

98-142 HSS 165 - MILK TESTING
CERTIFICATION

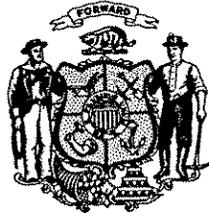
WISCONSIN LEGISLATIVE COUNCIL STAFF

LCRC
FORM 2

RULES CLEARINGHOUSE

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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE 98-142

AN ORDER to repeal HSS 165.02 (4), (12) (b) and (14), 165.03 (1) (b) to (d), 165.14 (2) (a) 11. and (3) (g), 165.20 (2) and 165.23 (1) (g); to amend HSS 165.01 (1) and (2), 165.02 (8), (9), (12) (intro.), (13) and (17), 165.03 (1) (intro.) and 165.04 (1) (intro.); and to repeal and recreate chapter ATCP 77, relating to certification of laboratories engaged in public health testing of milk, water and food.

Submitted by **DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION**

09-21-98 RECEIVED BY LEGISLATIVE COUNCIL.
10-19-98 REPORT SENT TO AGENCY.

RNS:MM:kjf:rv;ksm

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]

Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached YES NO

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CLEARINGHOUSE RULE 98-142

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]

I. Statutory Authority

a. The rule does not comply with the statutory requirement set forth at s. 93.12, Stats., to designate the laboratory examinations the department deems necessary for the protection of the health of the public. The rule repeals the provisions in s. HSS 165.03 that designate the water, milk and food examinations which are necessary for the protection of the health of the public. If the department is intending that the lists of tests in s. ATCP 77.02 (1) will serve this purpose, this should be clarified.

b. The rule fails to comply with the following statutory requirement, set forth at s. 93.12 (3), Stats., as follows:

Substantial failure of any laboratory to show evidence of quality control procedures, sufficient to comply with current standards and practice as prescribed by the department, shall result in denial or revocation of the certificate of approval.

In order to comply with the statute, the rule must be revised to set forth standards and practices for quality control procedures and to provide for the denial or revocation of a certificate of approval for failure of a laboratory to follow those standards and practices.

c. The rule fails to comply with the following statutory requirement, set forth at s. 93.12 (4), Stats.:

A certificate of approval shall be revoked by the department if the minimum standards established by the department for certification are not met within two successive evaluations.

Sections ATCP 77.24 (1) and 77.34 (1) should be revised to comply with the statutory requirement.

2. Form, Style and Placement in Administrative Code

a. The chapter, section and paragraph titles in the rule should be rewritten to conform to proper drafting style. [See s. 1.05 (2) (a), (b) and (d), Manual.]

b. Currently, s. HSS 165.03 has only one subsection. As amended, that subsection will have only one paragraph. It is not appropriate drafting style to divide a rule unit into only one subunit. [See s. 1.03 (intro.), Manual.] Therefore, each of the subdivisions in current par. (a) should become subsections. As redrafted, s. HSS 165.03 should read as follows:

HSS 165.03 Examinations necessary for the protection of the health of the public. The department designates the following examinations of body fluids, tissues, discharges, respiratory and environmental air as necessary for the health of the public:

(1) Microbiology tests.

...

c. In s. ATCP 77.01 (1), “, as defined under sub. (15), at a laboratory” is unnecessary.

d. The definition provided for the term “operator” in s. ATCP 77.01 (11) should be rewritten to read: “(11) “Operator” means a person who owns or controls a laboratory or that person’s employes or agents.” However, including the employes and agents within the definition of “operator” is unworkable in several parts of the rule. For example, s. ATCP 77.04 (1) (intro.) requires an operator to apply for certification of a laboratory. Paragraph (a) requires the application to include the operator’s correct legal name and address. Clearly, this requirement applies only to the owner or person in control of a laboratory and not to an operator’s employes.

e. It appears that s. ATCP 77.02 (1) (intro.) should be rewritten as follows:

(1) WHO MUST BE CERTIFIED. Except as provided under sub. (4), no individual may perform any of the following tests to determine whether milk, water or food complies with public health standards required under federal or state law unless the laboratory at which the test is performed has been certified under s. ATCP 77.08 for the performance of that test:

f. Section ATCP 77.04 (1) (e) 3. should be rewritten to clarify that in order to obtain certification, a laboratory must meet the proficiency evaluation requirements set forth in s. ATCP 77.24 (1) or ATCP 77.34 (1).

g. Should s. ATCP 77.06 (1) specify that an annual certification fee must be paid for each separate laboratory at which a test is to be performed?

h. In s. ATCP 77.06 (4) (a), the phrase "at the operator's laboratory" should be changed to "the laboratory for which the operator is seeking certification."

i. Section ATCP 77.08 (1) states that the department "may" certify an operator if the operator and laboratory comply with the requirements of the chapter. Should "may" be changed to "shall"? If not, the rule should specify the circumstances under which certification may be denied to an operator who has met the requirements of the chapter.

j. Section ATCP 77.08 (1) authorizes the department to conditionally certify an operator pending action by the operator to correct deficiencies. Is there a maximum length of time for which an operator may be conditionally certified? Are there certain deficiencies for which a conditional certificate may not be issued?

k. It appears that under ch. ATCP 77, the "laboratory administrator" will be fulfilling the role previously fulfilled by the laboratory director, as set forth under s. HSS 165.20. However, s. ATCP 77.12, relating to laboratory administrators, does not set forth any qualifications that must be met by a laboratory administrator. In contrast, s. HSS 165.20 (2), which is repealed by the rule, sets forth various educational and experience requirements for directors of milk, food and water laboratories.

l. In s. ATCP 77.14 (1) (c), it appears that the second occurrence of "operator" should be changed to "department."

m. Section ATCP 77.14 (2) (a) authorizes the department to inspect a certified laboratory whenever the operator "materially alters laboratory facilities, equipment or *procedures*" (emphasis added). Should the rule establish a requirement that the operator notify the department of any material alteration of laboratory procedures? It does not appear that the notice requirement in s. ATCP 77.10 (3) is sufficient to ensure that notice is provided in this instance.

n. In s. ATCP 77.14 (2) (intro.), it appears that "authority" should be changed to "laboratory."

o. In the third line of s. ATCP 77.22 (2) (a), it appears that "under" should be inserted after "tests."

p. Section ATCP 77.22 (3) should be rewritten to clearly specify the standards that must be met for an analyst to obtain certification to perform a test. In addition, the rule should clearly state that an analyst may not perform a test unless the analyst is certified to perform that test. Also, should s. ATCP 77.22 (4) (b) specify that a test may not be performed at a operator's laboratory if, as a result of a staffing change, there is no longer at least one analyst certified to perform the test working at the operator's laboratory?

q. In s. ATCP 77.24 (2), it appears that the terms "operator" and "analyst" are used interchangeably.

r. In s. ATCP 77.24 (3), it is unclear what the requirements are for approval of a proficiency evaluator. Is approval by the Food and Drug Administration a prerequisite to departmental approval? If so, this requirement should be set forth in the text of the rule.

s. In s. ATCP 77.32, what action should be taken if an analyst is found not to be proficient?

t. Section ATCP 77.34 (5) (a) should specify how often an operator must examine "at least 10 samples." Is this an annual requirement?

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In the last sentence under the heading "Laboratory Facilities" in the analysis to the rule, it appears that "it" should be changed to "laboratory."

b. Each of the subdivisions in s. ATCP 77.02 (1) (c) should end with a period.

c. In s. ATCP 77.04 (1) (intro.), "initial" should be inserted before "certification."

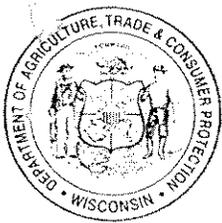
d. In s. ATCP 77.14 (2) (b), it is unclear what is meant by "a new analyst." Is this term meant to refer to an analyst who has not previously performed a certain test or to an analyst who has been newly hired to work at the laboratory?

e. In s. ATCP 77.20 (2) (a), the first occurrence of "and" should be changed to "or."

f. Section ATCP 77.22 (3) should clearly state that an analyst may not perform any test under s. ATCP 77.02 (1) (a) or (b) unless the analyst has been certified by the department to perform that test.

g. Although the analysis to the rule states that "[t]his rule does not make major changes in the current lab certification program," the reduction in the number of proficiency evaluations that must be performed by a certified laboratory appears to be major. For example, s. HSS 165.14 (2) (a) 11., which is repealed by the rule, requires a laboratory which engages in milk testing to evaluate, at a minimum, 34 proficiency testing specimens each year, while the proposed rule, in s. ATCP 77.24 (1), would require the evaluation of only one specimen annually.

h. Section ATCP 77.32 should state whether an analyst must be certified in order to perform tests under s. ATCP 77.02 (1) (c), as is required for analysts who perform tests under s. ATCP 77.02 (1) (a) and (b). In addition, must a laboratory have at least one analyst certified to perform a test under s. ATCP 77.02 (1) (c) as a precondition to the department certifying the operator to perform that test?



State of Wisconsin
Tommy G. Thompson, Governor



Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

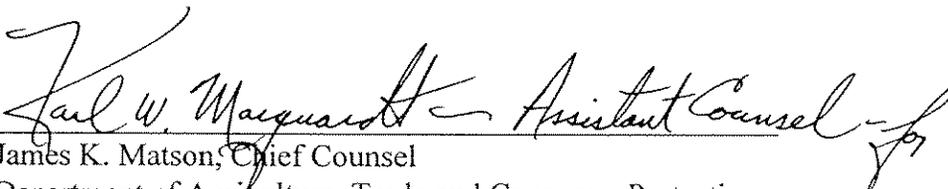
**NOTICE OF SUBMITTAL OF PROPOSED RULE TO
WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE**

The Wisconsin Department of Agriculture, Trade and Consumer Protection has referred a proposed rule to the Wisconsin Legislative Council Rules Clearinghouse.

The proposed rule amends chapters ATCP 77, Wis. Adm. Code, relating to certification of laboratories engaged in public health testing of milk, water and food. Public hearings are required and will be held after the Wisconsin Legislative Council Rules Clearinghouse completes its review of the proposed rule.

The Division of Food Safety is primarily responsible for promulgation of this rule. If you have questions regarding this rule, you may contact Laura Traas of the Division of Food Safety at (608) 224-4700 or Attorney Karl Marquardt at (608) 224-5031.

Dated this 15th day of September, 1998


Assistant Counsel

James K. Matson, Chief Counsel
Department of Agriculture, Trade and Consumer Protection



State of Wisconsin
Tommy G. Thompson, Governor

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary



September 21, 1998

Wisconsin Legislative Council
Rules Clearinghouse
1 East Main Street, Room 401
Madison, WI 53702

Re: Proposed Amendment of Chapter ATCP 77, Wis. Adm. Code,
Relating to Certification of Laboratories Engaged in Public Health Testing of
Milk, Water and Food

Dear Sir/Madam:

In compliance with s. 227.15, Stats., the Department of Agriculture, Trade and Consumer Protection is referring the above rule for review by the Rules Clearinghouse. The proposed rule has been approved for public hearing by the Board of Agriculture, Trade and Consumer Protection, but no hearings will be held until the Rules Clearinghouse review is complete. The proposed rule and accompanying fiscal estimate are attached.

The authority and rationale for the proposed rule are set forth in the rule and accompanying analysis by the department. If you have any questions concerning the proposed rule, you may contact Laura Traas, Division of Food Safety at (608) 224-4700, you may also contact Attorney Karl Marquardt at 224-5031.

Sincerely,

Margaret C. Maly
Administrative Assistant
Office of Legal Counsel

Enclosures

cc: Laura Traas - Division of Food Safety
Karl Marquardt - Office of Legal Counsel

**PROPOSED ORDER OF THE STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION
ADOPTING, AMENDING OR REPEALING RULES**

1 The state of Wisconsin department of agriculture, trade and consumer protection proposes the
2 following order to repeal ss. HSS 165.02(4), (12)(b) and (14), 165.03(1)(b) to (d),
3 165.14(2)(a)11. and (3)(g), 165.20(2), and 165.23(1)(g); to amend HSS 165.01(1) and (2),
4 165.02(8), (9), (12)(intro.), (13) and (17), 165.03(1)(intro.) and 165.04(1)(intro.); and to repeal
5 and recreate ch. ATCP 77 relating to certification of laboratories engaged in public health testing
6 of milk, water and food.

**Analysis Prepared by the Department of
Agriculture, Trade and Consumer Protection**

Statutory authority: ss. 93.07(1) and 93.12(3), (5) and (7), Stats.

Statutes interpreted: ss. 93.06(7) and (8), 93.08, 93.12, 93.14, 93.15,
93.16 and 97.12, Stats.

The 1995-97 biennial budget act, 1995 Wis. Act 27, transferred much of the administration of Wisconsin's laboratory certification program from the Department of Health and Family Services ("DHFS") to the Department of Agriculture, Trade and Consumer Protection ("DATCP").

Under this program, DATCP is now responsible for certifying laboratories that test milk, food and drinking water for compliance with public health standards. (DHFS retains jurisdiction over certain public health laboratories, such as medical laboratories.) Laboratory certification helps ensure that public health lab tests are accurate and reliable.

* This rule is the foundation for the lab certification program now located in DATCP. This rule *
does not make major changes in the current lab certification program. However, this rule streamlines and clarifies current rules so they will be easier to read and understand. This rule repeals former DHFS lab certification rules under ch. HSS 165, Wis. Adm. Code. It also repeals and recreates DATCP's interim lab certification rules under ch. ATCP 77, Wis. Adm. Code.

Coverage

Under s. 93.12, Stats., and this rule, DATCP must certify laboratories that perform certain tests on milk, water or food, to determine compliance with federal, state or local public health

standards. This rule specifies the tests for which a laboratory must be certified. Both private and public laboratories must be certified under this rule. However, certification is not required for any of the following:

- The United States government.
- Milk testing by DATCP.
- 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 .
- 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.

Scope of Certification

DATCP must certify a laboratory on an annual basis. An annual certification expires on December 31 of each year. A person who operates 2 or more laboratories must obtain a separate certification for each lab. DATCP must specify, in its certification, the tests which the laboratory is certified to perform.

Applying for Certification

A laboratory must apply to DATCP for certification, and must pay an annual certification fee of \$216 per test. If DATCP certifies a lab to perform a test for less than a full year, the lab must pay a certification fee of \$18 for each full month of certification.

DATCP must act on a certification application within 40 calendar days after it receives a complete application. A laboratory may apply, at any time, for certification to perform additional tests. A certified laboratory must file an annual renewal application by December 31 of each year.

Granting and Withdrawing Certification

DATCP may certify a laboratory that complies with this rule. DATCP may conditionally certify a laboratory pending action to correct deficiencies which DATCP has identified. DATCP may summarily suspend a conditional certification if the laboratory fails to correct the deficiencies within the time specified by DATCP.

Laboratory Facilities

A laboratory must have adequate facilities, equipment and supplies to perform the tests for which DATCP certifies that laboratory. A laboratory must also maintain the facilities, equipment and supplies in proper working condition. This rule establishes some specific facility and

maintenance requirements. Under this rule, a laboratory must notify DATCP whenever the it remodels lab facilities or installs new equipment that materially affects the performance of certified tests.

Laboratory Procedures

A certified laboratory must perform tests according to recognized methods. This rule incorporates, by reference, authoritative lab manuals which spell out those recognized methods. As required under s. 227.21, Stats., DATCP has requested permission from the attorney general and the revisor of statutes to incorporate these manuals by reference in this rule.

Laboratory Administrator

A certified laboratory must designate an administrator who personally supervises the operations of the laboratory. The administrator or a designated agent of the administrator must be present at the laboratory during daytime business hours, and must do all of the following on behalf of the lab operator:

- Supervise the lab and its compliance with this rule.
- Review and approve the lab's certification applications to DATCP.
- Supervise the procurement and maintenance of lab facilities, equipment and supplies.
- Facilitate DATCP inspections of the lab.
- Notify DATCP of changes in lab facilities or personnel that affect the lab's certification.
- Notify lab customers if DATCP suspends or revokes the lab's certification.
- Report lab test results to the appropriate regulatory agency, if required by law.
- Supervise lab recordkeeping.

Laboratory Analysts

Analysts who perform tests at a certified laboratory must be proficient in performing those tests. Whenever DATCP first certifies a laboratory, or performs its biennial inspection of a certified laboratory, DATCP must evaluate the proficiency of all the analysts who are then performing tests for which the lab is certified. DATCP evaluates the analysts by watching them perform the tests.

must each analyst be certified?

DATCP may not certify a laboratory to test milk unless DATCP specifically certifies the proficiency of at least one analyst to perform each test for which the lab is certified. (This is

different from DATCP's general evaluation lab analysts, described above.) DATCP must follow specific federal procedures when certifying individual milk analysts, and must maintain a list of certified analysts. An analyst's certification remains in effect until the analyst leaves the lab, or until DATCP suspends or revokes the analyst's certification.

A laboratory must notify DATCP if the lab no longer has certified analysts on staff to perform milk tests. A laboratory must also notify DATCP whenever the lab assigns a new analyst to perform any test for which the lab is certified.

any qualification required for analysts?

Inspecting a Laboratory

DATCP must inspect a laboratory at all of the following times:

- Before certifying the laboratory for the first time.
- At least once every 2 years after it certifies the laboratory.
- Before certifying the laboratory to perform a test for which it was not previously certified.

DATCP may inspect a laboratory whenever any of the following occurs:

- The laboratory materially alters its facilities, equipment or procedures.
- The laboratory assigns a new analyst to perform a test for which the lab is currently certified.
- DATCP concludes that an inspection is necessary to determine whether the lab complies with this rule.

Milk and Water Laboratories; Proficiency Evaluation

A laboratory certified to test milk or water must undergo an annual lab proficiency evaluation. In an annual lab proficiency evaluation, the laboratory must examine samples prepared by an approved evaluator. The contents of the samples are known to the evaluator, but not to the laboratory. The evaluator must rate the laboratory's proficiency (not the proficiency of individual analysts) by comparing the laboratory's results to the known contents of the samples, and must report those results and ratings to DATCP.

DATCP, or ^{annual?} another evaluator approved by DATCP, must evaluate a lab's proficiency in performing milk or food tests. The Wisconsin state lab of hygiene, or another evaluator approved by DATCP, must evaluate a lab's proficiency in performing water tests.

DATCP must approve lab evaluation procedures. A laboratory is not required to undergo an annual proficiency evaluation for any test unless DATCP has approved an evaluation procedure for that test. An evaluation procedure must include standards for all of the following:

- The evaluator's preparation of test samples.
- The lab's examination of test samples.
- Deadlines for examining test samples and reporting test results.
- The evaluator's review and rating of operator proficiency.

This rule specifies evaluation procedures for milk and water tests. To pass an annual milk test evaluation, a laboratory must accurately test at least 80 percent of the samples provided by the evaluator. To pass an annual water test evaluation, a laboratory must accurately test at least 90 percent of the samples provided by the evaluator.

Laboratory Records

A laboratory must keep complete records related to all of the following:

- The training, experience and proficiency testing of analysts. *what's better would?*
- Laboratory evaluations.
- Laboratory policies and procedures.
- Laboratory facilities, equipment and supplies, including records related to procurement, calibration, testing and maintenance.
- Quality control procedures and monitoring.
- Tests performed at the laboratory, including 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.
- Test reports filed with the department and other government agencies.

A laboratory must keep these records for at least 5 years, and must make them available for inspection and copying by DATCP upon request. A laboratory may not falsify any records.

Notice to DNR and Lab of Hygiene

Pursuant to s. 93.12(5), Stats., the department has given notice of this rule to the department of natural resources and the state laboratory of hygiene.

check NJ 165

1 **SECTION 1.** HSS 165.01(1) and (2) are amended to read:

2 HSS 165.01(1) STATUTORY REQUIREMENT. Section 252.22, Laboratories, approval
3 of, Wis. Stats., requires in part: that laboratories, except physician office laboratories serving not
4 more than 2 physicians, performing clinical laboratory tests ~~or examinations of milk, water, and~~
5 ~~food products~~ for the purpose of protecting the health of the public shall apply to the department
6 of health and social services for an evaluation of the examinations and appropriate certification;
7 that the certification normally will be valid for 12 months and subject to revocation, denial, or
8 suspension for cause; that the department of health and social services shall establish certification
9 standards; and that laboratories shall not operate without a certificate.

10 (2) OTHER PROGRAM RELATIONSHIPS. In addition to functioning for the
11 attainment of reliable clinical, ~~water, milk, and food product~~ testing, the certification program
12 endeavors to assure the development of clinical and disease control laboratory services to meet
13 the needs and requirements of a number of federal and state health related programs and to
14 achieve better laboratory morbidity reporting systems for disease detection and management. The
15 health related laws or programs receiving input from the laboratory evaluation and certification
16 program include the infant metabolic disorder testing law, alcohol analyses for implied consent
17 and coroner motor vehicle and snowmobile death laws, codes for controlling enteric disease
18 cases and carriers, the Wisconsin Hospital Approval Act, federal Medicare, Medicaid
19 certification, and interstate laboratory licensure law, ~~and appropriate municipal, state, and federal~~
20 ~~laws controlling the quality of laboratory testing services for water, milk, and food products.~~

21 (165) **SECTION 2.** HSS 165.02(4) is repealed.

22 **SECTION 3.** HSS 165.02(8), (9) and (12)(intro.) are amended to read:

1 HSS 165.02(8) "Facility" means a clinical laboratory; or a blood bank laboratory; ~~or a~~
2 ~~laboratory engaged in the testing of milk, water, or food products.~~

3 (9) "Laboratory" or "clinical laboratory" means a facility where microbiological,
4 biological, physical, serological, chemical, hematological, immunological, cytological, or
5 microscopic examinations of specimens taken from the human body, ~~milk, water, food products,~~
6 or other matter, are performed for screening, diagnostic, and treatment purposes.

7 (12)(intro.) "Laboratory specialty" or "specialty" means a science discipline used for the
8 examination of materials derived from the human body or other matter, for the purpose of disease
9 prevention, laboratory screening, diagnosis or treatment of patients, ~~or the examination of milk,~~
10 ~~water or food products for the purpose of determining purity, potability or freedom from harmful~~
11 ~~substances.~~ For purposes of this chapter, laboratory specialties include but are not limited to the
12 following:

13 **SECTION 4.** HSS 165.02(12)(b) is repealed.

14 **SECTION 5.** HSS 165.02(13) is amended to read:

15 HSS 165.02(13) "Local public health agency laboratory" means a laboratory operated by
16 a single city or county health department, a multiple county health department, or a city-county
17 health department which performs clinical, ~~milk, water, or food~~ tests for the prevention,
18 detection, diagnosis, and control of disease.

19 **SECTION 6.** HSS 165.02(14) is repealed.

20 **SECTION 7.** HSS 165.02(17) is amended to read:

21 HSS 165.02(17) "Proficiency testing program" means those activities which are required
22 by the department to define, monitor, and measure the accuracy of testing by a laboratory and

1 which meet the applicable requirements of federal agencies for licensure or certification of
2 clinical ~~and milk, water and food~~ laboratories.

3 SECTION 8. HSS 165.03(1)(intro.) is amended to read:

4 HSS 165.03(1)(intro.) (1) EXAMINATIONS. The department designates the following
5 clinical, ~~water, milk, or food~~ examinations as necessary for the protection of the health of the
6 public.

7 SECTION 9. HSS 165.03(1)(b) to (d) are repealed.

8 SECTION 10. HSS 165.04(1)(intro.) is amended to read:

9 HSS 165.04(1)(intro.) APPLICATION AND EXCEPTIONS. All clinical laboratories,
10 and blood banks, ~~and laboratories performing milk, water microbiology, and food products~~
11 testing for the protection of the health of the public shall apply to the department for evaluation
12 and certification, except:

13 SECTION 11. HSS 165.14(2)(a)11. and (3)(g) are repealed.

14 SECTION 12. HSS 165.20(2) is repealed.

15 SECTION 13. HSS 165.23(1)(g) is repealed.

16 SECTION 14. Chapter ATCP 77 is repealed and recreated to read:

17 CHAPTER ATCP 77
18 LABORATORY CERTIFICATION
19 SUBCHAPTER I

20 GENERAL REQUIREMENTS

21 ATCP 77.01 DEFINITIONS. In this chapter:

22 (1) "Analyst" means an individual who performs a test, as defined under sub. (15), at a

23 laboratory.

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

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

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

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

8 (6) "Food safety administrator" means the administrator of the department's division of
9 food safety.

10 (7) "Individual" means a natural person.

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

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

14 (10) "Milk" means the lacteal secretion of cows, sheep or goats, and includes dairy
15 products made from milk.

16 (11) "Operator" means a person who owns or controls a laboratory. "Operator" includes ²
17 the operator's employees and agents. *also include work for parts of the rule such as 77.04 (1) or 77.10(2)*

18 (12) "Person" means an individual, corporation, partnership, cooperative association,
19 limited liability company, trust, or other organization or entity. "Person" includes counties,
20 municipalities, the state of Wisconsin and agencies of the state. *take this out and change 77.02(1)(c)*

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

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

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

4 **ATCP 77.02 CERTIFICATION REQUIRED.** (1) WHO MUST BE CERTIFIED.

5 Except as provided under sub. (4), no laboratory operator may perform any of the following tests
6 to determine whether milk, water or food complies with public health standards required under
7 federal or state law unless the department certifies that operator to perform those tests at that
8 laboratory:

9 (a) Milk. Any of the following tests related to milk:

- 10 1. Standard plate count.
- 11 2. Plate loop count.
- 12 3. Petrifilm aerobic count.
- 13 4. Coliform plate count.
- 14 5. Petrifilm coliform count.
- 15 6. Charm BsDa.
- 16 7. Charm I/ cowside II.
- 17 8. Charm II competitive.
- 18 9. Charm II sequential.
- 19 10. Charm II cloxacillin.
- 20 11. Charm II sulfa.
- 21 12. Charm II tetracycline.
- 22 13. Delvotest P.

- 1 14. Delvotest P 5 pack.
- 2 15. LacTek B/L.
- 3 16. LacTek ceftiofur.
- 4 17. Penzyme milk.
- 5 18. Penzyme III.
- 6 19. SNAP B/L.
- 7 20. Direct microscopic somatic cell count.
- 8 21. Optical somatic cell count.
- 9 22. Pasteurized milk containers.
- 10 23. Phosphatase test; Scharer rapid method.
- 11 24. Phosphatase test; fluorophos.
- 12 25. Phosphatase test; Charm II.
- 13 26. Other tests performed to comply with ch. ATCP 60 or 80

14 (b) Food. Any of the following tests related to food:

- 15 1. Standard plate count.
- 16 2. Plate loop count.
- 17 3. Petrifilm aerobic count.
- 18 4. Coliform plate count.
- 19 5. Petrifilm coliform count.
- 20 6. Other tests under ch. ATCP 75 to detect pathogens in food.

21 (c) Water. Any of the following tests related to water:

- 22 1. Multiple tube fermentation procedure (MTF) ← *parens*

- 1 2. Membrane filter technique (MF) e
- 2 3. Enzymatic substrate (MMO-MUG) o
- 3 4. Clark's Presence/Absence (P/A) ,
- 4 5. Heterotrophic plate count (HPC) ,
- 5 6. Other tests under ch. NR 809 or 812 to detect microbiological contaminants in drinking
- 6 water.

7 (2) SCOPE OF CERTIFICATION. (a) The department shall issue a certification under
8 sub. (1) on an annual basis. An annual certification expires on December 31 of each year.

9 (b) A person who operates 2 or more laboratories under sub. (1) shall obtain a separate
10 certification for each laboratory. A certification may not be transferred between persons or
11 laboratories.

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

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

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

17 (a) The United States government.

18 (b) Milk testing by the department.

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

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

1 **ATCP 77.04 APPLYING FOR CERTIFICATION. (1) INITIAL APPLICATION.**

2 An operator shall apply for certification under s. ATCP 77.02 on a form provided by the
3 department. The operator shall submit a separate application for each laboratory location. An
4 application shall include all of the following:

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

9 (b) The name, address and telephone number of the laboratory.

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

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

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

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

15 2. Written test procedures ^{to be (if not certified) yes we use it} used for each test, or an identification of the standard test
16 methods used for each test.

17 3. Proof of analytical proficiency in each test. Proof may consist of quality assurance
18 test results from comparison studies, split samples or proficiency tests. ^{to be (if not certified) yes we use it}

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

21 Wisconsin Department of Agriculture, Trade and Consumer Protection
22 Division of Food Safety, Bureau of Food Safety and Inspection
23 Laboratory Certification Program
24 P.O. Box 8911
25 Madison, WI. 53708-8911
26 (608) 224-4719

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

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

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

9 (c) The certification fees required under s. ATPC 77.06.

10 **NOTE:** The department will send renewal application forms to certified
11 laboratories approximately 6 weeks before their current annual
12 certifications expire.

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

15 **ATCP 77.06 CERTIFICATION FEES.** (1) FEE AMOUNTS. Except as provided
16 under sub. (2) or (3), an operator shall pay an annual certification fee of \$216 for each test for
17 which the operator is certified, *at each location?*

18 (2) PARTIAL FEES. If the department certifies an operator to perform a test for less
19 than a full calendar year, the operator shall pay a fee of \$18 for each full month of certification
20 for that test.

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

1 (4) PAYING CERTIFICATION FEES. (a) If the department has not previously
2 certified an operator to perform any of the tests listed under s. ATCP 77.02(1) at the operator's
3 laboratory, the department shall bill the operator under sub. (1) or (2) after the department
4 inspects the laboratory under s. ATCP 77.14(1)(a). The department may not certify the operator
5 to perform any test until the operator pays the required certification fee for that test. *which test?*

6 (b) If the operator of a certified laboratory applies for certification to perform additional
7 tests under sub. (5), or files a renewal application under s. ATCP 77.04(2), the operator shall
8 include with that application the fees required under sub. (1) or (2).

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

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

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

16 (c) The fees required under sub. (1) or (2).

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

19 **ATCP 77.08 GRANTING AND WITHDRAWING CERTIFICATION.** (1)

20 GRANTING CERTIFICATION. The department may certify an operator under s. ATCP 77.02
21 if the operator and laboratory comply with this chapter. The department may conditionally
22 certify an operator pending action by the operator to correct deficiencies which the department
23 has identified. The department may summarily suspend a conditional certification, without prior
when can they refuse? 5
explain - and specify these can't be done to pub. health

1 hearing, if the operator fails to correct the deficiencies within the time specified by the
2 department.

3 (2) DEADLINE FOR ACTION ON CERTIFICATION REQUEST. The department
4 shall do all of the following within 40 calendar days after the department receives a complete
5 application under s. ATCP 77.04:

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

7 (b) Take one of the following actions:

8 1. Grant the application.

9 2. Grant the application subject to conditions.

10 3. Deny the application.

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

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

16 (4) SUMMARY SUSPENSION. The food safety administrator may issue a written
17 notice, summarily suspending all or part of an operator's certification, if the food safety
18 administrator finds in the suspension notice that the operator has not complied with this chapter,
19 that the noncompliance poses an imminent threat to the health or safety of the public or
20 laboratory workers, and that the noncompliance is likely to continue unless the food safety
21 administrator summarily suspends the operator's certification. The operator may contest the
22 summary suspension according to s. ATCP 1.03(3).

Internal Quality Control - 165.19

HFS 165.18 most extensive

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) 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.

(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 at least once a day when the instrument is in use, 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.

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

4 (3) NOTICE OF MATERIAL CHANGES. An operator shall notify the department
5 whenever the operator remodels laboratory facilities or installs new equipment if the remodeling
6 or installation materially affects the performance of tests under s. ATCP 77.02(1) for which the
7 operator is certified.

*Compliance
see HFS 123.02(12)*

*Can operator be held liable for this?
Shouldn't something be subjective?*

8 **ATCP 77.12 LABORATORY ADMINISTRATOR.**

9 The laboratory administrator or
10 a designated agent of the administrator shall be present at every certified laboratory during
11 daytime business hours. The laboratory administrator shall do all of the following on behalf of
12 the laboratory operator:

all?

- 12 (1) Supervise the laboratory and its compliance with this chapter.
- 13 (2) Review and approve, for submission to the department, every certification application
14 which the operator submits for that laboratory under s. ATCP 77.04.
- 15 (3) Supervise the procurement and maintenance of laboratory facilities, equipment and
16 supplies, and notify the department of material changes under s. ATCP 77.10(3).
- 17 (4) Facilitate department inspections of the laboratory. At the request of the department,
18 the administrator shall grant the department access to laboratory facilities, equipment and
19 records, and shall arrange for analysts to demonstrate their testing proficiency.
- 20 (5) Notify the department of changes in laboratory analysts under s. ATCP 77.22(4).
- 21 (6) Notify all laboratory customers if the department suspends or revokes all or part of
22 the laboratory's certification.

3) Personnel (law?)

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

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

3 **ATCP 77.14 INSPECTING A LABORATORY.** (1) MANDATORY

4 INSPECTIONS. The department shall inspect a laboratory at all of the following times:

5 (a) Before certifying the operator under s. ATCP 77.02, for the first time, to perform tests
6 at that laboratory. *initially*

7 (b) At least once every 2 years after the department first certifies the operator under s.
8 ATCP 77.02 to perform tests at that laboratory.

9 (c) Before the department certifies the operator to perform a test under s. ATCP 77.02(1)
10 which the ~~operator~~ ^{dept} has not previously certified that operator to perform at that laboratory.

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

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

14 (b) The operator assigns a new analyst to perform a test for which the operator is
15 currently certified. *or another job has been performed to previously?*

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

18 (3) INSPECTION AUTHORITY. The department may exercise its authority under s.
19 93.08, 93.14, 93.15, 93.16 and 97.12, Stats., in support of an inspection under this chapter. The
20 department may suspend or revoke the certification of any operator who obstructs or fails to
21 permit an inspection under this section.

22 NOTE: The department ^{signals} conducts its inspections during laboratory
23 business hours. The department ordinarily pre-arranges inspection dates
24 and times that are acceptable to laboratory operators, but is not required to

2
rule
1st + 3rd sentence

1 do so. A person who obstructs or interferes with an inspection may also
2 be subject to penalties under s. 93.21(2) or (4) or s. 97.12(4), Stats.

3 **ATCP 77.16 LABORATORY RECORDS.** (1) RECORDS REQUIRED. An

4 operator shall make complete records related to all of the following:

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

7 (b) Laboratory evaluations required under this chapter.

8 (c) Laboratory policies and procedures.

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

11 (e) Quality control procedures and monitoring.

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

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

16 NOTE: For example, see reporting requirements under chs. ATCP 60, 70
17 and 80, and chs. NR 809 and 812.

18
19 (2) RECORD RETENTION; AVAILABILITY. (a) Milk and food laboratories shall
20 retain all records under sub. (1) for at least 2 years. Water laboratories shall retain all records
21 under sub. (1) for at least 5 years.

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

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

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

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

4 **SUBCHAPTER II**

5 **MILK AND FOOD LABORATORIES**

6 **ATCP 77.20 MILK AND FOOD LABORATORIES; PROCEDURES.** (1) TEST

7 **METHODS.** An operator shall perform tests under s. ATCP 77.02(1)(a) and (b) according to
8 methods specified in applicable reference materials under sub. (2), or according to methods
9 which the department approves in writing.

10 (2) **REFERENCE MATERIALS.** (a) General. An operator who performs any test
11 under s. ATCP 77.02(1)(a) and (b) shall keep, at the certified laboratory, the manufacturer's
12 complete operating and maintenance instructions for equipment used to perform that test. *make avail
to call
an analyst?*

13 (b) Milk tests. An operator who performs any test under s. ATCP 77.02(1)(a) shall keep
14 the following reference materials at the certified laboratory: *avail to analysts?
see IFS 165.18(1)(d)*

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

16 2. *2-12* The "Standard Methods for the Examination of Dairy Products," 16th edition,
17 published by the American Public Health Association, Inc.

18 (c) Food tests. An operator who performs any test under s. ATCP 77.02(1)(b) shall keep
19 all of the following reference materials at the certified laboratory:

20 1. The authoritative reference manual, if any, that applies to each type of food testing for
21 which the laboratory is certified. *5 how to determine*

22 2. The "Compendium of Methods for Microbiological Examination of Foods," 3rd
23 edition, published by the American Public Health Association, Inc.

1 3. The FDA "Bacteriological Annual Manual," 8th edition, if the operator performs a
2 microbiological test on food.

3 NOTE: Copies of reference manuals cited under sub. (2) are on file with
4 the department, the secretary of state and the revisor of statutes. To find
5 out how to order these manuals from the publishers, you may contact the
6 department at the following address:

7 Wisconsin Department of Agriculture, Trade and Consumer Protection
8 Division of Food Safety, Bureau of Food Safety and Inspection
9 Laboratory Certification Program
10 P.O. Box 8911
11 Madison, WI. 53708-8911
12 (608) 224-4719

13 (3) CULTURE MEDIA. An operator who performs any test under s. ATCP 77.02(1)(a)
14 or (b) shall ensure that culture media used for laboratory tests are effectively sterilized before
15 they are used. Culture media shall be autoclaved for the total cycle time and sterilization time
16 specified by the media manufacturer or by the applicable test method under this section.

17 **ATCP 77.22 MILK AND FOOD LABORATORIES; ANALYSTS.**

18 (1) PROFICIENCY. Analysts who perform tests under s. ATCP 77.02(1)(a) or (b) at a
19 certified laboratory shall be proficient in performing those tests.

20 (2) EVALUATING PROFICIENCY. (a) Whenever the department performs a
21 mandatory inspection of a laboratory under s. ATCP 77.14(1), the department shall evaluate the
22 proficiency of every analyst who performs tests ^{under} s. ATCP 77.02(1)(a) or (b) for which the
23 department is certifying that laboratory. The department shall evaluate the analysts' proficiency
24 by watching them perform the tests.

25 (b) The department may, at any time during laboratory business hours, evaluate the
26 proficiency of analysts performing tests which the operator is certified to perform at that
27 laboratory.

(3) CERTIFIED ANALYSTS. (a) The department may not certify an operator to perform any test under s. ATCP 77.02(1)(a) or (b) unless the department has certified the proficiency of at least one analyst to perform that test at the operator's laboratory.

(b) The department shall use the appropriate FDA 2400 series forms to evaluate and certify an analyst's proficiency in performing a test under s. ATCP 77.02(1)(a). If the analyst performs plate loop counts or electronic somatic cell counts, the department shall check the analyst's ability to perform the statistical comparisons required by those tests.

(c) The department shall maintain a list of the analysts whom the department has certified to perform tests under s. ATCP 77.02(1)(a) and (b) at each certified laboratory. The list shall identify the tests which each analyst is certified to perform. *Can analyst perform test if not certified? This isn't stated clearly*

(d) An analyst's certification to perform a test under s. ATCP 77.02(1)(a) or (b) remains in effect until the analyst leaves the laboratory, or until the department suspends or revokes the analyst's certification.

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

- 1. The operator assigns a new analyst to perform any test under s. ATCP 77.02(1)(a) or (b) for which the operator is certified.
- 2. There is a change in the name of any analyst certified under sub. (3).

(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 sub. (3)(a).

ATCP 77.24 MILK AND FOOD LABORATORIES; PROFICIENCY

EVALUATION. (1) EVALUATION REQUIRED. Except as provided under sub. (4), the

② *required for*

1 department may not issue or renew an operator's certification to perform any test under s. ATCP
2 77.02(1)(a) or (b) unless, within the year immediately preceding that certification or renewal, the
3 laboratory passes a proficiency evaluation for that test.

4 (2) FORM OF EVALUATION. In a laboratory proficiency evaluation under sub. (1), an
5 operator shall examine samples prepared by an approved evaluator under sub. (3). The contents
6 of the samples shall be known to the evaluator but not to the operator. The analysts who
7 examine the samples shall be those who normally perform those tests at the certified laboratory.
8 The evaluator shall rate the operator's proficiency by comparing the operator's results to the
9 known contents of the samples, and shall report those results and ratings to the department.

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

12 NOTE: The department will approve an evaluator under sub. (3) if that
13 evaluator is approved for the same purpose by FDA.

14 (4) EVALUATION PROCEDURE; GENERAL. A proficiency evaluation under sub.
15 (1) shall be conducted according to a standard evaluation procedure which the department
16 *who submits procedure for approval? Also - 77:34(4)*
~~approves in writing.~~ An operator is not required to complete a proficiency evaluation for any test
17 unless the department has approved a standard evaluation procedure for that test. A standard
18 evaluation procedure shall include standards for all of the following:

- 19 (a) The evaluator's preparation of proficiency evaluation samples.
- 20 (b) The operator's examination of proficiency evaluation samples.
- 21 (c) Deadlines for examining proficiency evaluation samples and reporting test results.
- 22 (d) The evaluator's review and rating of the operator's proficiency.

method of ?
②

1 (5) MILK AND DAIRY PRODUCT TESTS; EVALUATION PROCEDURE. Standard
2 evaluation procedures for tests under s. ATCP 77.02(1)(a) shall incorporate the following
3 requirements:

4 (a) To pass a proficiency evaluation on any of the following tests, the operator shall
5 obtain satisfactory results according to FDA's "Evaluation of Milk Laboratories," 1995 edition,
6 on at least 80 percent of the proficiency evaluation samples which the operator tests:

- 7 1. Plate counts.
- 8 2. Direct microscopic somatic cell counts.
- 9 3. Electronic somatic cell counts.

10 (b) To pass a proficiency evaluation on any test in which the result is reportable as
11 positive or negative, an operator shall report the correct result on at least 80 percent of the
12 proficiency evaluation samples which the operator tests.

13 (c) An operator shall complete the proficiency evaluation using the appropriate test
14 method under s. ATCP 77.20.

15 SUBCHAPTER III

16 WATER LABORATORIES

17 ATCP 77.30 WATER LABORATORIES; PROCEDURES. (1) TEST METHODS.

18 An operator shall perform tests under s. ATCP 77.02(1)(c) according to methods specified in
19 applicable reference materials under sub. (2), or according to methods which the department
20 approves in writing.

21 (2) REFERENCE MATERIALS. An operator who performs any test under s. ATCP
22 77.02(1)(c) shall keep all of the following reference materials at the certified laboratory:

accessible to analyst?

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

3 (b) The U.S. environmental protection agency "Manual for the Certification of
4 Laboratories Analyzing Drinking Water," 4th edition.

5 (c) "Standards Methods for the Examination of Water and Wastewater," 18th or 19th
6 edition, published by the American Public Health Association, the American Water Works
7 Association and the Water Environment Federation.

8 (3) CULTURE MEDIA. An operator who performs any tests under s. ATCP 77.02(1)(c)
9 shall ensure that culture media used for those tests are effectively sterilized before they are used.
10 Culture media shall be autoclaved for the total cycle time and sterilization time specified by the
11 media manufacturer or by the applicable test method under this section.

12 **ATCP 77.32 WATER LABORATORIES; ANALYSTS.** Whenever the department
13 performs a mandatory inspection of a water laboratory under s. ATCP 77.14(1), the department
14 shall evaluate the proficiency of an analyst who performs tests under s. ATCP 77.02(1)(c) for
15 which the department is certifying the water laboratory. The department shall use the United
16 States environmental protection agency "Manual for the Certification of Laboratories Analyzing
17 Drinking Water," 4th edition, to evaluate the analyst's proficiency.

18 **ATCP 77.34 WATER LABORATORIES; PROFICIENCY EVALUATION.**

19 (1) EVALUATION REQUIRED. Except as provided under sub. (4), the department may not
20 issue or renew an operator's certification to perform any test under s. ATCP 77.02(1)(c) unless,
21 within the year immediately preceding that certification or renewal, the laboratory passes a
22 proficiency evaluation for that test. The department shall suspend the certification of an operator
23 who has failed more than one of the operator's last 3 proficiency evaluations under this section.

1 (2) FORM OF EVALUATION. In a laboratory proficiency evaluation under sub. (1), an
2 operator shall examine samples prepared by an approved evaluator under sub. (3). The contents
3 of the samples shall be known to the evaluator but not to the operator. The analysts who
4 examine the samples shall be those who normally perform those tests at the certified laboratory. *should
with analyst
be
as a
sample?*
5 The evaluator shall rate the operator's proficiency by comparing the operator's results to the
6 known contents of the samples, and shall report those results and ratings to the department.

7 (3) APPROVED EVALUATOR. The state of Wisconsin laboratory of hygiene, or
8 another evaluator approved by the department in writing, shall serve as a proficiency evaluator
9 under sub. (2).

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

- 15 (a) The evaluator's preparation of proficiency evaluation samples.
- 16 (b) The operator's examination of proficiency evaluation samples.
- 17 (c) Deadlines for examining proficiency evaluation samples and reporting test results.
- 18 (d) The evaluator's review and rating of the operator's proficiency.

19 (5) DRINKING WATER TESTS; EVALUATION PROCEDURES. Beginning on July
20 1, 1999, standard evaluation procedures for tests under s. ATCP 77.02(1)(c) shall include the
21 following requirements:

- 22 (a) An operator who is evaluated for proficiency in testing for total coliform and fecal
23 coliform shall examine at least 10 samples of at least 100 ml. each. The evaluator shall provide

1 full volume samples, or the concentrate and diluents needed to reconstitute the concentrates to
2 full volume. Each sample set shall include all of the following:

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

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

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

11 4. One to 4 blank samples.

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

17 (c) To pass a proficiency evaluation under par. (a), an operator shall report the correct
18 result on 100 percent of the samples tested.

19 **SECTION 15. EFFECTIVE DATE.** The rules contained in this order shall take effect
20 on the first day of the month following publication in the Wisconsin administrative register, as
21 provided under s. 227.22(2) (intro.), Stats.

Dated this _____ day of _____, 19 ____.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary

FISCAL ESTIMATE

DOA-2048 (R 10/94)

- ORIGINAL UPDATED
 CORRECTED SUPPLEMENTAL

LRB or Bill No. / Adm. Rule No.
ATCP 77

Amendment No. (If Applicable)

Subject
Laboratory Certification

Fiscal Effect

State: No State Fiscal Effect
Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation

- Increase Existing Appropriation Increase Existing Revenues
 Decrease Existing Appropriation Decrease Existing Revenues
 Create New Appropriation

- Increase Costs - May be possible to Absorb Within Agency's Budget Yes No
 Decrease Costs

Local: No local government costs

1. Increase Costs
 Permissive Mandatory
 2. Decrease Costs
 Permissive Mandatory

3. Increase Revenues
 Permissive Mandatory
 4. Decrease Revenues
 Permissive Mandatory

5. Types of Local Governmental Unit Affected:

- Towns Villages Cities
 Counties Others _____
 School Districts WTCS Districts

Fund Source Affected

- GPR FED PRO PRS SEG SEG-S

Affected Ch. 20 Appropriations

Assumptions Used in Arriving at Fiscal Estimate

The laboratory evaluation and certification program for milk water and food laboratories was transferred from the Department of Health and Family Services to the Department of Agriculture, Trade and Consumer Protection in July, 1996. The current ch. ATCP 77 was adopted at that time to allow DATCP to collect fees to cover the cost of the program. Certification requirements which apply to milk water and foods laboratories are currently in ch. HFS 165.

The proposed repeal and recreation of ch. ATCP 77 will complete the transfer of the certification program for milk water and food laboratories from DHFS to DATCP. The proposed rule does not substantially change the way in which a lab survey is conducted. The proposed rule uses concepts from ch. HSS 165 for certification of clinical laboratories, but changes the language to that which is specific and more appropriate for milk, water, and food laboratories. Therefore, there will be no state fiscal effect from the addition of the substantive provisions in ch. ATCP 77. The fee structure adopted in January, 1997, is not changed in the proposed rule.

There may be a small effect on local government costs. Under ch. HSS 165, water laboratories were not required to run proficiency tests. The proposed rule requires all laboratories that do official testing to participate in some form of proficiency testing. A municipal water plant would pay approximately \$300 per year to obtain the samples plus the cost of testing the samples.

Long - Range Fiscal Implications

Agency/prepared by: (Name & Phone No.)

DATCP
C. T. Leitzke, 608/224-4711

Authorized Signature/Telephone No.

Barbara Knapp
Barbara Knapp (608) 224-4746

Date

8/25/98

Initial Regulatory Flexibility Analysis

The repeal and recreation of ch. ATCP 77, Wis. Adm. Code, Laboratory Certification will have a small fiscal impact on small businesses as defined in s. 227.114 (1)(a), Stats. Approximately 200 laboratories are currently licensed and inspected by the department. The laboratories range from small establishments that are only certified for one test to large dairy cooperatives that have a full service milk testing laboratory at one or more locations.

The proposed laboratory certification rule replaces the existing rule (HSS 165). The standards are based on established federal (FDA and EPA) guidelines and are designed to be consistent with other state and local requirements. The changes from HSS 165 are designed to replace the clinical language with language that is more applicable to milk, water, and food testing laboratories. The fee structure outlined in the current ATCP 77 is unchanged.

Key issues in the proposed rule include:

- modifying all language that refers to clinical laboratory testing and substituting language that is applicable to milk, water, and food laboratories;
- application requirements;
- procedures for suspending or revoking a laboratory's certification;
- basic requirements for laboratory facilities and equipment;
- responsibilities of a laboratory administrator;
- record keeping and reporting requirements, including the reporting of changes in laboratory facilities, equipment and personnel;
- adding the requirement for proficiency testing for water laboratories and identification of acceptable levels of performance.

The addition of the required proficiency testing for water laboratories will have a fiscal impact on municipal water plants. These water labs will pay approximately \$300 per year for proficiency samples and the cost of testing those samples. The proposed laboratory certification rules will have a negligible fiscal impact on private water labs and milk and food laboratories. It should not be necessary for any type of certified laboratory to retain additional professional services to comply with this rule.

Dated this 24th day of August, 1998.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE, AND CONSUMER PROTECTION

By Steven B. Steinhoff
Steven B. Steinhoff, Administrator
Division of Food Safety