

IDEXX

Literature Cover Sheet

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Topic: US EPA Colisure™ Approval

Title: US Federal Register

Date: December 5, 1994

Source: <http://www.epa.gov/fedrgstr/EPA-WATER/1994/December/Day-05/pr-21DIR/fulltext.html>

Highlights:

- US EPA approved the Colisure as a compliance test for simultaneously determining the presence of total coliforms and *E. coli*.
- Five methods are now approved:
 1. Colilert (MMO-MUG)
 2. Colisure
 3. Total Coliform Multiple Tube Fermentation
 4. Total Coliform Membrane Filtration
 5. Total Coliform Presence-Absence



Orion. Technical Bulletin 601; "Standard Method of Test for Nitrate in Drinking Water", PN 221290-001, ATI Orion, 529 Main Street, Boston, MA 02129, July 1994.

Technicon. 1972. Industrial Method No. 129-71W, "Fluoride in Water and Wastewater", Technicon Industrial Systems, Tarrytown, NY 10591, December 1972.

Technicon. 1989. Method No. 380-75WE, "Fluoride in Water and Wastewater", Technicon Industrial Systems, Tarrytown, NY 10591, February 1976.

USGS. 1989. Methods 1-3720-85, 1-3300-85, 1-1030-85, 1-1601-85, 1-2598-85, 1-1700-85 and 1-2700-85 in *Techniques of Water Resources Investigations of the U.S. Geological Survey*, Book 5, Chapter A-1, 3rd ed., U.S. Geological Survey, Books and Open File Reports Section, Box 25425, Federal Center, Denver, CO 80225-0425, 1989.

USGS. 1993. Method 1-2601-90 in *Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediments*, Open File Report 93-125, U.S. Geological Survey, Books and Open File Reports Section, Box 25425, Federal Center, Denver, CO 80225-0425, 1993.

List of Subjects

40 CFR Part 141

Environmental Protection, Chemicals, Corporation by reference, governmental relations, Water supply.

40 CFR Part 143

Chemicals, Incorporation by reference, Intergovernmental relations, Water supply.

Dated: November 25, 1994.

Carol M. Browner, Administrator.

For the reasons set out in the preamble, parts 141 and 143 of title 40, Code of Federal Regulations, are amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9.

2. Section 141.21 is amended by revising paragraph (f)(3), removing and reserving (f)(4), revising the next to last sentence of (f)(5), revising the second sentence of (f)(6)(i), revising the second sentence of (f)(6)(ii), Adding (f)(6)(iv), and adding a new sentence as the next to last sentence in (f)(8) to read as follows:

§ 141.21 Coliform sampling.

(f) * * *
 (3) Public water systems must conduct total coliform analyses in accordance with one of the analytical methods in the following table. These methods are contained in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005. A description of the Colisure Test may be obtained from the Millipore Corporation, Technical Services Department, 80 Ashby Road, Bedford, MA 01730. The toll-free phone number is (800) 645-5476.

Organism	Methodology	Citation
Total Coliforms ¹	Total Coliform Fermentation Technique ^{2,4}	9221A, B.
	Total Coliform Membrane Filter Technique.	9222A, B, C.
	Presence-Absence (P-A) Coliform Test ⁵	92210.
	ONPG-MUG Test ⁶	9223.
	Colisure Test ⁷	

¹ The time from sample collection to initiation of analysis may not exceed 30 hours.
² Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between this medium and lauryl tryptose broth using the water normally tested, and this comparison demonstrates that the false-positive rate for total coliforms, using lactose broth, is less than 10 percent.
³ If inverted tubes are used to detect gas production, the media should cover these tubes at least one-half to two-thirds after the sample is added.
⁴ No requirement exists to run the completed phase on 10 percent of all total coliform-positive confirmed tubes.
⁵ Six-times formulation strength may be used if the medium is filter-sterilized rather than autoclaved.
⁶ The ONPG-MUG Test is also known as the Autoanalysis Coldert System.
⁷ The Colisure Test must be incubated for 28 hours before examining the results. If an examination of the results at 23 hours is not convenient, then results may be examined at any time between 28 hours and 48 hours.

(4) [Reserved]
 (5) * * * The preparation of EC medium is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, Method 9221E—p. 9-52, paragraph 1a. * * *

(6) * * *
 (i) * * * EC medium is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, Method 9221E—p. 9-52, paragraph 1a. * * *

(ii) * * * Nutrient Agar is described in the 18th edition of *Standard Methods for the Examination of Water and Wastewater*, 1992, p. 9-47 to 9-48.

(iii) * * *
 (iv) The Colisure Test. A description of the Colisure Test may be obtained from the Millipore Corporation, Technical Services Department, 80 Ashby Road, Bedford, MA 01730.

(8) * * * A description of the Colisure Test may be obtained from the Millipore Corp., Technical Services Department, 80 Ashby Road, Bedford, MA 01730. * * *

3. Section 141.22(a) is amended by removing the next to last sentence and revising the last sentence to read as follows:

§ 141.22 Turbidity sampling and analytical requirements.

* * * * * Turbidity measurements shall be made as directed in § 141.74(a)(1).

4. Section 141.23 is amended by removing paragraph (k)(2) and redesignating paragraph (k)(4) as (k)(2), by removing paragraph (k)(3) and redesignating paragraph (k)(5) as (k)(3), by removing and reserving paragraph (q), and revising paragraph (k)(1) to read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

(k) * * *
 (1) Analysis for the following contaminants shall be conducted in accordance with the methods in the following Table, or their equivalent as determined by EPA. Criteria for analyzing arsenic, barium, beryllium, cadmium, calcium, chromium, copper, lead, nickel, selenium, sodium, and thallium with digestion or directly without digestion, and other analytical test procedures are contained in *Technical Notes on Drinking Water Methods*, EPA-600/R-94-173, October 1994. This document also contains approved analytical test methods which remain available for compliance monitoring until July 1, 1996. These methods will not be available for use after July 1, 1996. This document is available from the National Technical Information Service, NTIS PB95-104766, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800-553-6847.

drinking water samples. Commenters opposed reducing this time from 30 hours (16th edition of Standard Methods) to 24 hours (18th edition of Standard Methods). The Standard Methods committee reduced the transit time because of its concern about coliform die-off in the sample over time. Commenters opposed reducing the time because it would (1) be logistically impractical if not impossible to do, (2) increase costs for sample transport and resampling, (3) cause hardships in sample collection, and (4) complicate and decrease laboratory flexibility. A few commenters claimed that the reduced transit time is not supported by data.

Coliforms usually die off over time, especially when water temperatures are warm, but EPA recognizes that there is debate among investigators over the rate of that decline. EPA is currently conducting additional studies on this question, using fecal coliforms and *E. coli*, and results are anticipated by the end of 1994. Given the logistical and other problems that might result by decreasing the transit time to 24 hours, EPA is deferring a decision on whether to reduce the transit time until more data become available. For the time being, the Agency has added a footnote to the Table in § 141.21(f)(3), allowing a maximum transit time of 30 hours. If EPA decides that a reduction from 30 hours is warranted, the Agency will work with the States to minimize the hardships identified in the public comments. Meanwhile, EPA strongly encourages States and systems to review their procedures and identify practical alternatives for providing samples to laboratories more quickly.

Other commenters objected to the requirement in the 18th edition of Standard Methods to hold samples at less than 10 °C during transit. The Standard Methods committee specified this value because of its concern about coliform die-off in the sample at higher temperatures, where the bacterial metabolism of coliforms and non-coliforms alike is normally greater.

Commenters objected to any EPA requirement that would require them to keep samples cool during sample transit. They asserted that this requirement would (1) be unnecessary and would complicate sample transport logistics, (2) increase sampling costs and shipping costs for both systems and laboratories, because coolers and ice packs cost money and samples are heavier and thus more expensive to ship, and (3) lead to problems with frozen samples or a significantly increased number of invalid samples. Commenters also stated that under the

presence-absence concept, sample cooling was less important than under the earlier rule based on coliform density.

EPA is deferring a decision on sample transit temperature until the Agency initiates a review, and possible revision, of the Total Coliform Rule. For the time being, the Agency has added a footnote to the Table in § 141.21(f)(3) encouraging, but not requiring, systems to hold samples at less than 10 °C during transit. Nevertheless, the Agency strongly encourages systems to cool their samples during transit, especially during warm summer months, to minimize coliform die-off. The Agency is currently conducting additional studies on this question, using fecal coliforms and *E. coli*, and results are anticipated by the end of 1994. If EPA decides that a reduction is warranted, the Agency will work with the States to minimize the hardships identified in the public comments.

* EPA is also approving a new method, the Colisure test, for simultaneously determining the presence of total coliforms and *E. coli*, both of which must be monitored under the Total Coliform Rule (40 CFR 141.21). Data supporting the use of this method was presented in the notice of July 14, 1994 (NOA).

Most commenters supported approval of the Colisure test, but several raised questions about the test, primarily concerning the incubation time. They cited the Broadway et al. (1992) data that indicated that only 64% and 69% of the bottles were total coliform-positive and *E. coli*-positive, respectively, after 24 hours compared to the 48-hour results. According to the Broadway et al. data, 85% and 88% of the bottles were total coliform-positive and *E. coli*-positive, respectively, after 28 hours compared to the 48-hour results.

EPA agrees with the commenters who contended that 24 hours of incubation was insufficient for the Colisure test. The Agency, however, believes that the recovery rate after 28 hours is reasonable, and will approve the Colisure test as a 28-hour test. Moreover, based on additional data from the product manufacturer showing that the false-positive rate after 48 hours is small, EPA will allow laboratories to hold the test up to 48 hours before observing results.

Chemical Methods

There were only minor comments on the proposal to update chemistry methods to the versions contained in the 18th edition of Standard Methods. The 18th edition versions contain no or

minor changes to earlier versions, and EPA received no comments to document specific hardships in converting to 18th edition chemical methods. Several commenters noted that, although thallium is not in the scope of SM 3113B, EPA erroneously approved SM 3113B for thallium (57 FR 31840, July 17, 1992). EPA agrees and will delete this approval in today's rule.

A commenter noted that the 18th edition version of SM 4500-Cl-G omits instructions that would allow measurement of total residual chlorine in drinking water samples using a colorimetric method. The Standard Methods Committee has written (Eaton, 1993b) that an editorial omission, not a technical change, occurred in recent versions of SM 4500-Cl-G. The error will be corrected in the next (19th) edition of Standard Methods. EPA corrects the error today by describing the omitted instructions in Technical Notes on Drinking Water Methods (EPA, 1994d).

E. Methods To Be Withdrawn and Replaced

General Comments Received on Withdrawal of Methods

One commenter suggested that all methods carry a "draft" status for three years after publication; other commenters asked EPA to approve new methods more quickly. It would defeat EPA's intent to provide modern technology quickly, if a method had to be published, proposed, and then kept in draft status for three years. EPA balances this problem by allowing optional use of old or new methods during a transitional period, which in the case of this rule extends to July 1, 1996 (or 18 months after publication, whichever is later).

Several commenters believed EPA was eliminating, or intended to eliminate, all autoanalyzer or colorimetric methods. This is incorrect; EPA is replacing only obsolete methods with equivalent ASTM, EPA and Standard Methods. EPA is not eliminating colorimetric or autoanalyzer technology for any regulated contaminant, except arsenic. Evidence of EPA's intent is in the 1993 methods manual (EPA, 1993a), which updated colorimetric methods for cyanide (335.4), nitrite and nitrate (353.2), and sulfate (375.2). EPA has and continues to approve autoanalyzer and colorimetric ASTM and Standard Methods for cyanide, fluoride, nitrite, nitrate and sulfate.

Some commenters stated that changing from EPA methods to equivalent Standard Methods and