

PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 109]

Bottled Water Systems; Permit by Rule

The Environmental Quality Board (Board) proposes to amend Chapter 109 (relating to safe drinking water). The proposed amendments would establish a permit by rule for in-State permitted bottled water systems that meet certain specified criteria, reduce compliance monitoring for radionuclides for bottled water systems, retail water facilities and bulk water hauling systems, allow label information on the cap of returnable containers and allow new or additional proprietary labels to be submitted to the Department following production or distribution of the new or additional label product. Other minor revisions are also included pertaining to the submission of the coliform monitoring siting plan applicable to all public water systems and clarifying consecutive water system monitoring for lead and cadmium.

This proposal was adopted by the Board at its meeting of March 17, 1998.

A. Effective Date

These amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. Contact Persons

For further information contact Frederick Marrocco, Acting Director, Bureau of Water Supply Management, P. O. Box 8467, Rachel Carson State Office Building, Harrisburg, PA 17105-8467, (717) 787-9035 or Pamela Bishop, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposal appears in Section I of this Preamble. Persons with a disability may use the AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) Web site (<http://www.dep.state.pa.us>).

C. Statutory Authority

The proposed rulemaking is being made under the authority of section 4 of the Pennsylvania Safe Drinking Water Act (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 sections 1917-A and 1920-A of The Administrative Code of 1929 (71 P. S. §§ 510-7 and 510-20).

D. Background and Purpose

The act authorizes the Department to regulate public water systems in this Commonwealth. The act defines "public water system" to include a system which provides water for bottling or bulk hauling for human consumption.

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 counter, unit servings of water in a customer's or the system's containers.

Beginning in December 1984, the overall requirements in Chapter 109 pertaining to these water systems became effective. Chapter 109 was amended at 22 Pa.B. 2621 (May 16, 1992) to place all requirements pertaining to these types of systems in one subchapter rather than having the requirements interspersed among requirements for other public water systems throughout Chapter 109.

Representatives of the large in-State bottled drinking water operations have expressed concerns over the time and expense involved in obtaining permit amendments and the types of in-plant modifications which require permit amendments. The primary reason for the concern was that the requirements were affecting their ability to implement timely business decisions. In response, a workgroup was formed consisting of several bottlers in this Commonwealth: the International Bottled Water Association (IBWA), NSF International (NSF), representatives of a large tap water system, an engineering/consulting firm and the League of Women Voters in addition to representatives of the Department and the Departments of Agriculture and Health. The purpose of the workgroup was to develop a framework for a permit by rule for bottled water systems to streamline the permitting process and minimize business disruption while ensuring regulatory efficiency, compliance and protection of public health. This is part of the Governor's PRIME (Privatize, Retain, Innovate, Modify and Eliminate) Initiative to provide better services to the regulated community and to make government smaller, more efficient and responsive.

Bottled water is regulated at the Federal level as a food product by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C.A. §§ 301—397). The Federal requirements applicable to bottled water include: food adulteration and misbranding provisions of Federal law; general food and specific bottled water Good Manufacturing Practice (GMP) regulations; standards of identity and quality for bottled water; and both civil and criminal penalties for noncompliance with these FDA requirements. The Commonwealth's existing regulations require compliance with the FDA requirements under 21 CFR 129 (relating to processing and bottling of bottled water).

The IBWA is the trade organization for the bottled water industry. In addition to the FDA requirements, the IBWA's Model Bottled Water Code for IBWA members provides information and standards on bottled water manufacturing practices, operational requirements and quality control for the bottled water industry.

The NSF is an internationally recognized third-party inspection and certification agency. The NSF's bottled water certification program verifies that a bottling facility and product waters meets the requirements of the Federal FDA regulations governing bottled water. The NSF conducts an annual unannounced audit of the bottling and processing facilities including source/product water testing. Bottlers meeting the certification requirements are allowed to use the registered NSF listing mark in their advertising, promotional activities and product listing. The IBWA members have an annual unannounced

onsite audit conducted by the NSF; however, the NSF certification is not a requirement of the IBWA membership.

The Bottled Water Workgroup met on several occasions resulting in the cooperative development of a proposed permit by rule framework for in-State bottlers which addresses the bottled water industry concerns.

The permit by rule proposal would provide in-State permitted bottlers an option to obtaining a permit amendment for substantial modifications (except for the addition of new sources or expanded use of existing permitted sources) to the bottling, processing or manufacturing facilities provided certain specified criteria are met. Specific criteria would include: the source type (groundwater not under the direct influence of surface water or finished water from a community water system, or both); the source water quality (does not exceed FDA quality standards for health related chemical and radiological contaminants and requires only disinfection to meet the Pennsylvania primary maximum contaminant levels); use of acceptable treatment technologies; and demonstrated compliance with the National standards of the FDA and the IBWA Model Bottled Water Code as determined by an annual onsite evaluation conducted by a third-party organization such as the NSF. The bottler would first notify the Department of the intent to operate under the permit by rule. A bottled water system operating under the permit by rule would file with the Department descriptions of substantial modifications such as replacement of equipment or addition of a new product line within 30 days of operation of the modification.

New in-State bottled water systems would still be required to obtain a public water system permit for the construction and operation of the bottled water system after which they could operate under the permit by rule option if qualified. The permit by rule does not include new sources or expanded use of existing permitted sources which would continue to require a permit amendment from the Department under the present permitting requirements. Any bottler seeking to use the permit by rule would have to comply with all other applicable laws administered by the Department as required by section 7 of the act (35 P.S. § 721.7) and comply with other requirements of Chapter 109, including design, construction, operation, monitoring and reporting.

The draft proposed permit by rule was presented to the Water Resources Advisory Committee (WRAC) at its November 12, 1997, meeting and to the Advisory Board for the Small Systems Technical Assistance Center (TAC) at its November 18, 1997, meeting. The TAC Board approved the proposed amendments. The WRAC's review and recommendations resulted in the following changes to the draft proposal:

1. Deletion of the IBWA from the authority to determine the acceptability of the third-party inspection organization in § 109.1005(c)(3) (relating to permit requirements) so that only the Department determines the acceptability of the third-party evaluation organization.
2. Deletion of "operationally" in § 109.1005(c)(3)(i) since it infers that the third-party inspection organization is involved with operating a bottled water system.
3. Addition of a new § 109.1005(c)(3)(v) pertaining to the evaluation organization demonstrating the capability through experience or training, or both, to implement and conduct the onsite evaluation.

The WRAC also recommended that § 109.1005(c)(5) be changed to require the bottler to notify the Department of

substantial modifications to the system "...from 30 days following operation of the modification..." to "...at least 30 days prior to the operation of the modification..." One of the purposes of developing a permit by rule was to streamline the permitting process. The recommendation would require the bottler to determine in advance what substantial modifications (including replacement of existing equipment) would be required and would not authorize operation of the modification within the 30-day period. This could result in a delay in resuming production which would be costly to the bottler and result in possible loss of market share. The Department believes the proposed 30 days' notice following operation is appropriate and does not preclude the bottler from submitting the information in advance of the operation of the proposed facilities.

The proposed amendments pertaining to radionuclide compliance monitoring, labeling requirements for returnable containers and coliform monitoring site plan submission address issues determined through the Regulatory Basics Initiative (RBI) which identified regulations for possible revision that were obsolete, prescriptive, redundant, needing clarification or more stringent than Federal regulations.

The average daily consumption of drinking water is assumed to be 2 liters per person per day in establishing drinking water standards. Because a container smaller than a half gallon cannot provide one person's drinking water needs for 1 day, the Department, by policy published in the Preamble at 20 Pa.B. 2621 to Chapter 109, announced its intention to regulate only those bottled water systems providing water for bottling in 1/2 gallon or larger containers. Many specialized bottled water products are marketed as beverages or pharmaceuticals, and generally in small containers. The Department has not regulated the products which are generally regulated under State and Federal food and drug laws. Consumers' demands for more convenience in bottled drinking water has led to an increase in the small bottled water product market. Bottlers who bottle the large containers also use the same water in bottling in the small containers. There may be bottlers who only produce the smaller sizes for distribution in this Commonwealth and thus are not regulated under the Department's safe drinking water regulations.

As part of this proposed rulemaking, the Department is requesting comment with supporting data on whether it should modify its policy on regulating small bottled products (less than one-half gallon) and bottlers of small bottled products.

E. Summary of Regulatory Requirements

1. *Section 109.1. Definitions.* Added definition for "IBWA," the International Bottled Water Association and revised the definition for "NSF" to reflect the new name of NSF International.

2. *Section 109.301(8). Consecutive water system monitoring for lead and cadmium.* Subparagraph (ii)(B) was deleted, subparagraph (ii)(C) was renumbered as (ii)(B) and references to lead and cadmium monitoring in subparagraph (iii) were deleted. The current regulations are confusing in that consecutive systems under subparagraph (iii) are required to monitor for lead and cadmium in accordance with subparagraph (ii)(B) which was reserved. The intent of the Department was to delete the lead and cadmium monitoring requirement in subparagraph (iii). Consecutive systems are required to monitor for lead under § 109.1101(c). Cadmium is a contaminant in the metals used to galvanize pipe and in brass used in

faucets and generally gets into finished water by corrosion of galvanized pipes or into the source water by improper waste disposal. Compliance monitoring for cadmium is required at the entry point to the distribution system. Since corrosion control measures to meet the lead action level would also minimize the corrosion of cadmium from galvanized pipe and brass faucets, the lead and cadmium monitoring requirements in subparagraph (iii) are unnecessary.

3. *Section 109.701(a)(5). Siting plan.* The "...November 16, 1992..." date was deleted and replaced with "...within 30 days of receipt of the Department's request for this information" for submission of a siting plan for coliform monitoring. The present requirement was identified under the RBI as obsolete.

4. *Section 109.1003(a)(1)(vii). General monitoring requirements.* The monitoring for compliance with radiological maximum contaminant levels (MCLs) for bottled water systems, retail water facilities and bulk water hauling systems was reduced from "...annually..." to "...once every 4 years..." The present requirement was identified under the RBI as more stringent than the Federal requirements.

5. *Section 109.1005. Permit requirements.* A new subsection (c) "Special permit by rule requirement for bottled water systems" was added. The proposed subsection would provide an option for in-State permitted bottlers to obtain a permit amendment for modifications (except for the addition of new sources or expanded use of existing permitted sources) to the bottling, processing or manufacturing facilities provided the bottled water system meets certain specified criteria. Specific criteria would include the source type (groundwater not under the direct influence of surface water or finished water from a community water system, or both) and water quality (does not exceed FDA quality standards for health related chemical and radiological contaminants and requires only disinfection to meet the Pennsylvania primary maximum contaminant levels), use of acceptable treatment technologies and demonstrated compliance with the National standards of the FDA and the IBWA Model Bottled Water Code as determined by an annual onsite evaluation conducted by a third-party organization such as NSF or other organizations acceptable to the Department. To be acceptable to the Department, the organization must be independent of the bottlers using its services, have policies and procedures indicating the organization will support the Department's enforcement actions, have a system to respond to bottlers' complaints with appropriate due process safeguards, maintain a quality assurance and quality control program, and demonstrate its capability to conduct an onsite evaluation program. The bottler would be required to notify the Department of the intent to operate under the permit by rule and would notify the Department within 30 days following operation of a substantial modification to the bottling, processing or manufacturing facilities for the bottled water products.

6. *Section 109.1007(a). General labeling requirements.* The present regulation requires containers of bottled water to have labels which are designed to remain affixed to the container during usage. Through guidance, the Department has included the cap on returnable bottles under the "...affixed to the container during use..." in subsection (a). The present requirements were identified under the RBI as being unclear. The proposed amendments reflect the guidance.

7. *Section 109.1008(a)(3). Reporting and recordkeeping requirements for bottled water and vended water systems,*

retail water facilities and bulk water hauling systems. Bottlers are now required to submit new or proprietary labels to the Department for approval prior to beginning production of the new bottled water product. Subsection (a)(3) has been revised to require the bottler to submit new or proprietary labels to the Department within 10 days following the production or distribution of the new or additional bottled water product. The bottler can also submit the new or additional labels to the Department in advance for a Department review if desired. The bottler will still be required to comply with § 109.1007 (relating to labeling requirement for bottled water systems, vended water systems and retail water facilities).

F. *Benefits, Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the proposed amendments.

Benefits

Bottlers in this Commonwealth who elect to operate under the permit by rule should realize time and cost savings from the streamlined permitting process by being able to make timely business decisions such as installation of a new or additional production line or replacement equipment without first obtaining a Department permit amendment. Along with the revised requirements for submitting new or additional product labels, this will provide bottlers in this Commonwealth greater flexibility and opportunity to respond to market conditions and increase competitiveness with out-of-State bottlers. The consumers of bottled water may also benefit from lower prices; however, this is difficult to quantify, due to the many factors affecting the retail price in producing bottled water products.

Over 90 bottled water systems, retail water facilities and bulk water hauling systems will benefit from the reduction in the compliance monitoring for radionuclides from annually to once every 4 years.

Compliance Costs

There should be no additional costs to State and local government or the regulated community to implement the proposed amendments.

The permit by rule is an option and a bottler of this Commonwealth is not required to operate under the permit by rule. Under the permit by rule option, there would be an annual cost estimated at \$600—\$800 for the third-party evaluation. Bottlers in this Commonwealth who are IBWA members or NSF certified should not experience an annual cost for the third-party inspection since this cost is included in IBWA's membership fee or NSF's certification fee. Bottlers in this Commonwealth who do not have an annual third-party evaluation and elect to operate under the permit by rule would experience the annual evaluation cost. However, this cost should be offset by the bottler not being required to pay a permit application fee of \$300 to \$750 for major amendments to the bottling process under the present permitting procedures and the cost savings from reducing the radionuclide compliance monitoring from annually to once every 4 years. Since the permit by rule is an option, it is difficult to estimate the additional costs (if any) to bottlers in this Commonwealth.

Compliance Assistance Plan

It is anticipated that extensive compliance assistance will not be necessary. The permit by rule is an option for bottlers in this Commonwealth. The other proposed amendments update, modify or clarify present requirements.

The Department will notify the regulated community through the *Environmental Protection Update Weekly Newsletter* and through revised Key Requirements summaries affected by the proposed amendments. The Key Requirements summaries are available to the regulated community and placed on the Department's Web site. If necessary, the Department will directly notify the regulated community, including out-of-State bottlers, through mailings. The Department staff will be available to assist the regulated community and any bottler in this Commonwealth considering operating under the permit by rule.

Paperwork Requirements

There should be no increase in the amount of paperwork. Overall, with the exception of the permit by rule, the proposed amendments update, clarify or revise present requirements and should not have any major impact on existing reporting, recordkeeping or other paperwork requirements.

Compared to obtaining a permit amendment under the present permitting process, bottlers in this Commonwealth would first notify the Department of the intent to operate under the permit by rule, file descriptions of substantial modifications within 30 days of operation of the modification and submit annual proof of compliance with the FDA standards and the IBWA Model Bottled Water Code based on the third-party evaluation. Bottlers operating under the permit by rule would still be required to comply with the other provisions of the act and regulations including design, construction, operation, reporting and recordkeeping. The Department anticipates the permit by rule would decrease paperwork requirements compared to obtaining a Department permit for modifications to the bottling, processing and manufacturing of bottled water. The reduction in radionuclide monitoring would reduce reporting and paperwork requirements for over 90 bottled water systems, retail water facilities and bulk water hauling systems.

G. Sunset Review

These amendments will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the amendments 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 April 28, 1998, the Department submitted a copy of the proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed regulatory analysis form prepared by the Department. A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Department within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review by the Department, the Governor and the General Assembly before final publication of the final-form regulations.

I. Public Comments

Written Comments—Interested persons are invited to submit comments, suggestions or objections regarding the

proposed amendments to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by June 8, 1998 (within 30 days of publication in the *Pennsylvania Bulletin*). Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by June 8, 1998 (within 30 days of publication in the *Pennsylvania Bulletin*). The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final-form regulations will be considered.

Electronic Comments—Comments may be submitted electronically to the Board at RegComments@A1.dep.state.pa.us and must also be received by the Board by June 8, 1998. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgment of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JAMES M. SEIF,
Chairperson

Fiscal Note: 7-337. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart C. PROTECTION OF NATURAL RESOURCES

ARTICLE II. WATER RESOURCES

CHAPTER 109. SAFE DRINKING WATER

Subchapter A. GENERAL PROVISIONS

§ 109.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

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IBWA—**The International Bottled Water Association, Alexandria, Virginia 22314.**

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NSF—**[The National Sanitation Foundation] NSF International, Ann Arbor, Michigan 48106.**

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Subchapter C. MONITORING REQUIREMENTS

§ 109.301. General monitoring requirements.

The monitoring and analytical requirements, including approved sampling procedures and analytical techniques, established by the EPA under the National Primary Drinking Water Regulations, 40 CFR Part 141 (relating to national primary drinking water regulations), as of December 8, 1984, are incorporated by reference. Public water suppliers shall monitor for compliance with MCLs in accordance with the requirements established in the National Primary Drinking Water Regulations, except as otherwise established by this chapter unless increased monitoring is required by the Department under § 109.302 (relating to special monitoring requirements).

Alternative monitoring requirements may be established by the Department and may be implemented in lieu of monitoring requirements for a particular National Primary Drinking Water Regulation if the alternative monitoring requirements are in conformance with the Federal act and regulations. The monitoring requirements shall be applied as follows:

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(8) *Monitoring requirements for public water systems that obtain finished water from another public water system.*

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(ii) Community consecutive water suppliers shall:

* * * * *

(B) [Reserved

(C)] Monitor the distribution system for compliance with the MCL for asbestos at the frequency indicated in paragraph (7)(i), when the Department determines that the system's distribution system contains asbestos cement pipe and optimum corrosion control measures have not been implemented.

(iii) Consecutive water suppliers are exempt from conducting monitoring for the MCLs for VOCs, SOCs and IOCs if the public water system from which the finished water is obtained complies with paragraphs (5)—(7), except that **[lead and cadmium monitoring is required in accordance with subparagraph (ii)(B), and]** asbestos monitoring is required in accordance with subparagraph (ii)**[(C)] (B).**

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Subchapter G. SYSTEM MANAGEMENT RESPONSIBILITIES

§ 109.701. Reporting and recordkeeping.

(a) *Reporting requirements for public water systems.* Public water systems shall comply with the following requirements:

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(5) *Siting plan.* The water supplier shall submit to the Department a written sample siting plan for routine coliform sampling as required by § 109.303(a)(2) **[by November 16, 1992]** within 30 days of receipt of the Department's request for this information.

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Subchapter J. BOTTLED WATER AND VENDED WATER SYSTEMS, RETAIL WATER FACILITIES AND BULK WATER HAULING SYSTEMS

§ 109.1003. Monitoring requirements.

(a) *General monitoring requirements.* Bottled water and vended water systems, retail water facilities and bulk water hauling systems shall monitor for compliance with the MCLs in accordance with **[the requirements under]** § 109.301 (relating to general monitoring requirements) and shall comply with § 109.302 (relating to special monitoring requirements). The monitoring requirements shall be applied as follows, except that systems which have installed treatment to comply with a primary MCL shall conduct quarterly operational monitoring for the contaminant which the facility is designed to remove:

(1) Bottled water systems, retail water facilities and bulk water hauling systems, for each entry point shall:

* * * * *

(vii) Monitor for compliance with radiological MCLs **[annually]** once every 4 years.

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§ 109.1005. Permit requirements.

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(c) Special permit by rule requirement for bottled water systems. A person owning or operating a bottled water system in this Commonwealth, permitted under this chapter shall obtain an amended permit before making substantial modifications to the processing and bottling facilities unless the bottled water system satisfies the conditions for a permit by rule in paragraphs (1)—(5). The permit-by-rule does not apply to the addition of new sources or the expanded use of existing permitted sources used by the bottled water system. For the addition of new sources or the expanded use of existing permitted sources, a permit amendment under subsection (f), relating to permit amendment applications, shall be obtained. The Department retains the right to require a bottled water system that meets the requirements of paragraphs (1)—(5) to obtain a permit, if, in the judgment of the Department, the bottled water system cannot be adequately regulated through the standardized specifications and conditions. A bottled water system which is released from the obligation to obtain a permit shall comply with the other requirements of this subchapter, including design, construction and operation requirements. The following are the conditions for a permit by rule:

(1) The bottled water system has as its sole sources of water permitted groundwater sources which are not under the direct influence of surface water as determined through a protocol established by the Department or approved by the Department or finished water from a Department approved community water system.

(2) The water quality of the source does not exceed the Food and Drug Administration quality standards for primary (that is, health-related) chemical and radiological contaminants specified in 21 CFR 165.110 (relating to beverages) as determined under sampling conducted under subsection (e)(4)(ii) and requires treatment no greater than disinfection to provide water of a quality that meets the primary MCLs established under Subchapter B (relating to MCLs and treatment techniques).

(3) Proof that the facilities meet the standards of the Food and Drug Administration in 21 CFR Parts 110, 129 and 165 (relating to processing and bottling of bottled drinking water; current good manufacturing practices; and beverages) and the IBWA model bottled water code as determined by an onsite evaluation conducted by a Nationally recognized, independent, not-for-profit third-party organization such as NSF or another organization acceptable to the Department. The onsite evaluation shall be conducted annually. The proof shall consist of the report issued by the organization which shall be submitted to the Department within

30 days following the completion of the onsite evaluation. To be acceptable to the Department, the organization shall:

(i) Demonstrate it is independent of the bottled water systems using the organization's services.

(ii) Have well developed, documented policies, procedures and contracts to support enforcement actions for meeting compliance objectives.

(iii) Have an established system for investigating complaints and taking appropriate actions, with an effective appeals process.

(iv) Maintain a documented ongoing quality assurance and quality control program.

(v) Demonstrate the capability through experience or training, or both, to implement and conduct an onsite evaluation program.

(4) A bottled water system intending to operate under this subsection shall submit written notification to the Department with documentation that the system complies with paragraphs (1)–(3).

(5) A bottled water system operating under this subsection shall file descriptions of substantial modifications made to the system with the Department within 30 days of operation of the modification. The description shall include documentation that the modification meets the following requirements as applicable:

(i) Compliance with the product water-contact materials and treatment chemical additives toxicological requirements of § 109.606 (relating to chemicals, materials and equipment) or alternatively, the Food and Drug Administration standards in 21 CFR Part 129.

(ii) Validated treatment technologies for the reduction of contaminants. Validation may be established by certification to an applicable ANSI/NSF standard or through protocols developed by organizations/consortia such as, but not limited to, NSF, the American Water Works Association Research Foundation and the EPA Technology Verification Program.

[(c)] (d) Permit amendments. A person may not substantially modify a bottled water or vended water system, retail water facility or bulk water hauling system operated under a public water system permit without obtaining a permit amendment from the Department or otherwise complying with subsection [(e)] (f).

* * * * *

[(d)] (e) Permit applications. An application for a public water system permit for a bottled water or vended water system, retail water facility or bulk water hauling system shall be submitted in writing on forms provided by the Department and shall be accompanied by plans, specifications, engineer's report, water quality analyses and other data, information or documentation reasonably necessary to enable the Department to determine compliance with the act and this chapter. The Department will make available to the applicant the *Public Water Supply Manual*, available from the Bureau of Water Supply [and Community Health] Management, Post Office Box 8467, Harrisburg, PA 17105-8467 which contains acceptable design standards and technical guidance. Water quality analyses shall be conducted by a laboratory certified under this chapter. An application for a public

water system permit for a bottled water or vended water system, retail water facility or bulk water hauling system shall include:

* * * * *

[(e)] (f) Permit amendment applications. A bottled water or vended water system, retail water facility or bulk water hauling system operating under a public water system permit shall obtain a permit amendment before making a substantial modification to the public water system.

(1) A water supplier shall submit an application for a major permit amendment in accordance with subsection [(d)] (e), if the proposed modification constitutes a major change to the public water system.

* * * * *

(iii) For vended water systems, typical modifications which may be considered major changes are proposed additions or deletions of treatment techniques or processes, new product lines or types of products and the addition to the system of machines not certified by NAMA. For new sources, the supplier shall obtain a separate and distinct permit in accordance with subsection [(d)] (e) unless the system qualifies for a permit by rule under subsection (b).

* * * * *

(3) The Department determines whether a particular modification requires a permit amendment under subsection [(e)] (f)(1) or a permit amendment under subsection [(e)] (f)(2). The Department's determination will include consideration of the magnitude and complexity of the proposed change and the compliance history of the public water system.

[(f)] (g) Emergency permits. In emergency [circumstances] situations, the Department may issue permits for construction, operation or modification to a bottled water or bulk water hauling system, which the Department determines may be necessary to assure that potable drinking water is available to the public.

(1) Emergency permits shall be limited in duration and may be conditioned on additional monitoring, reporting and the implementation of appropriate emergency response measures. The Department may revoke an emergency permit if it finds the water system is not complying with drinking water standards or the terms or conditions of the permit. An authorization for construction, operation or modifications obtained under an emergency permit will not extend beyond the expiration of the emergency permit unless the public water system receives a permit or permit amendment under subsection [(d)] (e) or [(e)] (f) for the construction, operation or modification initiated during the emergency.

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[(g)] (h) Department's review. Applications for public water system permits and permit amendments for bottled water and vended water systems, retail water facilities and bulk water hauling systems will be reviewed in accordance with the following procedures:

* * * * *

(3) As a condition of receiving a public water system permit, a bottled water system shall comply with the standards of the Food and Drug Administration contained

in 21 CFR Part 129. Evidence shall be presented demonstrating compliance with subsection [(d)] (e)(7)(iii).

* * * * *

[(h)] (i) *Permit fees.*

(1) An application for a new permit or major permit amendment under subsection [(e)] (f)(1) for a bottled water or vended water system, retail water facility or bulk water hauling system shall be accompanied by a check in the amount of \$750 payable to the "Commonwealth of Pennsylvania," except that:

(i) An application from an out-of-State bottled water system submitting proof of out-of-State approval under subsection [(d)] (e)(6) shall be accompanied by a fee of \$100.

* * * * *

(2) A fee is not required for an emergency permit under subsection [(f)] (g) or a minor permit amendment under subsection [(e)] (f)(2).

§ 109.1007. Labeling requirements for bottled water systems, vended water systems and retail water facilities.

(a) *General labeling requirements.* Containers of bottled water distributed in this Commonwealth by bottled water systems, retail water facilities or, when appropriate, vended water systems, shall have labels which are designed to remain affixed to the container during use and which include the following information **as required by this section. Labels with the following information on the caps of bottled water containers designed for reuse by the bottler are deemed to meet this requirement if the Department-issued identification number and the manufacture date, lot or batch number are on the bottle:**

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§ 109.1008. System management responsibilities.

(a) *Reporting and recordkeeping requirements for bottled water and vended water systems, retail water facilities and bulk water hauling systems.* Bottled water and vended water systems, retail water facilities and bulk

water hauling systems shall comply with the reporting requirements in § 109.701(a) and (d) (relating to reporting and recordkeeping).

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(3) For bottled water systems and, if applicable, vended water systems and retail water facilities, new or additional proprietary labels shall be reported to the Department in writing, along with copies of the labels, **[at least] within 10 days [prior to commencing] following production or distribution of the new or additional label product. The new or additional proprietary labels may be submitted to the Department prior to the product production if the water supplier desires initial Department review. The new or additional proprietary labels shall comply with § 109.1007 (relating to labeling requirements for bottled water systems, vended water systems and retail water facilities).**

(b) *Operation and maintenance plan requirements.* Bottled water, vended water, retail water and bulk water suppliers shall develop an operation and maintenance plan for each system. The operation and maintenance plan shall conform to the guidelines contained in Part III of the Department's *Public Water Supply Manual* which is available from the Bureau of Water Supply **[and Community Health] Management**, Post Office Box 8467, Harrisburg, Pennsylvania 17105. The water supplier shall implement the operation and maintenance plan in accordance with this chapter, and if appropriate in accordance with accepted practices of the bottled water, vended water, retail water facility or bulk water hauling industry. The plan shall be reviewed and updated as necessary to reflect changes in the operation or maintenance of the water system. The plan shall be bound and placed in locations which are readily accessible to the water system's personnel, and shall be presented upon request to the Department.

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