

<b>Regulatory Analysis Form</b>		This space for use by IRRC 99 FEB 23 AM 10:15 INDEPENDENT REGULATORY REVIEW COMMISSION <b>Bush</b> IRRC Number: <b>1948</b>
(1) Agency  Department of Environmental Protection		
(2) I.D. Number (Governor's Office Use)  7-337		
(3) Short Title  Bottled Water Systems: Permit by Rule		
(4) PA Code Cite  25 Pa Code Chapter 109	(5) Agency Contacts & Telephone Numbers  Primary Contact: Sharon Freeman, 783-1303  Secondary Contact: Barbara Sexton, 783-1303	
(6) Type of Rulemaking (Check One)  <input type="checkbox"/> Proposed Rulemaking <input checked="" type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted	(7) Is a 120-Day Emergency Certification Attached?  <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language.  The amendments establish a permit by rule for Pennsylvania permitted bottled water systems meeting specified criteria, reduce compliance monitoring requirements for radionuclides for bottled water systems, retail water facilities and bulk water hauling systems, allow label information on the caps of returnable bottles and allow submission of new or additional proprietary labels within 10 days following production of the new or additional label bottled water product. Other amendments are also included pertaining to coliform monitoring siting plan submission deadline which applies to all public water systems and clarifying the lead and cadmium compliance monitoring which applies to consecutive water systems.		
(9) State the statutory authority for the regulation and any relevant state or federal court decisions.  Section 4 of the Pennsylvania Safe Drinking Water Act of May 1, 1984 (P.L. 206, No. 43), 35 P.S. §721.4 and Sections 1917-A and 1920-A of the Administrative Code of 1929, 71 P.S. §§510-7 and 510-20		

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

This amendment is not mandated by any federal or state law or court order or federal regulation. The permit by rule is part of the PRIME (Privatize, Retain, Innovate, Modify and Eliminate) Initiative to provide better services to the regulated community and make government smaller, more efficient and responsive. Some amendments update or clarify present requirements while others 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.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Pennsylvania bottlers 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 was that the requirements are affecting their ability to implement timely business decisions in responding to the bottled water market conditions. The proposed permit by rule would streamline the permitting process for modifications (such as addition of a new product or replacement of equipment) to the bottling, processing and manufacturing of bottled drinking water, result in more efficient and effective use of Department field staff and increase Pennsylvania bottlers' competitiveness with out of state bottlers.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Not applicable. Under Act 43, the Pennsylvania Safe Drinking Water Act, bottled water systems are regulated as public water systems.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Pennsylvania bottlers will benefit by having an option to obtaining a permit amendment from the Department for the construction or installation of substantial modifications (such as a new product line or replacement of equipment) to the bottling facilities. Under the permit by rule, Pennsylvania bottlers would not have to pay the \$300 - \$750 application fee for permit amendment applications. The permit by rule will provide Pennsylvania bottlers 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 involved in producing bottled water products which affect the retail price.

All bottled water systems, retail water facilities and bulk water hauling systems will benefit from the reduced radionuclide compliance monitoring from annually to once every four years.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)

This amendment clarifies language and reduces monitoring costs but does not impose any additional mandatory requirement. The permit by rule is a compliance option. The amendments are not expected to produce any adverse impacts.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

The permit by rule is an option and any Pennsylvania bottler who qualifies is not required to operate under the permit by rule. All bottled water systems, retail water facilities and bulk water hauling systems are required to comply with the reduced radionuclide compliance monitoring. All public water systems would be required to comply with the 30 day submission deadline for identifying coliform monitoring sites.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The framework for the permit by rule was developed in consultation with a workgroup of representatives of several Pennsylvania bottlers, the International Bottled Water Association (IBWA), NSF International, a large tap water system, an engineering/consulting firm, the League of Women Voters and the Departments of Health and Agriculture. The draft final version of the amendments was reviewed and approved by the Water Resources Advisory Committee (WRAC) at their September 9, 1998 meeting. The draft final amendments were also placed on the Department's Web site.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

Under the permit by rule option, there would be an annual cost estimated at \$600-\$800 for the third-party evaluation. Pennsylvania bottlers who are IBWA members or NSF certified should not experience an annual cost for the third-party inspection since this cost is included in the membership fee or NSF's certification fee. The evaluation cost should be offset for all Pennsylvania bottlers operating under the permit by rule since the bottler would not be required to pay the application fee of \$300 - \$750 for major amendments to the bottling process under the present permitting procedures and the savings from the reduction in the radionuclide compliance monitoring. Since the permit by rule is an option, it is difficult to estimate the costs and/or savings to Pennsylvania bottlers. However, Pennsylvania bottlers operating under the permit by rule should realize time and cost savings from the streamlined permitting process by being able to implement timely business decisions such as installation of a new or additional production line without first waiting for a Department permit amendment. Pennsylvania bottlers 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 based on the third-party evaluation. It is not anticipated there will be any additional legal, accounting or consulting procedures from the proposed amendments. There will be a savings to the regulated community from the reduction of the radionuclide monitoring from annually to once every four years which is estimated at around \$ 37,000 over a four year period.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

The permit by rule option would apply to over 40 in-State Pennsylvania bottled water systems. The amendments pertaining to submitting new or additional product labels and allowing labeling information on the cap of returnable bottles apply to almost 90 in-State and out-of state bottled water systems. These systems, for the most part, are privately owned businesses and there should be no additional costs imposed on local government.

The amendments pertaining to updating the coliform siting plans submission deadline which apply to all public water systems and clarifying the consecutive water systems monitoring for lead and cadmium should not have any impact on local government.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.

There should not be any additional costs to state government resulting from the amendments. Additional Department staff will not be needed to implement these amendments. However, there may be insignificant revenue losses since the permit by rule would not have any associated fees compared to a major permit amendment which requires an application fee of \$300 - \$750. Generally, less than 10 permit amendments per year are issued to in-State bottlers. However, any revenue loss resulting from the permit by rule should be outweighed by the increased efficiency and time and cost savings to the Department from eliminating the technical review of permit amendment applications and annual inspections of bottling facilities for those bottlers operating under the permit by rule. The costs and/or savings to state government cannot be determined since it depends on the number of in-State bottlers who would operate under the permit by rule and the number of modifications to the bottling facilities made each year.

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(20) In the table below, provide an estimate of the fiscal savings and cost associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>	0	12,600	12,600	12,600	0	12,600
<b>Local Government</b>	NA	NA	NA	NA	NA	NA
<b>State Government</b>	0	*	*	*	*	*
<b>Total Savings</b>	0	12,600	12,600	12,600	0	12,600
<b>COSTS:</b>						
<b>Regulated Community</b>	0	*	*	*	*	*
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Costs</b>	0	*	*	*	*	*
<b>REVENUE LOSSES:</b>						
<b>Regulated Community</b>	0	0	0	0	0	0
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	*	*	*	*	*
<b>Total Revenue Losses</b>	0	*	*	*	*	*

(20a) Explain how the cost estimates listed above were derived.

Over 90 bottled water and bulk water hauling systems use around 90 groundwater sources (wells and springs) of supply. The annual cost of radionuclide compliance monitoring was estimated as follows:

Gross alpha: 90 samples @ \$ 40/sample = \$ 3,600 per year  
 Radium226 : 45 samples @ \$100/sample = \$ 4,500 per year  
 Radium228 : 45 samples @ \$100/sample = \$ 4,500 per year  
 Total = \$12,600 per year

Since the radionuclide compliance monitoring would be reduced from annually to once every four years, the cost savings would be \$12,600 for each of three years and the cost would be \$12,600 for the last year of a four year period.

\* Since the permit by rule is an option and not a mandate, additional costs or savings to Pennsylvania bottlers and revenue losses and savings to state government could not be quantified. See Responses to Questions #17 and #19.

### Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-3	FY-2	FY-1	Current FY
Safe Drinking Water	4,945,663	5,291,226	5,595,129	6,304,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There should not be any adverse effects. Overall, the benefits will outweigh the costs as there will be no significant costs on state and local governments. The permit by rule option should result in cost savings to Pennsylvania bottlers by allowing the bottlers to implement timely business decisions (such as addition of a new production line) to respond to bottled water market demands faster than if required to first obtain a permit amendment from the Department. Consumers may also benefit from reduced prices for bottled water products. However, these are difficult to quantify because of the many factors involved in producing bottled water. 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 four years.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory options to the permit by rule were not considered. Under the act, bottled water systems are regulated as public water systems subject to the permitting requirements of the act. Nonregulatory options were not considered for the radionuclide monitoring and the coliform siting plan submission since these are required by federal regulations. Generally, the remaining amendments clarify, update and modify the present requirements.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

Other regulatory alternatives considered included clarifying the types of in plant modifications requiring permit amendments, centralized permitting of in-State bottled water systems and privatizing the oversight of the bottling operations through a mandated third-party evaluation. However, these did not completely address the concerns or needs of Pennsylvania's bottled water industry and/or would result in an increased regulatory compliance cost.

### Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The amendments do not contain any provisions that are more stringent than federal standards.

(25) How does the regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

Some states require approvals or permits while other states simply require an annual fee for distribution of bottled drinking water. Overall, the permit by rule should increase the competitiveness of Pennsylvania bottlers against out-of-State bottlers.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulations being amended are 25 Pa Code §109.1, §109.301, §109.701, §109.1003, §109.1005, §109.1007 and §109.1008. The proposed amendments will not affect any other existing or proposed regulations of the Department or other state agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

None.

### Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Under the present permitting process, the bottler would have to first obtain a Department permit amendment prior to substantially modifying (such as the addition of a new product line or replacement of equipment) the bottling facilities. Compared to obtaining a permit amendment under the present process, the permit by rule option should reduce the paperwork requirements. Pennsylvania bottlers 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 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 other amendments should not have any major impact on existing reporting, recordkeeping or other paperwork requirements. The reduction in radionuclide monitoring would reduce reporting and paperwork requirements for bottled water systems, retail water facilities and bulk water hauling systems.

The amendments will require revisions to the technical guidance to field staff and other documents such as the Key Requirements Summary for Bottled, Vended Retail and Bulk Water Hauling Systems.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The permit by rule option addresses the special needs of Pennsylvania's bottled water industry.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

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

(31) Provide the schedule for continual review of the regulation.

The regulation will be reviewed in accordance with the sunset review schedule published by the Department.

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FOR FILING DOCUMENTS  
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REVIEW COMMISSION



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<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>_____ (DEPUTY ATTORNEY GENERAL)</p> <p>_____ DATE OF APPROVAL</p> <p>Check if applicable Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>DEPARTMENT OF ENVIRONMENTAL PROTECTION ENVIRONMENTAL QUALITY BOARD _____ (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. 7-337</p> <p>DATE OF ADOPTION: _____</p> <p>BY: <u>James M. Seif</u> JAMES M. SEIF, CHAIRMAN _____ (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p><u>R. E. Grimaldi</u></p> <p><u>2/16/99</u> _____ DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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ORDER ADOPTING REGULATIONS

DEPARTMENT OF ENVIRONMENTAL PROTECTION  
ENVIRONMENTAL QUALITY BOARD

Bottled Water Systems: Permit by Rule

25 Pa. Code Chapter 109

Notice of Final Rulemaking  
Department of Environmental Protection  
Environmental Quality Board  
(25 Pa. Code, Chapter 109)  
(Safe Drinking Water)

**Preamble**

The Environmental Quality Board (Board) by this order amends 25 Pa. Code, Chapter 109 (relating to safe drinking water). The amendments 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.

The Board approved these final amendments at its February 16, 1999 meeting.

**A. Effective Date**

These amendments are effective 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. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (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**

These amendments are being promulgated 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 Summary**

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 systems providing water for bottling or bulk handling became effective. Chapter 109 was amended at 20 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 the 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. §§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, 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 NSF; however, the NSF certification is not a requirement of 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 provides in-State permitted bottlers an option to obtaining a permit amendment for substantial modifications to the bottling, processing or manufacturing facilities provided certain specified criteria are met. Specific criteria include: the source type (ground water 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 modifications to the collection facilities, including the addition of new 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 and comply with other requirements of Chapter 109 including design, construction, operation, monitoring and reporting.

The 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 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 four years...." The present requirement was identified under the RBI as more stringent than the federal requirements. The radionuclide compliance monitoring results (annual monitoring) over the past eight years indicates there has not been any violation of the radionuclide MCLs.

For submission of a siting plan for coliform monitoring, the "...November 16, 1992..." date is deleted and replaced with "...within 30 days of receipt of the Department's request for this information." The present requirement was identified under the RBI as obsolete.

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..." The present requirements were identified under the RBI as being unclear. The amendments reflect the guidance.

The final rulemaking was presented to the Water Resources Advisory Committee (WRAC) at its September 9, 1998 meeting. The WRAC approved the final rulemaking.

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. In the Preamble to the proposed rulemaking at 28 Pa.B. 2265 (May 9, 1998), the Department requested comments 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. Since the Department did not receive any comments, the present policy will be continued until data is forthcoming which indicates the need to regulate this segment of the bottled water market.

#### **E. Summary of Comments and Responses on the Proposed Rulemaking**

The proposed rulemaking was published at 28 Pa.B. 2265 (May 9, 1998) with a 30-day public comment period. The Board received comments from two commentators during the public comment period. The Board also received comments from the Independent Regulatory Review Commission (IRRC). Summaries of all comments received and the Department's responses may be found in a Comment and Response Document which is available from the contact persons listed in Section B of this Preamble.

Some sections have been modified from the proposed rulemaking based on the comments received in addition to other modifications. A list of the modified sections and a summary of the major comments received are provided as follows:

1. *§ 109.1005(a). Permit requirements.* A minor change revising (d) to (e) in the last sentence.
2. *§ 109.1005(c). Permit requirements.* The commentators expressed concern that the provision requiring a permit amendment for "...the expanded use of existing permitted sources used by the bottled water system..." would unintentionally expand or enlarge the scope of the permit amendment requirements. The IRRC commented this should be clarified since the intent of the permit by rule was not to expand the permitting requirements.

The Department agrees that the intent of the permit by rule was not to expand the permit requirements. The language under question was intended to specify that the permit by rule only applies to the processing, manufacturing and bottling facilities. The specific language dealing with new sources and expanded use of existing sources is deleted in the final amendments and replaced with language specifying the permit by rule does not apply to the collection facilities. Collection is defined as “the parts of a public water system occurring prior to treatment, including source, transmission facilities and pretreatment storage facilities.” This clarifies that the permit by rule only applies to the bottling, processing and manufacturing facilities for bottled water.

3. *§ 109.1005(c)(1). Permit requirements.* In response to the IRRC comment that the Department identify the protocols that may be used by the Department in making the determination whether the bottled water system uses groundwater sources that are not under the direct influence of surface water, paragraph (1) has been modified to identify the *Guidance for Surface Water Identification Protocol* as the protocol the Department will use.

4. *§ 109.1005(c)(3)(i). Permit requirements.* The commentators expressed concern over the requirement that the third-party evaluator demonstrate that it is independent of the bottled water systems using the organization’s services. The concern was that this would eliminate from consideration industry organizations (which have membership in IBWA or receive financial support from the bottled water industry) with the knowledge and information that would enable them to serve as particularly effective evaluators. The IRRC commented that how “independence” from the bottled water industry will be determined should be further explained or defined.

The independence of the inspection or evaluation organization is a key element of the permit by rule in assuring regulatory compliance and public health protection. In response to the comments, language has been added requiring the evaluation/inspection organization be accredited by the American National Standards Institute (ANSI) as a third-party evaluation/inspection organization. The ANSI is a nationally recognized accreditation agency for third-party certification organizations and agencies including testing/inspection organizations. Accredited inspection organizations certify compliance with specific requirements and standards including government regulations. ANSI evaluates the accreditation applicant’s organizational structure to determine if the organization is “controlled” by the party that would be inspected or evaluated. If there is a potential conflict of interest, ANSI will recommend corrective measures to enable the organization to be accredited as a third-party inspection organization.

For accreditation by ANSI, the third-party organization must also have a method for handling complaints, a system for appeal of unresolved or other complaints or disagreements, an effective internal quality control system appropriate to the type, range and volume of work performed, and sufficient staff with the necessary education, training and experience to carry out the work for which it claims to be competent and subject to effective supervision. Requiring ANSI accreditation for a third-party inspection agency or organization is addressed, in the proposed rulemaking, in subparagraph (c)(3)(i) pertaining to independent of the bottled water systems, subparagraph (c)(3)(iii) pertaining to having an established system for investigating complaints and an appeals process, subparagraph (c)(3)(iv) pertaining to a documented quality assurance and control program and subparagraph (c)(3)(v) pertaining to the capability through experience and/or training to conduct the on-site evaluation program.

In the final amendments, the requirement that the inspection organization be accredited by ANSI as a third-party inspection agency replaces the proposed language in subparagraph (c)(3)(i), and subparagraphs (c)(3)(iii), (iv) and (v) are deleted.

5. § 109.1005(c)(3)(ii). *Permit requirements.* Added “Department” to clarify the third-party organization has policies and procedures that would support any required Department enforcement actions.

6. § 109.1005(c)(5)(ii). *Permit requirements.* For validation of treatment technologies, the IRRC questioned what other organizations will be acceptable and recommended the Department publish a list of acceptable organizations annually. Evaluating organizations and protocols for conformance with the requirement could be resource intensive. The intent was to minimize the need for Department approval of protocols and evaluation organizations. In the final amendments, the reference to protocols is deleted and the subsection revised to reference treatment technologies certified under the appropriate ANSI/NSF Standard by a third-party acceptable to the Department and those verified under the EPA Environmental Technology Verification Program. Language was added that treatment facilities approved by the Department for the bottled water system operating under the permit by rule are also considered validated treatment technologies. This allows a bottler operating under the permit by rule to add or use these permitted treatment technologies to a new product line or for an expansion of the bottling facilities.

For certifying treatment technologies under the appropriate ANSI/NSF Standard, the final amendments specify the certification organization (other than the NSF) must be accredited by ANSI as a third-party certification organization and meet the requirements, as applicable, under § 109.606(d).

7. § 109.1005(c)(6). *Permit requirements.* Subparagraph (6) was added requiring publication in the *Pennsylvania Bulletin* of the Department’s determination that the bottled water system has complied with subsections (c)(1)-(4) and is operating under the permit by rule and of notices submitted under subsection (c)(5) for modifications to the bottling and processing facilities. Presently, major permit amendments require publication in the *Pennsylvania Bulletin*. The Department believes these notifications under the permit by rule should also be published in the *Pennsylvania Bulletin*.

8. § 109.1005(g) *Permit requirements.* The term “circumstances” which was replaced with “situations” in the proposed rulemaking is retained in the final rulemaking.

9. § 109.1008(b). *System management responsibilities.* The four digit extension was added to the Bureau’s Zip Code.

#### **F. Benefits, Costs and Compliance**

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

## **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 four years.

## **Compliance Costs**

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

The permit by rule is an option and any bottler in 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 four 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 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 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. 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 final rulemaking updates, clarifies or revises 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 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)), the Department, on April 28, 1998, submitted a copy of the proposed rulemaking, published at 28 Pa.B. 2265 (May 9, 1998), to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment. In compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of the comments as well as other documentation.

In preparing these final regulations, the Department has considered all comments received from IRRC and the public. The Committees did not provide comments on the proposed rulemaking.

This final regulation was (deemed) approved by the House Environmental Resources and Energy Committee on \_\_\_\_\_ and was (deemed) approved by the Senate Environmental Resources and Energy Committee on \_\_\_\_\_. IRRC met on \_\_\_\_\_, and approved the final regulation in accordance with section 5.1(e) of the Act.

**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 Pa. 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 proposal published at 28 Pa. B. 2265.
- (4) These regulations are necessary and appropriate for the administration and enforcement of the authorizing acts identified in Section C of this Preamble.

**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 by amending §§ 109.1, 109.301, 109.701, 109.1003, 109.1005, 109.1007, and 109.1008 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.
- (b) The Chairman 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 Chairman shall submit this order and Annex A to the IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.
- (d) The Chairman 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 upon publication in the *Pennsylvania Bulletin*.

BY:

JAMES M. SEIF  
Chairman  
Environmental Quality Board

**Annex A**

**Title 25. ENVIRONMENTAL RESOURCES**

**PART I. DEPARTMENT OF  
ENVIRONMENTAL PROTECTION**

**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:

\* \* \* \* \*

IBWA - THE INTERNATIONAL BOTTLED WATER ASSOCIATION, ALEXANDRIA, VA  
22314.

NSF - [The National Sanitation Foundation] NSF INTERNATIONAL, Ann Arbor, Michigan 48105.

\* \* \* \* \*

**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:

\* \* \* \* \*

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

\* \* \* \* \*

(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).

\* \* \* \* \*

#### 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:

\* \* \* \* \*

(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.

\* \* \* \* \*

#### 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 FOUR YEARS.

\* \* \* \* \*

§ 109.1005. Permit Requirements.

(a) *General permit requirement.* A person may not construct or operate a bottled water or vended water system, retail water facility or bulk water hauling system without first having obtained a public water system permit under subsection (b) or ~~[(d)]~~ (e).

\* \* \* \* \*

(c) SPECIAL PERMIT BY RULE REQUIREMENT FOR BOTTLED WATER SYSTEMS. A PERSON OWNING OR OPERATING A BOTTLED WATER SYSTEM IN PENNSYLVANIA 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 IN PARAGRAPHS (1) - (5). THE PERMIT BY RULE DOES NOT APPLY TO THE COLLECTION FACILITIES. [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 THE [A] DEPARTMENT'S GUIDANCE FOR SURFACE WATER IDENTIFICATION 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 SOURCES DOES NOT EXCEED THE FOOD AND DRUG ADMINISTRATION QUALITY STANDARDS FOR PRIMARY (THAT IS, HEALTH-RELATED) CHEMICAL AND RADIOLOGICAL CONTAMINANTS SPECIFIED IN 21 CFR PART 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 PROVISIONS OF 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; TO 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 OTHER 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] BE ACCREDITED BY ANSI AS A THIRD-PARTY INSPECTION/EVALUATION ORGANIZATION.

(ii) HAVE WELL DEVELOPED, DOCUMENTED POLICIES, PROCEDURES, AND CONTRACTS TO SUPPORT DEPARTMENT 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 AND/OR TRAINING, OR BOTH, TO IMPLEMENT AND CONDUCT AN ON-SITE 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 TO 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 (RELATING TO PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER).

(ii) VALIDATED TREATMENT TECHNOLOGIES FOR THE REDUCTION OF CONTAMINANTS. [VALIDATION MAY BE ESTABLISHED BY CERTIFICATION] VALIDATED TREATMENT TECHNOLOGIES ARE THOSE THAT HAVE BEEN PERMITTED BY THE DEPARTMENT UNDER THIS CHAPTER AT THE BOTTLED WATER SYSTEM OPERATING UNDER THE PERMIT BY RULE OR CERTIFIED TO AN APPLICABLE ANSI/NSF STANDARD BY NSF OR OTHER CERTIFICATION ORGANIZATION ACCEPTABLE TO THE DEPARTMENT OR [THROUGH PROTOCOLS DEVELOPED BY ORGANIZATIONS/CONSORTIA SUCH AS, BUT NOT LIMITED TO, NSF, AMERICAN WATER WORKS ASSOCIATION RESEARCH FOUNDATION AND] VERIFIED UNDER THE EPA ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM. TO BE ACCEPTABLE TO THE DEPARTMENT, A CERTIFICATION ORGANIZATION OTHER THAN NSF SHALL BE ACCREDITED BY ANSI AS A THIRD-PARTY CERTIFICATION ORGANIZATION AND MEET THE REQUIREMENTS UNDER § 109.606(d) (RELATING TO CHEMICALS, MATERIALS AND EQUIPMENT) AS APPLICABLE TO THE APPROPRIATE ANSI/NSF STANDARD FOR THE TREATMENT TECHNOLOGY.

(6) THE DEPARTMENT WILL PUBLISH A NOTICE IN THE PENNSYLVANIA BULLETIN OF ITS DETERMINATION THAT A BOTTLED WATER SYSTEM HAS COMPLIED WITH SUBSECTIONS (c)(1)-(4) AND IS OPERATING UNDER THE PERMIT BY RULE. THE DEPARTMENT WILL PUBLISH A NOTICE IN THE PENNSYLVANIA BULLETIN OF DESCRIPTIONS SUBMITTED UNDER SUBSECTION (c)(5) OF SUBSTANTIAL MODIFICATIONS MADE BY A BOTTLED WATER SYSTEM OPERATING UNDER THE PERMIT BY RULE.

[(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.

\* \* \* \* \*

[(g)] (h) *Department 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 PROVIDED THE DEPARTMENT-ISSUED IDENTIFICATION NUMBER AND THE MANUFACTURE DATE, LOT OR BATCH NUMBER ARE ON THE BOTTLE:

\* \* \* \* \*

§ 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).

\* \* \* \* \*

(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 THE PROVISIONS OF § 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 17105-8467. 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.

\* \* \* \* \*

**DEPARTMENT OF ENVIRONMENTAL PROTECTION  
COMMENT AND RESPONSE DOCUMENT  
25 PA CODE CHAPTER 109  
SAFE DRINKING WATER  
BOTTLED WATER PERMIT BY RULE**

**EQB DOCKET No. 7-337  
March 17, 1998**

**Bureau of Water Supply Management  
Department of Environmental Protection  
P.O. Box 8467  
Harrisburg, PA 17105-8467**

**LIST OF COMMENTATORS**

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3. Independent Regulatory Review Commission

## **CHAPTER 109. SAFE DRINKING WATER BOTTLED WATER PERMIT BY RULE**

### **§ 109.1005. Permit requirements.**

#### **Comment #1**

The commentators expressed concern that the provision in §109.1005(c) requiring a permit amendment under subsection (f) for "...the expanded use of existing permitted sources used by the bottled water system..." would unintentionally expand or enlarge the scope of the permit amendments requirements. The language appears to impose a permit amendment requirement for any "expanded use" of an existing permitted source. Generally, increases in the amount of water withdrawn within an approved safe yield do not require a permit amendment which are for "substantial modifications" to the system. A recommendation was made to add the phrase "...if required by subsection (f)..." to clarify that a permit amendment would only be required if the change represents a "substantial modification" to the system. (1 & 2)

This new provision should be clarified since the understanding was that the intent of the permit by rule was not to expand the permit requirements. (3)

#### **Response #1**

The Department agrees that the intent of the permit by rule was not to expand the permit requirements. The language under question was to specify that the permit by rule only applies to the processing, manufacturing and bottling facilities for producing bottled water products and not the source(s) used. Therefore, the proposed provision will be replaced by "...The permit by rule does not apply to the collection facilities." Collection is defined in Chapter 109 as "the parts of a public water system occurring prior to treatment, including source, transmission facilities and pretreatment storage facilities." Substantial modifications to the collection facilities require a permit amendment under Section 109.1005(f). Examples of "substantial modifications" are contained in subsection (f). The Department determines if the modification is a "substantial modification" requiring a permit amendment considering the magnitude and complexity of the proposed modification and the compliance history of the bottled water system. Bottlers operating under the permit by rule have the opportunity to contact the Department to determine if a proposed modification to the collection facilities constitutes a "substantial modification."

#### **Comment #2**

In subsection (c)(1), the protocols should be identified that may be used by the Department in making the determination whether the bottled water system uses groundwater sources that are not under the direct influence of surface water. (3)

#### **Response #2**

For determining whether the groundwater source is directly affected by surface water, the Department uses the *Guidance for Surface Water Identification Protocol*. This Protocol specifies the procedures

and methods used for data collection and analysis in evaluating whether the groundwater source is under the direct influence of surface water. The language in the proposal will be modified to read "...permitted groundwater sources which are not under the direct influence of surface water as determined through the Department's *Guidance for Surface Water Identification Protocol* or finished water from a Department approved community water system."

### **Comment #3**

The commentators expressed concern over the requirement in §109.1005(c)(3)(i) that the third-party evaluator demonstrate that "it is independent of the bottled water systems using the organization's services..." It was believed this would eliminate from consideration industry organizations that have the knowledge and information that would enable them to serve as particularly effective evaluators. Some inspection organizations include membership in the bottled water industry organization or receive financial support from the bottled water companies. The commentators recommended adding the word "...operationally..." before "...independent..." to ensure the objectivity of the evaluations but not eliminating from consideration the expert organizations who may have among their members companies from the bottled water industry. (1 & 2)

It should be further defined or explained how "independence" from the bottled water industry will be determined. (3)

### **Response #3**

Examples of inspection organizations with membership in or which receive financial support from the bottled water companies were not provided. It is crucial that the evaluation or inspection agency be independent from the bottled water industry. This is a key element of the permit by rule in assuring regulatory compliance and public health protection.

The American National Standards Institute (ANSI) is a nationally recognized accreditation agency for third-party certification organizations and agencies including testing/inspection organizations. Accredited inspection organizations certify compliance with specific requirements and standards including government regulations. The ANSI evaluates the accreditation applicant's organizational structure to determine if the organization is "controlled" by the party that would be inspected or evaluated. If there is a potential conflict of interest, ANSI will recommend corrective measures to enable the organization to be accredited as a third-party inspection organization.

For accreditation by ANSI, the third-party organization must also have a method for handling complaints, a system for appeal of unresolved or other complaints or disagreements, an effective internal quality control system appropriate to the type, range and volume of work performed, and sufficient staff with the necessary education, training and experience to carry out the work for which it claims to be competent and subject to effective supervision. Requiring ANSI accreditation as a third-party inspection agency or organization would address subsection (c)(3)(i) pertaining to demonstrating independence from the bottled water systems using its services, subsection (c)(3)(iii) pertaining to having an established system for investigating complaints and an appeals process, subsection (c)(3)(iv) pertaining to a documented quality assurance and control program and subsection (c)(3)(v) pertaining to the capability through experience and/or training to conduct the on-site evaluation program.

In the final amendments, the requirement that the inspection organization be accredited by ANSI as a third-party inspection agency will replace the present language in subsection (c)(3)(i) and subsections (c)(3)(iii), (iv) and (v) will be deleted.”

#### **Comment #4**

Subsection (c)(5)(ii) allows validation of treatment technologies through “protocols developed by...but not limited to, NSF, the American Water Works Association Research Foundation and the EPA Technology Verification Program.” We question what other organizations will be acceptable and recommend the Department publish an annual list of organizations whose standards it deems acceptable. (3)

#### **Response #4**

The Department believes providing an annual listing of all organizations could be resource intensive. The Department would have to determine the acceptability of such organizations and evaluate their testing protocol to assure compliance with the requirement. In addition to Universities and colleges, industry or trade organizations could conceivably request Department acceptance. The Department’s intent was to minimize the need for approval of evaluation organizations and protocols.

In the final amendments, the Department will delete the reference to protocols and refer to only treatment technologies certified under the appropriate ANSI/NSF Standard by the NSF or other certification organizations acceptable to the Department and those technologies verified under the EPA Environmental Technology Verification Program.

In addition, the final amendments will include as validated treatment technologies those that have been permitted by the Department for the bottler operating under the permit by rule. The permit by rule pertains to permitted in-State bottled water systems. For the initial permit application, the Department evaluates the proposed treatment technologies to determine acceptability. These treatment technologies may not be certified or verified. Under the proposed amendments, the bottler operating under the permit by rule would not be able to add these treatment technologies to a new or additional product line or expanded bottling facilities. This was not the Department’s intent. Treatment technologies that have been permitted by the Department for the bottler operating under the permit by rule would be validated treatment technologies. This would allow a bottler operating under the permit by rule to add these permitted treatment technologies to a new product line or for an expansion of the bottling facilities.

To be acceptable to the Department, the final amendments will specify the certification organization must be accredited by ANSI as a third-party certification organization and meet the requirements, as appropriate, under § 109.606(d). This requirement for ANSI accreditation is to assure an independent certification organization. (See Response #3)



**Rachel Carson State Office Building  
P.O. Box 2063  
Harrisburg, PA 17105-2063  
February 23, 1999**

**The Secretary**

Mr. Robert E. Nyce  
Executive Director  
Independent Regulatory Review Commission  
14th Floor, Harristown II  
Harrisburg, PA 17101

RE: Final Rulemaking – Bottled Water Systems Permit by Rule (#7-337)

Dear Bob:

Pursuant to Section 5.1(a) of the Regulatory Review Act, enclosed is a copy of a final-form regulation for review by the Commission. This rulemaking was approved by the Environmental Quality Board (EQB) for final rulemaking on February 16, 1999.

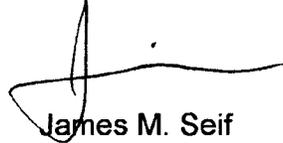
This final rulemaking streamlines the permitting process by establishing a permit by rule option for in-state permitted bottled water systems that meet specified criteria. The criteria include the source type and water quality, use of acceptable treatment technologies and demonstrated compliance with the national standards of the FDA and the International Bottled Water Association (IBWA). Other amendments clarify monitoring, labeling, and system responsibility requirements contained in Chapter 109 that were identified under the Regulatory Basics Initiative (RBI). The rulemaking is part of Governor Ridge's PRIME (Privatize, Retain, Innovate, Modify and Eliminate) Initiative.

In developing the permit by rule, DEP formed the Bottled Water Workgroup. The Workgroup was comprised of several Pennsylvania bottlers, IBWA, NSF International, representatives of a large tap water system, an engineering firm and the League of Women Voters. The proposed rulemaking was adopted by the EQB on March 17, 1998 and published May 9, 1998, with a 30-day public comment period. There were three commentators to the proposal, and minor modifications have been made to the final rulemaking in response to the comments.

The Department will provide the Commission with any assistance required to facilitate a thorough review of this final-form regulation. Section 5.1(e) of the Act provides that the Commission shall, within ten days after the expiration of the committee review period, approve or disapprove the final-form regulation.

For additional information, please contact Sharon Freeman, Regulatory Coordinator, at 783-1303.

Sincerely,

A handwritten signature in black ink, appearing to read 'James M. Seif', with a long horizontal flourish extending to the right.

James M. Seif  
Secretary

Enclosure

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT

RECEIVED

I.D. NUMBER: 7-337

99 FEB 23 AM 10:15

SUBJECT: Bottled Water Systems: Permit by Rule

INDEPENDENT REGULATORY  
REVIEW COMMISSION

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION



TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation

a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE

SIGNATURE

DESIGNATION

*[Signature]* 2/23/99  
*[Signature]* 2/23/99

HOUSE COMMITTEE ON ENVIRONMENTAL  
RESOURCES & ENERGY

*[Signature]* 2/23/99  
*[Signature]* 2/23/99

SENATE COMMITTEE ON ENVIRONMENTAL  
RESOURCES & ENERGY

2/23/99 *[Signature]*

INDEPENDENT REGULATORY REVIEW COMMISSION

ATTORNEY GENERAL

LEGISLATIVE REFERENCE BUREAU

February 16, 1999