboratory shall pay the fee as provided in par. (b).

(a) If the department certifies an operator of a milk or food laboratory to perform a test for less than a full calendar year, the operator shall pay a fee of $42 for each full month of certification for that test. This fee does not apply to a laboratory that is authorized under s. ATCP 77.23 only to conduct drug residue screening tests on milk samples.

(b) If the department certifies an operator of a water laboratory to perform a test for less than a full calendar year, the operator shall pay a fee of $35 for each full month of certification for that test.

(3) FEE EXEMPTIONS. A county or municipality that contracts with the department to license and inspect retail food establishments as the department's agent under s. 97.41, Stats., is not required to pay any certification fee.

(4) PAYING CERTIFICATION FEES. (a) If the department has not previously certified an operator to perform any of the tests listed under s. ATCP 77.02 at the laboratory for which the operator is seeking certification, the department shall bill the operator under this section after the department inspects the laboratory under s. ATCP 77.14 (1) (a). The department may not certify the operator to perform any test until the operator pays the required certification fee for that test.

(b) If the operator of a certified laboratory applies for certification to perform additional tests under sub. (5), or files a renewal application under s. ATCP 77.04 (2), the operator shall include with that application the fees required under this section.

(5) ADDITIONAL TESTS. The operator of a certified laboratory may, at any time, apply for certification to perform additional tests which the department has not yet certified the operator to perform at that laboratory. The operator shall apply on a form provided by the department. The application shall include all of the following:

(a) The additional tests for which the operator seeks certification.

(b) Documentation, under s. ATCP 77.04 (1) (e), that the operator is qualified to perform each additional test under par. (a).

(c) The fees required under this section.

Note: An operator may apply under sub. (5) at any time during a license year, and need not wait until the annual license renewal.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; am. (1) and (2) and cr. (1) (a) to (d), Register, December, 1999, No. 528, eff. 1–1–00; emerg. am. (1) (a) to (c), cr. (1) (e), r. and recr. (2), eff. 11–15–01; CR 01–124: am. (1) (a) to (c), cr. (1) (e), r. and recr. (2) Register December 2002 No. 564, eff. 1–1–03; CR 05–044: cr. (2) (intro.), am. (4) and (5) (c) Register December 2005 No. 600, eff. 1–1–06; CR 07–037: am. (1) (a), (b) and (d) Register April 2008 No. 628, eff. 5–1–08; **CR 19–076: am. (1) (a) to (d), (2) (a), (b) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.08 Granting and withdrawing certification. (1) GRANTING CERTIFICATION. The department shall certify an operator under s. ATCP 77.03 if the operator and laboratory comply with this chapter. The department may conditionally certify an operator pending action by the operator to correct deficiencies which the department has identified. The department may summarily suspend a conditional certification, without prior hearing, if the operator fails to correct the deficiencies within the time specified by the department.

(2) DEADLINE FOR ACTION ON CERTIFICATION REQUEST. Within 40 calendar days after the department receives a complete application under s. ATCP 77.04, the department shall do all the following:

(a) Inspect the laboratory if an inspection is required under s. ATCP 77.14 (1).

(b) Grant the application, grant the application subject to conditions, or deny the application.

(3) MILK AND FOOD LABORATORIES; CERTIFIED ANALYSTS. (a) The department may not certify an operator to perform any test under s. ATCP 77.02 (1) or (2) unless the department has certified all of the analysts who perform that test at that laboratory.

(4) SUSPENDING OR REVOKING CERTIFICATION. The department may suspend or revoke an operator's certification for cause, including a violation of this chapter or failure to file required laboratory reports with other government agencies. The department shall comply with applicable requirements under ch. 227, Stats., and ch. ATCP 1.

Note: See ss. 93.06 (7) and 93.12, Stats.

(5) SUMMARY SUSPENSION. The food and recreational safety administrator may issue a written notice, summarily suspending all or part of an operator's certification, if the food and recreational safety administrator finds in the suspension notice that the operator has not complied with this chapter, that the noncompliance poses an imminent threat to the health or safety of the public or laboratory workers, and that the noncompliance is likely to con-

tinue unless the food and recreational safety administrator summarily suspends the operator's certification. The operator may contest the summary suspension according to s. ATCP 1.03 (3).

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; **CR 19–076: am. (5) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.10 Laboratory facilities. (1) ADEQUATE FACILITIES. A certified laboratory shall have all of the following:

(a) Adequate facilities, equipment and supplies to perform the tests which the operator is certified to perform at that laboratory.

(b) At least 5 linear feet of level bench top working space per analyst.

(c) At least 50 foot candles of light on each bench top.

(d) Effective climate controls to maintain proper temperature and humidity for testing.

(2) QUALITY CONTROL AND MAINTENANCE. The operator of a certified laboratory shall do all of the following:

(a) Maintain laboratory facilities, equipment and supplies in proper working condition.

(b) Maintain temperature–controlled equipment, including incubators, water baths, refrigerators and freezers, so that the equipment functions effectively. The operator shall measure and record equipment temperatures at least daily when the equipment is in use and the laboratory is staffed with trained personnel.

(c) Maintain autoclaves to ensure proper temperature and pressure throughout the entire sterilization cycle, and keep a record of autoclave maintenance.

(d) Calibrate each electronic test instrument as recommended by the instrument manufacturer, and record the results.

(e) Ensure that each reagent and solution is clearly labeled to show its identity, its titer or concentration, its expiration or preparation date, instructions for proper storage, and other pertinent information. An operator shall store reagents and solutions according to the manufacturer's specifications.

(f) Ensure that glassware is free of chips, excessive scratches or cloudiness. Glassware used for measurement, including pipettes, graduated cylinders and volumetric flasks, shall have clear graduations.

(3) NOTICE OF MATERIAL CHANGES. An operator shall notify the department whenever the operator remodels laboratory facilities or installs new equipment if the remodeling or installation materially affects the performance of tests under s. ATCP 77.02 which the operator is certified to perform at that laboratory.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; **CR 19–076: am. (2) (b) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.12 Laboratory administrator. The laboratory administrator or a designated agent of the administrator shall be present at every certified laboratory during daytime business hours. The laboratory administrator shall do all of the following on behalf of the laboratory operator:

(1) Supervise the laboratory and its compliance with this chapter.

(2) Review and approve, for submission to the department, every certification application which the operator submits for that laboratory under s. ATCP 77.04.

(3) Supervise the procurement and maintenance of laboratory facilities, equipment and supplies, and notify the department of material changes under s. ATCP 77.10 (3).

(4) Facilitate department inspections of the laboratory. At the request of the department, the administrator shall grant the department access to laboratory facilities, equipment and records, and shall arrange for analysts to demonstrate their testing proficiency.

(5) Notify the department of changes in laboratory analysts under s. ATCP 77.22 (10).

(6) Notify all laboratory customers if the department suspends or revokes all or part of the laboratory's certification.

(7) Report test results to the appropriate regulatory agency, if required by law.

(8) Supervise laboratory recordkeeping under s. ATCP 77.16.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99.

ATCP 77.14 Inspecting a laboratory. (1) MANDATORY INSPECTIONS. The department shall inspect a laboratory at all of the following times:

(a) Before certifying the operator under s. ATCP 77.03, for the first time, to perform tests at that laboratory.

(b) At least once every 2 years after the department first certifies the operator under s. ATCP 77.03 to perform tests under s. ATCP 77.02 (1) at that laboratory and at least once every 3 years after the department first certifies the operator under s. ATCP 77.03 to perform any tests under s. ATCP 77.02 (2) or (3).

(c) Before the department certifies the operator to perform a test under s. ATCP 77.02 which the department has not previously certified that operator to perform at that laboratory unless the laboratory is currently certified for a test that utilizes the same or very similar methodology.

(2) DISCRETIONARY INSPECTIONS. The department may inspect a certified laboratory whenever any of the following occurs:

(a) The operator materially alters laboratory facilities or equipment.

(b) The operator assigns a new analyst to perform a test for which the operator is currently certified.

(c) The department concludes that an inspection is necessary to determine whether the operator, or the operator's laboratory, complies with this chapter.

(3) INSPECTION AUTHORITY. The department may exercise its authority under ss. 93.08, 93.14, 93.15, 93.16 and 97.12, Stats., in support of an inspection under this chapter. The department may suspend or revoke the certification of any operator who obstructs or fails to permit an inspection under this section.

Note: The department conducts its inspections during laboratory business hours. The department ordinarily pre–arranges inspection dates and times that are acceptable to laboratory operators, but is not required to do so. A person who obstructs or interferes with an inspection may also be subject to penalties under s. 93.21 (2) or (4) or s. 97.12 (4), Stats.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; **CR 19–076: am. (1) (b), (c) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.16 Laboratory records. (1) RECORDS REQUIRED. An operator shall make complete records related to all of the following:

(a) The training, experience and proficiency testing of every analyst who performs tests for which the laboratory is certified.

(b) Laboratory evaluations required under this chapter.

(c) Laboratory policies and procedures.

(d) Laboratory facilities, equipment and supplies, including records related to procurement, calibration, testing and maintenance.

(e) Quality control procedures and monitoring.

(f) Tests performed at the laboratory, including records related to the nature of the test, the person for whom the test is performed, the assigned analysts, the test methods used, the date and time of testing, and the test results obtained.

(g) Test reports filed with the department and other government agencies.

Note: For example, see reporting requirements under chs. ATCP 65 and 70 and chs. NR 809 and 812.

(2) RECORD RETENTION; AVAILABILITY. (a) The operator of a milk or food laboratory shall retain all records under sub. (1) for at least 2 years. The operator of a water laboratory shall retain all records under sub. (1) for at least 5 years.

(b) An operator shall make records under sub. (1) available to the department for inspection and copying upon request.

(c) An operator may keep records under sub. (1) in hard copy or electronic form, or both, provided that the department can obtain ready access to the records.

(d) An operator shall take reasonable security measures to prevent record loss, damage or tampering.

(3) FALSIFYING RECORDS. No operator may falsify any laboratory records.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99.

Subchapter II — Milk and Food Laboratories

ATCP 77.20 Milk and food laboratories; procedures. (1) TEST METHODS. An operator who performs any test listed under s. ATCP 77.02 (1) and (2) shall perform that test according to methods specified in applicable reference materials under sub. (2), or according to methods which the department approves in writing.

(2) REFERENCE MATERIALS. (a) *General*. An operator who performs any test listed under s. ATCP 77.02 (1) or (2) shall keep, at the certified laboratory, the manufacturer's complete operating and maintenance instructions for equipment used to perform that test.

(b) *Milk tests.* An operator who performs any test listed under s. ATCP 77.02 (1) shall keep the following reference materials at the certified laboratory:

1. The FDA 2400 series laboratory evaluation forms for that test.

2. The "Standard Methods for the Examination of Dairy Products," 17th edition, published by the American Public Health Association.

(c) *Food tests.* An operator who performs any test listed under s. ATCP 77.02 (2) shall keep or have online access to all of the following reference materials at the certified laboratory:

1. The authoritative reference manual, if any, that applies to each type of food testing for which the laboratory is certified.

2. The "Compendium of Methods for the Microbiological Examination of Foods," 4th edition, published by the American Public Health Association.

3. The FDA "Bacteriological Analytical Manual," current on–line edition, if the operator performs a microbiological test on food.

Note: Copies of "Standard Methods for the Examination of Dairy Products" and "Compendium of Methods for the Microbiological Examination of Foods" are on file with the department and the legislative reference bureau and may be obtained from the "APHA Bookstore" at http://secure.apha.org/iMIS/APHA/Store .

Copies of the "Bacteriological Analytical Manual" are on file with the department and the legislative reference bureau and may be viewed online at http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

(3) CULTURE MEDIA. Culture media used for any test listed under s. ATCP 77.02 (1) or (2) shall be effectively sterilized before they are used. Culture media shall be autoclaved for the total cycle time and sterilization time specified by the media manufacturer or by the applicable test method under this section.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (2) (b) 2. and (c) 2. and 3., Register January 2008 No. 625, eff. 2–1–08; **CR 19–076: am. (2) (c) (intro.), (3) Register May 2020 No. 773, eff. 6–1–20**.

ATCP 77.22 Milk and food laboratories; certified analysts. (1) CERTIFICATION REQUIRED. (a) Except as provided in par. (b), no analyst may perform a test listed under s. ATCP 77.02 (1) or (2) unless the department certifies that analyst under this section to perform that test.

(b) Paragraph (a) does not apply to an individual who is solely engaged in performing a drug residue screening test, provided that the department has approved that individual under s. ATCP 77.23 (2) to perform that test.

(c) The department shall certify the analysts employed at a laboratory when it conducts a mandatory inspection of that laboratory under s. ATCP 77.14 (1). The department may certify new analysts, or certify analysts to perform other tests, at other times.

(2) TERM OF CERTIFICATION. An analyst's certification to perform a test remains in effect until one of the following occurs:

(a) The laboratory administrator or designated agent requests the analyst's certification to be withdrawn.

(b) The certified laboratory does not pay the annual license fee for the analyst.

(c) The department suspends or revokes the analyst's certification.

(3) COMPETENCY EVALUATION. (a) Before the department certifies an analyst to perform any test listed under s. ATCP 77.02 (1) or (2), the department shall observe and evaluate that analyst's competency to perform that test.

(b) Whenever the department performs a mandatory inspection of a laboratory under s. ATCP 77.14 (1), the department shall perform a competency evaluation under par. (a) of every analyst who performs a test listed under s. ATCP 77.02 (1) or (2).

(c) The department shall use an appropriate FDA 2400 series form or if no FDA 2400 series form applies, another standard form to evaluate an analyst's competency under par. (a). If an analyst performs plate loop counts, electronic bacteria counts, or electronic somatic cell counts, the department shall check the analyst's accuracy based on any statistical comparisons required by those tests.

(4) ANNUAL PROFICIENCY EVALUATION. An analyst who performs a test listed under s. ATCP 77.02 (1) or (2) shall complete an annual proficiency evaluation for that test if an annual proficiency evaluation is required under s. ATCP 77.24.

(5) CONDITIONAL CERTIFICATION. If the department determines under sub. (3) that an analyst is competent to perform a test, but the analyst has not yet completed a proficiency evaluation under s. ATCP 77.24 for that test, the department shall conditionally certify the analyst. If a conditionally certified analyst fails a proficiency evaluation under s. ATCP 77.24, the department shall summarily suspend the analyst's certification to perform that test.

(6) FULL CERTIFICATION. If the department determines under sub. (3) that an analyst is competent to perform a test, and the analyst also passes a proficiency evaluation under s. ATCP 77.24 for that test, the department shall fully certify that analyst to perform that test.

(7) PROVISIONAL CERTIFICATION AND RESTORATION OF FULL CERTIFICATION. (am) An analyst shall be placed in provisional certification if one of the following occurs:

1. If a fully certified analyst fails a proficiency evaluation under s. ATCP 77.24 for any test, the department shall issue a notice stating that the analyst is provisionally certified to perform that test.

2. If the department conducts a biennial inspection of a laboratory under s. ATCP 77.14 (1) and a fully certified analyst is not present to demonstrate competence to perform the test(s) they are certified for, the department shall issue a laboratory report stating that the analyst is provisionally certified to perform that test.

(c) If an analyst is provisionally certified because of failing a proficiency evaluation under s. ATCP 77.24 and that analyst passes a proficiency evaluation under s. ATCP 77.24 on a new set of proficiency samples, the department shall restore the analyst to full certification.

(d) If an analyst is provisionally certified because they were not present to demonstrate their competence to perform the tests they are certified for during the biennial inspection of the laboratory, they shall remain in provisional certification status until they again demonstrate their competence during an inspection of the laboratory.

(e) If a provisionally certified analyst fails a proficiency evaluation on a new set of proficiency samples, or is not present to demonstrate their competence during a biennial inspection of the laboratory, the department shall summarily suspend the analyst's certification to perform that test.

(8) RESTORING CERTIFICATION. The department may restore the certification of any analyst whose certification is summarily suspended under sub. (5) or (7) if the analyst completes a training program approved by the department and passes a proficiency evaluation under s. ATCP 77.24 on a new set of proficiency samples. The department shall restore the analyst to full certification, even if the analyst was conditionally certified when certification was suspended.

(9) LIST OF CERTIFIED ANALYSTS. The department shall maintain, for each certified laboratory, a list of analysts currently certified to perform tests listed under s. ATCP 77.02 (1) and (2). The list shall identify the tests which each analyst is certified to perform.

(10) NOTICE OF CHANGES. (a) An operator shall notify the department within 30 days after any of the following occurs:

1. An analyst certified under this section is no longer employed by the laboratory.

2. There is a change in the name of any analyst certified under this section.

(b) An operator shall notify the department of a staffing change within 7 days after that change occurs if, as a result of that change, the operator no longer meets applicable certification requirements under s. ATCP 77.08 (3).

History: Cr. Register, September, 1999, No. 525, eff. 10−1−99; r. (2) (b) and renum. (2) (c) to be (2) (b), Register, December, 1999, No. 528, eff. 1−1−00; emerg. r. and recr. (1), eff. 11−15−01; CR 01−124: r. and recr. (1) Register December 2002 No. 564, eff. 1−1−03; **CR 19−076: r. and recr. (2), am. (3) (c), r. and recr. (7) Register May 2020 No. 773, eff. 6−1−20; renum. (intro.), (a), (b) to (am), 1., 2. under s. 13.92 (4) (b) 1., Stats., Register May 2020 No. 773**

ATCP 77.23 Drug residues in milk; screening tests.

(1) LABORATORY APPROVED. (a) The department may approve a laboratory to perform a drug residue test as a screening test, even though the laboratory is not certified under s. ATCP 77.03 to perform the test as a confirmatory test. An approval expires on December 31 of each year. An approved laboratory shall comply with s. ATCP 65.76 (2) (b).

(b) The department may not approve a laboratory under par. (a) unless all of the following apply:

1. The department has approved at least one individual under sub. (2) to perform the drug residue screening test at the approved laboratory.

2. The laboratory has written agreements with one or more certified laboratories to provide the confirmatory testing required under s. ATCP 65.76 (2) (b) 3.

(c) The department shall inspect a laboratory under par. (a) before approving the laboratory to perform a visual read drug residue screening test, and before approving any individual under sub. (2) to perform a visual read drug residue screening test at that laboratory.

(2) ANALYSTS APPROVED. (a) No individual may perform a drug residue screening test unless the department approves that individual to perform that test at a laboratory approved under sub. (1).

(b) Before the department approves an individual under par. (a) to perform a visual read test, the department shall perform an on−site competency evaluation under sub. (4).

(c) The department's approval under par. (a) expires on December 31 of each year unless, by that date, the laboratory operator attests to the department that the individual has successfully completed an annual proficiency evaluation under sub. (5).

(d) The department may suspend or revoke an approval under par. (a) for cause.

(3) APPROVAL FEES. A laboratory operator shall pay the following fees to acquire and maintain a laboratory approval under sub. (1):

(a) An initial fee of $732, except as provided in par. (b) or (c).

(b) An initial fee of $180 if the laboratory tests milk for only one dairy plant operator and all the following apply:

1. The dairy plant operator receives only grade B milk.

2. The dairy plant operator receives milk from not more than 5 producers.

3. The dairy plant operator receives not more than 10,000 lbs. of raw milk per week.

(c) An initial fee of $72 if the laboratory does not apply for approval to perform any visual read test.

(d) A fee of $36 for each individual, in excess of 3 individuals, that the department evaluates under sub. (4) at the time of the initial laboratory inspection under sub. (1) (c).

(e) An annual renewal fee of $72 for each annual renewal of the laboratory approval, except that the renewal fee is $36 if the laboratory qualifies under par. (b).

(f) A fee of $180 for each laboratory visit, other than the initial inspection under sub. (1) (c), that the department makes for the purpose of evaluating individuals under sub. (4). This single fee of $180 covers all of the individual evaluations performed during the department's visit, regardless of the number of individuals evaluated.

(4) COMPETENCY EVALUATION. Before the department approves an individual to perform a visual read test, the department shall observe and evaluate that individual's competency to perform that test. The department shall use an appropriate FDA 2400 series form to conduct the evaluation.

Note: FDA 2400 series forms are on file with the department, the secretary of state and the legislative reference bureau.

(5) ANNUAL PROFICIENCY EVALUATION. (a) An individual approved to perform a drug residue screening test shall complete an annual proficiency evaluation. An evaluator approved by the department shall administer the annual proficiency evaluation. The department may approve the laboratory operator to serve as evaluator, except that an independent evaluator shall administer annual proficiency evaluations for analysts performing visual read tests. The evaluator shall report the results of each proficiency evaluation to the department within 7 days after the evaluation is completed.

(b) In a proficiency evaluation, the evaluated individual shall examine the number of samples required under either par. (d) or (e). The evaluator may prepare the samples used in proficiency evaluations, except for samples used in a visual read proficiency test. The contents of the samples shall be known only to the evaluator, and not to the evaluated individual. The evaluator shall evaluate the individual's proficiency by comparing the individual's results to the known contents of the samples, and shall report those results to the department.

(c) A proficiency evaluation under par. (a) shall be conducted according to a standard evaluation procedure that the department approves in writing. A standard evaluation procedure shall comply with this subsection and shall include standards for all the following:

1. The evaluator's preparation of proficiency evaluation samples.

2. The analyst's examination of proficiency evaluation samples.

3. Deadlines for examining proficiency evaluation samples and reporting test results.

4. The evaluator's review and rating of the individual's proficiency.

(d) For a drug residue screening test other than a visual read test, a proficiency evaluation under par. (a) shall include 3 samples. To pass the proficiency evaluation, the individual shall interpret all 3 sample results correctly.

(e) For a visual read test, a proficiency evaluation under par. (a) shall include at least 6 but not more than 20 samples. To pass a proficiency evaluation involving 6 to 10 samples, an individual

shall interpret no more than one sample result incorrectly. To pass a proficiency evaluation involving 11 to 20 samples, an individual shall interpret no more than 2 sample results incorrectly.

(6) FAILED PROFICIENCY EVALUATION; LOSS OF APPROVAL. (a) If an individual approved to perform a drug residue screening test fails his or her first annual proficiency evaluation related to that test, the individual is no longer approved to perform that test.

(b) If an individual approved to perform a drug residue screening test passes his or her first annual proficiency evaluation related to that test, but subsequently fails 2 consecutive annual proficiency evaluations, the individual is no longer approved to perform that test.

(c) The department may restore an approval lost under par. (a) or (b) if the individual completes a training program approved by the department and passes an on–site competency evaluation under sub. (4). If the individual subsequently fails his or her first annual proficiency evaluation related to the drug residue screening test, the individual may no longer perform that test. The department may again restore the approval if the individual again meets the restoration requirements under this paragraph.

(7) LIST OF APPROVED ANALYSTS. The department shall maintain, for each laboratory approved under sub. (1), a list of individuals currently approved to perform drug residue screening tests at that laboratory. The list shall identify the drug residue screening tests that each individual is approved to perform.

(8) NOTICE OF STAFFING CHANGES. (a) A laboratory operator shall notify the department within 30 days after any of the following occurs:

1. An individual approved under sub. (2) leaves employment with that laboratory.

2. There is a change in the name of any individual approved under sub. (2).

(b) A laboratory operator shall notify the department within 7 days after a staffing change if, as a result of that change, the laboratory has no individuals approved under sub. (2) to perform a drug residue screening test that the laboratory is authorized to perform.

History: Emerg. cr. eff. 11–15–01; CR 01–124: cr. Register December 2002 No. 564, eff. 1–1–03; CR 07–006: r. and recr. (1), am. (3) (d) and (f), Register January 2008 No. 625, eff. 2–1–08; CR 07–037: am. (3) (a) and (c) to (e) Register April 2008 No. 628, eff. 5–1–08; CR 14–073: am. (1) (a), (b) 2. Register August 2016 No. 728, eff. 9–1–16; **CR 19–076: am. (3) (a), (b) (intro.), (c) to (f) Register May 2020 No. 773, eff. 6–1–20.**

ATCP 77.24 Milk and food analysts; proficiency evaluation. (1) ANNUAL PROFICIENCY EVALUATION REQUIRED. Except as provided in sub. (4), the department may not renew an analyst's certification to perform any test listed under s. ATCP 77.02 (1) or (2) unless, within the year immediately preceding that renewal, the analyst passes a proficiency evaluation for that test. The proficiency evaluation shall comply with this section.

(2) FORM OF EVALUATION. In a proficiency evaluation under sub. (1), an analyst shall examine samples prepared by an approved evaluator under sub. (3). The contents of the samples shall be known only to the evaluator. The evaluator shall rate the analyst's proficiency by comparing the analyst's results to the known contents of the samples, and shall report those results and ratings to the department. The reported results and ratings are rebuttably presumed to be valid for purposes of s. ATCP 77.22 and this section.

(3) APPROVED EVALUATOR. The department, or another evaluator approved by the department in writing, shall serve as a proficiency evaluator under sub. (2).

Note: The department will approve an evaluator under sub. (3) if FDA approves that evaluator for the same purpose.

(4) EVALUATION PROCEDURE; GENERAL. A proficiency evaluation under sub. (1) shall be conducted according to a standard evaluation procedure which the department approves in writing. An analyst is not required to complete a proficiency evaluation for any test unless the department has approved a standard evaluation procedure for that test. A standard evaluation procedure shall comply with applicable requirements under sub. (5), and shall include standards for all of the following:

(a) The evaluator's preparation of proficiency evaluation samples.

(b) The analyst's examination of proficiency evaluation samples.

(c) Deadlines for examining proficiency evaluation samples and reporting test results.

(d) The evaluator's review and rating of the analyst's proficiency.

(5) MILK TESTS; EVALUATION STANDARDS. (a) Proficiency evaluations for the following tests under s. ATCP 77.02 (1) shall test include at least the following number of samples:

1. At least six but not more than 20 samples for standard plate count, petrifilm aerobic count, plate loop count, petrifilm rapid aerobic count, peel plate aerobic count, or phosphatase tests.

2. At least eight but not more than 20 samples for direct microscopic somatic cell counts, electronic somatic cell counts, drug residue tests, or coliform tests.

(b) To pass a proficiency evaluation under par. (a) which involves 6 to 10 samples, an analyst shall obtain no more than one unacceptable sample result. To pass a proficiency evaluation under par. (a) which involves 11 to 20 samples, an analyst shall obtain no more than 2 unacceptable sample results.

(c) In a proficiency evaluation for any of the following tests, a sample result is unacceptable if it falls outside the statistical limits established in FDA's "Evaluation of Milk Laboratories," 2017 edition:

1. Standard plate count.
2. Petrifilm aerobic count.
3. Plate loop count.
4m. Petrifilm Rapid Aerobic Count.
5m. Peel Plate Aerobic Count.
6. Direct microscopic somatic cell count.
7. Electronic somatic cell count.

(d) In a proficiency evaluation for a test, such as a drug residue or phosphatase test, in which sample test results are reportable as positive or negative, a sample result is unacceptable if the analyst fails to report the correct positive or negative result.

(e) In a proficiency evaluation for a coliform test, a sample result is unacceptable if the analyst fails to report the correct result.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (2) and (5) (e), Register January 2008 No. 625, eff. 2–1–08; **CR 19–076: am. (5) (a) 1., (c) (intro.), renum. (5) (c) 4., 5., to (5) (c) 6., 7., cr. (5) (c) 4m., 5m. Register May 2020 No. 773, eff. 6–1–20**.

Subchapter III — Water Laboratories

ATCP 77.30 Water laboratories; procedures. (1) TEST METHODS. An operator who performs any test listed under s. ATCP 77.02 (3) shall perform that test according to methods specified in applicable reference materials under sub. (2), or according to methods which the department approves in writing.

(2) REFERENCE MATERIALS. An operator who performs any test listed under s. ATCP 77.02 (3) shall keep all of the following reference materials at the certified laboratory:

(a) The manufacturer's complete operating and maintenance instructions for equipment used to perform that test.

(b) The U.S. environmental protection agency "Manual for the Certification of Laboratories Analyzing Drinking Water," 5th edition.

(c) "Standard Methods for the Examination of Water and Wastewater," 18th, 19th, 20th, 21st, or 23rd edition, published by the American Public Health Association, the American Water Works Association and the Water Environment Federation.

Note: Copies of "Standard Methods for the Examination of Water and Waste Water" are on file with the department and the legislative reference bureau and may

be obtained from the "APHA Bookstore" at http://secure.apha.org/iMIS/APHA/Store .

(3) CULTURE MEDIA. Culture media for any test listed under s. ATCP 77.02 (3) shall be effectively sterilized before they are used. Culture media shall be autoclaved for the total cycle time and sterilization time specified by the media manufacturer or by the applicable test method under this section.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (2) (b) and (c), Register January 2008 No. 625, eff. 2–1–08.

ATCP 77.32 Water laboratory analysts. (1) OPERATOR TO DOCUMENT COMPETENCY. In every initial or renewal application for water laboratory certification, a laboratory operator shall document that the analysts who perform each test under s. ATCP 77.02 (3) for which the laboratory seeks certification are properly trained to perform that test, and can accurately test positive and negative blind samples. Analysts are not required to be certified by the department.

(2) DEPARTMENT TO AUDIT COMPETENCY. Whenever the department performs a mandatory inspection of a water laboratory under s. ATCP 77.14 (1), the department shall observe and evaluate the competency of at least one analyst who performs tests under s. ATCP 77.02 (3) for which the department is certifying the water laboratory. The department shall use the United States environmental protection agency "Manual for the Certification of Laboratories Analyzing Drinking Water," 5th edition, to evaluate the analyst's competency.

Note: Copies of the "Manual for the Certification of Laboratories Analyzing Drinking Water" are on file with the department and the legislative reference bureau and may be obtained from the U.S. Environmental Protection Agency at https://www.epa.gov/dwlabcert/laboratory–certification–manual–drinking–water.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (2), Register January 2008 No. 625, eff. 2–1–08.

ATCP 77.34 Water laboratories; proficiency evaluation. (1) EVALUATION REQUIRED. Except as provided in sub. (4), the department may not issue or renew an operator's certification to perform any test listed under s. ATCP 77.02 (3) unless, within the year immediately preceding that certification or renewal, the laboratory passes a proficiency evaluation for that test.

(2) FORM OF EVALUATION. In a laboratory proficiency evaluation under sub. (1), an operator shall assign an analyst to examine samples prepared by an approved evaluator under sub. (3). The contents of the samples shall be known only to the evaluator. The analyst who examines the samples shall be an analyst who normally performs that test at the certified laboratory. The evaluator shall rate the operator's proficiency by comparing the analyst's results to the known contents of the samples, and shall report those results and ratings to the department. The reported results and ratings are rebuttably presumed to be valid for purposes of this section.

(3) APPROVED EVALUATOR. The state of Wisconsin laboratory of hygiene, or another evaluator approved by the department in writing, shall be the evaluator in a proficiency evaluation under sub. (1).

(4) EVALUATION PROCEDURE; GENERAL. A proficiency evaluation under sub. (1) shall be conducted according to a standard evaluation procedure which the department approves in writing. An operator is not required to complete a proficiency evaluation for any test unless the department has approved a standard evaluation procedure for that test. A standard evaluation procedure shall include standards for all the following:

(a) The evaluator's preparation of proficiency evaluation samples.

(b) The operator's examination of proficiency evaluation samples.

(c) Deadlines for examining proficiency evaluation samples and reporting test results.

(d) The evaluator's review and rating of the operator's proficiency.

(5) DRINKING WATER TESTS; EVALUATION PROCEDURES. Beginning on July 1, 1999, standard evaluation procedures for tests under s. ATCP 77.02 (3) shall include the following requirements:

(a) An operator who is evaluated for proficiency in testing for total coliform and fecal coliform or E. coli shall examine at least 10 samples of at least 100 ml. each annually. The evaluator shall provide full volume samples, or the concentrate and diluents needed to reconstitute the concentrates to full volume. Each sample set shall include all of the following:

1. One to 4 samples of an aerogenic strain of Escherichia coli which, if properly tested according to methods under s. ATCP 77.30 (1), will test positive for total coliform and E. coli.

2. One to 4 samples of Enterobacter sp. or other microorganisms which, if properly tested according to methods under s. ATCP 77.30 (1), will test positive for total coliform and negative for E. coli.

3. One to 4 samples of Pseudomonas sp. or other microorganisms which, if properly tested according to methods under s. ATCP 77.30 (1), will test negative for total coliform and E.coli.

4. One to 4 blank samples.

(b) An operator testing proficiency evaluation samples under par. (a) shall report the test results to the evaluator. The evaluator shall report the test results to the department within 40 calendar days after the evaluator mails or delivers the samples under par. (a) to the operator. For each sample tested, the evaluator shall report the operator's test result for total coliform and E. coli, and shall indicate whether that test result is correct or incorrect.

(c) To pass a proficiency evaluation under par. (a), an operator shall report the correct result on 90% of the samples tested, with no false negatives.

(6) FULL CERTIFICATION. The department may fully certify an operator to perform a test if, in a proficiency evaluation under this section, the operator meets applicable performance standards under subs. (4) and (5).

(7) PROVISIONAL CERTIFICATION; SUSPENSION. (a) If, in any proficiency evaluation under this section, an operator fails to meet applicable performance standards under subs. (4) and (5), the department shall issue a notice stating that the operator's certification to perform that test is provisional.

(b) A provisionally certified operator may regain full certification by meeting applicable standards under subs. (4) and (5) on the next 2 consecutive proficiency evaluations.

(c) If a provisionally certified operator fails to meet applicable performance standards under subs. (4) and (5) on either of the next 2 proficiency evaluations, the department shall summarily suspend the operator's certification to perform that test. The department may fully restore the operator's certification if the operator does both of the following:

1. Documents the steps which the operator has taken to correct the performance deficiency.

2. Meets applicable performance standards under subs. (4) and (5) on a new proficiency evaluation.

History: Cr. Register, September, 1999, No. 525, eff. 10–1–99; CR 07–006: am. (2), Register January 2008 No. 625, eff. 2–1–08; **CR 19–076: am. (5) (a) 1. to 3., (b), Register May 2020 No. 773, eff. 6–1–20; correction in (5) (a) 1. made under s. 35.17, Stats., Register May 2020**.