

Notice of Final Rulemaking
[25 PA. CODE CH. 109]
Safe Drinking Water; Revised Total Coliform Rule

The Environmental Quality Board (Board) by this order amends 25 Pa. Code, Chapter 109 (relating to safe drinking water) to read as set forth in Annex A. The amendments supplement the Total Coliform Rule by requiring public water systems (PWSs) that are vulnerable to microbial contamination to perform assessments to identify sanitary defects and subsequently take action to correct them.

The amendments will protect public health through a multibarrier approach designed to guard against microbial contamination by evaluating the effectiveness of treatment and the integrity of drinking water distribution systems, and by finding and fixing sanitary defects.

The amendments will apply to all PWSs.

The proposed rulemaking relating to this final rule was included in a two-part proposal which was submitted to the Board for consideration at its meeting on April 21, 2015. One part contained proposed regulations necessary to assume primacy with respect to the Federal Revised Total Coliform Rule (RTCR) and the other part of the proposal included amendments to various other portions of Chapter 109. In response to a motion made at that meeting, the Board voted to approve the portion of the proposed rulemaking regarding the RTCR but to split the other proposed amendments into a separate rulemaking to provide an opportunity for further consideration by the Technical Assistance Center for Small Drinking Water Systems Advisory Board (TAC) and other interested parties. This final-form rulemaking exclusively concerns the RTCR.

This final-form rulemaking was adopted by the Board at its meeting on June 21, 2016.

A. Effective Date

This final-form rulemaking will go into effect upon publication in the *Pennsylvania Bulletin*.

B. Contact Persons

For further information, contact Lisa D. Daniels, Director, Bureau of Safe Drinking Water, P. O. Box 8467, Rachel Carson State Office Building, Harrisburg, PA 17105-8467, (717) 787-9633; or William Cumings, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

C. Statutory Authority

The rulemaking is being made under the authority of section 4 of the Pennsylvania Safe Drinking Water Act (35 P. S. § 721.4), which grants the Board the authority to adopt rules and regulations governing the provision of drinking water to the public, and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which authorizes the Board to promulgate rules and regulations necessary for the performance of the work of the Department.

D. Background and Purpose

In February 2013, the United States Environmental Protection Agency (EPA) adopted regulations amending 40 CFR Part 141 (relating to National primary drinking water regulations) to implement an RTCR. See 78 FR 10269 (February 13, 2013). Minor corrections to the RTCR were published at 79 FR 10665 (February 26, 2014). The compliance date for the RTCR is April 1, 2016. To maintain primacy with respect to the RTCR, it is imperative that the Board adopt regulations which are at least as stringent as those in the Federal regulations.

According to the preamble to the Federal RTCR, the rule aims to increase public health protection through the reduction of sanitary defects that could provide potential pathways of entry for fecal contamination into the distribution system of a PWS or could indicate a failure or imminent failure of a barrier that is already in place. See 78 FR 10269, 10276. Since fecal contamination may contain waterborne pathogens including bacteria, viruses and parasitic protozoa, a decrease in fecal contamination should reduce the risk from these contaminants.

In addition, the Federal rule aims for greater public health protection than the 1989 Total Coliform Rule (TCR) in a cost-effective manner by: maintaining the objectives of the 1989 TCR (that is, to evaluate the effectiveness of treatment, to determine the integrity of the distribution system and to signal the possible presence of fecal contamination); using the optimal indicator for the intended objectives (that is, using total coliforms as an indicator of system operation and condition rather than an immediate public health concern and using *E. coli* as a fecal indicator); and requiring systems that may be vulnerable to contamination, as indicated by the nature of their operation, to have in place procedures that will minimize the incidence of contamination (for example, requiring start-up procedures for seasonal systems). The EPA, therefore, anticipates greater public health protection under the RTCR compared to the 1989 TCR because of the RTCR's more preventive approach to identifying and fixing problems that affect or may affect public health. See 78 FR 10269, 10272, 10273.

The final-form rulemaking was presented to the Small Water Systems Technical Assistance Center Advisory Board on March 16, 2016. The TAC made several recommendations that were incorporated into this final-form rulemaking. Section E includes more information about the TAC's recommendations. The changes described in Section E reflect comments received on repeat monitoring and public notification. TAC also requested that repeat monitoring requirements be further clarified in RTCR technical guidance, which the Department intends to do.

The Board requested comments on whether only fixed alternative repeat monitoring locations should be allowed or if a standard operating procedure (SOP) for choosing locations may also be allowed and why. The Department agrees with the comments received regarding the alternative fixed location and has incorporated that provision into the final-form regulation. However, a recommendation to allow the use of a standard operating procedure (SOP) to establish criteria for selecting repeat sample sites on a case-by-case basis is not being added to this final-form rulemaking. The Department believes that repeat sample sites must be properly documented in the system's sample siting plan in order to ensure appropriate monitoring by the system and allow for proper oversight by the Department. However, nothing in this rulemaking discourages or prevents a water system from using advanced technology to conduct investigations and collect additional special samples when determining the cause and extent of sanitary defects.

The Independent Regulatory Review Commission requested that the Board provide its rationale for requiring one-hour notification to the Department for the detection of *E. coli*. The detection of *E. coli* warrants one-hour reporting to the Department and this notification occurs under current regulations at § 109.701(a)(3)(i) and § 109.701(a)(3)(ii). However, there are situations under the RTCR that would not be covered under § 109.701(a)(3)(i) and (ii). For example, seasonal systems conducting start-up monitoring, as required under § 109.301(3)(v), that learn of *E. coli*-positive start-up samples are not required to notify the department under § 109.701(a)(3)(i) or § 109.701(a)(3)(ii). Therefore, § 109.701(a)(3)(iv) is necessary, so that seasonal systems notify the Department within one hour in order to confer with the Department regarding potential steps to take in order to address the *E. coli* results prior to serving water to the public thereby protecting the public health.

The Independent Regulatory Review Commission also requested that the Board explain how DEP's regulation of bottled water fits into the regulatory framework of EPA's RTCR and the Food and Drug Administration's (FDA) regulations on bottled water. The FDA regulations do not preempt the Department from regulating bottled water systems in the manner set forth in these regulations. As noted in testimony presented to a Congressional Subcommittee by a Deputy Commissioner of the FDA, "[i]n addition to FDA, state and local governments also regulate bottled water. FDA relies on state and local government agencies to approve water sources for safety and sanitary quality, as specified in [21 CFR] 129.3(a)." See Statement of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, July 8, 2009. The cited regulation, 21 CFR 129.3(a), provides that an "[a]pproved source . . . means a source of water and the water therefrom , , , that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government jurisdictions having jurisdiction."

The Pennsylvania Safe Drinking Water Act, 35 P.S. 721.1 *et seq.*, authorizes the Department to regulate public water systems within the Commonwealth. The Act defines a "public water system" as including "a system which provides water for bottling or bulk hauling for human consumption." As stated in the Preamble to the April 24, 1999 Permit by Rule for Bottled Water Systems, systems providing water for bottling include:

1. Bottled water systems, which provide water for bottling in sealed containers.
2. Vended water systems, which provide water for bottling through the use of water vending machines.
3. Retail water facilities which provide water for bottling by dispensing, at a store, unit servings of water in a customer's or the system's containers.

See 29 Pa.B. 2231 (April 24, 1999).

E. Summary of Changes to the Proposed Rulemaking

§ 109.202. State MCLs, MRDLs and treatment technique requirements

Proposed section 109.202(c)(4)(iii) (relating to State MCLs, MRDLs and treatment technique requirements) was deleted in response to public comments. That section would have authorized the Department to direct a PWS to conduct a Level 1 or Level 2 assessment if circumstances exist which may adversely affect drinking water quality. Commentators suggested that § 109.4(4) (relating to general requirements) obligates PWSs to take investigative action when necessary, but that these investigations should not be confused with assessments under the RTCR.

§ 109.301. General monitoring requirements

Section 109.301(3) (relating to general monitoring requirements) was amended in response to public comments. The added language clarifies that when PWSs forego *E. coli* testing and assume that a sample is *E. coli*-positive Tier 1 public notification is only required in the event that an *E. coli* violation occurs.

Section 109.301(3)(i)(E) was proposed to be added in the proposed rulemaking to reflect 40 CFR 141.854(c)(2). This section provides that a community water system serving 1,000 or fewer persons may be required to begin monitoring on an alternate schedule. No changes to this clause are being made in final-form rulemaking; however, the TAC requested that clarification be provided in this Order in relation to this clause. To clarify, although required for primacy, this clause will not be applied in Pennsylvania as long as all PWSs are required to monitor for total coliform no less frequently than monthly. The special monitoring evaluation described in the Federal rule applies only to PWSs monitoring less frequently than monthly.

Proposed section 109.301(3)(ii)(B) relating to check samples was amended in response to public comments. The added language provides clarification that a PWS is not required to identify or collect a check sample at only one repeat monitoring location on either side of a routine location that tests positive for total coliform. Instead, a PWS may identify all connections within five connections upstream and five connections downstream as potentially available repeat monitoring locations and then, when needed, select from those identified sites the available taps for sampling. Further, the added language allows PWSs to obtain Department approval of sites identified in the sample siting plan that are located outside of five connections. This language incorporates the "alternative fixed locations" allowed under the Federal rule and offers greater flexibility to PWSs.

Proposed section 109.301(3)(ii)(D) was amended in response to public comment. The added language clarifies that when any check sample is total coliform positive and additional check samples are required, the PWS must continue to collect check samples from the same three locations that were sampled in response to the routine sample testing positive. The added language is based on information provided from the EPA. The TAC provided comment regarding this language and its suggested language to provide additional clarification to this clause has been incorporated.

Section 109.301(3)(ii)(F) was added in response to public comment. The clause provides PWSs the opportunity to collect check samples from locations not identified in its sample siting plan in the event that the locations identified in the plan are unavailable. This added clause provides greater flexibility to PWSs and dispels concerns that if an identified repeat monitoring location is unavailable then a PWS has no alternative for complying with the rule. The TAC provided comment regarding this language and its suggested edits to provide additional clarification to this clause have been incorporated.

§ 109.409. Tier 2 public notice—categories, timing and delivery of notice

Proposed section 109.409(a)(3) (relating to tier 2 public notice—categories, timing and delivery of notice) which concerns failure to report *E. coli* MCL or positive *E. coli* routine or check sampling results was deleted and moved to the Tier 3 requirements of § 109.410(a)(5) in response to public comments.

§ 109.410. Tier 3 public notice—categories, timing and delivery of notice

Section 109.410(a)(5) (relating to tier 3 public notice—categories, timing and delivery of notice) was moved from proposed § 109.409(a)(3) in response to public comments and now reflects 40 CFR 141.204(a)(6).

Section 109.410(a)(6) concerning failure to submit a completed assessment form was added as a Tier 3 notice category in response to public comments and now reflects 40 CFR 141.204(a)(6).

Section 109.410(a)(7) concerning failure to submit certification of completion of seasonal system start-up procedures was added as a Tier 3 notice category in response to public comments and now reflects 40 CFR 141.204(a)(6).

§ 109.701. Reporting and recordkeeping

Proposed section 109.701(a)(9)(i) (relating to reporting and recordkeeping) which would have required a PWS to provide notice to the Department if a Level 1 or Level 2 assessment was triggered, was deleted to eliminate a reporting burden on PWSs. The Federal rule does not require PWSs to notify the state when an assessment is triggered.

Section 109.701(a)(9)(ii) was renumbered as § 109.701(a)(9)(i).

Section 109.701(a)(9)(iii) was renumbered as § 109.701(a)(9)(ii).

§ 109.810. Reporting and notification requirements

Proposed language in section 109.810(b) (relating to reporting and notification requirements) was amended by adding language to ensure that laboratories also provide sufficient notification to a public water supplier and the Department in the event that a seasonal start-up sample tests positive for total coliform to help ensure seasonal systems do not open prior to obtaining a negative test result.

F. Benefits, Costs and Compliance

Benefits

This rulemaking will affect all 8,868 PWSs serving approximately 12.75 million Pennsylvanians. The residents of this Commonwealth will benefit from the avoidance of a full range of health effects from the consumption of contaminated drinking water such as acute illness, endemic and epidemic disease, waterborne disease outbreaks and death.

As discussed by the EPA in the preamble to the Federal RTRC, the benefits of the Federal rule are largely unquantifiable but include the potential for decreased incidence of endemic illness from fecal contamination and other waterborne pathogens, increased knowledge regarding system operation, accelerated maintenance and repair, avoided costs of outbreaks and reductions in averting behavior. See 78 FR 10269, 10308—10320.

Compliance costs

Compliance costs were derived from the EPA's economic analysis. The Federal preamble defined these costs as "the net change in costs resulting from revisions to the 1989 TCR rather than absolute total costs of implementing the 1989 TCR as revised by the RTRC." National costs were adjusted to represent the ratio of PWSs in this Commonwealth compared to the number of PWSs Nationwide. It is estimated that water systems in this Commonwealth will bear nearly \$1.72 million of this total annual cost. The following figures represent estimated annual cost by system type: community water systems—\$126.77 per system/year; nontransient noncommunity water systems—\$128.90 per system/year; and transient noncommunity water systems: \$229.31 per system/year.

This estimate includes costs for all PWSs being required to monitor for total coliform monthly. It is important to note that mandating monthly monitoring for all PWSs will eliminate the Federal requirement to collect three additional samples in the month following a total coliform positive sample. Based on a 5-year average of approximately 580 positive samples per year, regulated noncommunity water systems are expected to not incur approximately \$40,000 per year in these extra sampling costs.

Compliance Assistance Plan

The Safe Drinking Water Program utilizes the Commonwealth's Pennsylvania Infrastructure Investment Authority Program to offer financial assistance to eligible PWSs. This assistance is in

the form of a low-interest loan, with some augmenting grant funds for hardship cases. Eligibility is based upon factors such as public health impact, compliance necessity and project/operational affordability.

The Safe Drinking Water Program established a network of regional and central office training staff that is responsive to identifiable training needs. The target audience in need of training may be either program staff or the regulated community.

In addition to this network of training staff, the Bureau of Safe Drinking Water has staff dedicated to providing both training and outreach support services to PWS operators. The Department's web site also provides timely and useful information for treatment plant operators.

Paperwork requirements

Paperwork requirements include the following: revisions to a sample siting plan; completion of a Level 1 or Level 2 assessment form, or both, when sample results indicate the presence of total coliform or *E. coli*, or both, in a sufficient number of samples as designated by the regulations; submission of a seasonal system start-up plan for PWSs that operate seasonally; and annual submission of a form to the Department certifying that a seasonal system start-up plan was implemented prior to opening for the season.

G. Sunset Review

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on September 22, 2015, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has considered all comments from IRRC, the Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on _____ these final-form regulations were deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and approved the final-form regulations.

I. *Findings of the Board*

The Board finds that

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and regulations promulgated thereunder at *1 Pennsylvania Code* §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law, and all comments were considered.
- (3) These regulations do not enlarge the purpose of the proposals published 45 Pa.B. 5943 (October 3, 2015).
- (4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

J. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

- (a) The regulations of the Department of Environmental Protection, *25 Pennsylvania Code*, Chapter 109, are amended to read as set forth in Annex A.
- (b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.
- (c) The Chairperson of the Board shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.
- (d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.
- (e) This order shall take effect immediately.

PATRICK MCDONNELL,
Acting Chairperson