RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 93]

Stream Redesignations (French Creek, et al.—Part A)

The Environmental Quality Board (Board) by this order amends §§ 93.9f, 93.9g, 93.9k, 93.9l, 93.9n—93.9p and 93.9r to read as set forth in Annex A.

This order was adopted by the Board at its meeting of May 21, 1998.

A. *Effective Date*

These amendments are effective upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. *Contact Persons*

For further information, contact Edward R. Brezina, Chief, Division of Water Quality Assessment and Standards, Bureau of Watershed Conservation, 10th Floor, Rachel Carson State Office Building, P. O. Box 8555, 400 Market Street, Harrisburg, PA 17105-8555, (717) 787-9637 or William J. Gerlach, Assistant Counsel, Bureau of Regulatory Counsel, 9th Floor, Rachel Carson State Office Building, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. 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 final rulemaking is available electronically through the Department of Environmental Protection's (Department) Web site (http://www.dep.state.pa.us).

C. *Statutory Authority*

The final rulemaking is being made under the authority of the following acts: sections 5(b)(1) and 402 of The Clean Streams Law (35 P. S. §§ 691.5(b)(1) and 691.402) and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which grant to the Board the authority to develop and adopt rules and regulations to implement the provisions of The Clean Streams Law. In addition, the Federal regulation at 40 CFR 131.32 sets forth certain requirements for portions of the Commonwealth's antidegradation program.

D. *Background of the Amendment*

The Commonwealth's water quality standards, which are set forth in part in Chapter 93 (relating to water quality standards), implement sections 5 and 402 of The Clean Streams Law and section 303 of the Federal Clean Water Act (33 U.S.C.A. § 1313). Water quality standards are in-stream water quality goals which are implemented by imposing specific regulatory requirements (such as treatment requirements and effluent limits) on individual sources of pollution.

The Department considers candidates for Special Protection status or redesignation in its ongoing review of water quality standards. In general, Special Protection waters must be maintained at their existing quality, and wastewater treatment requirements must comply with § 95.1 (relating to general requirements). Candidates may be identified by the Department based on routine waterbody investigations. Requests for consideration may also be initiated by other agencies, such as the Fish and Boat Commission (FBC), and by the general public through a rulemaking petition to the Board.

The Department evaluated the following streams in response to requests from Department and FBC staff, and from five petitioners submitting petitions to the Board: West Branch Brandywine Creek and Tributaries, Grimes Run, Milligan Run, South Branch Little Aughwick Creek, Sugar Valley Run, Indiantown Run and Muddy Run were reviewed based on a request by Department staff; Stony Brook, Mill Creek, South Branch Cole Creek, Browns Run and Toms Run were reviewed based on a request by the FBC; and the remaining streams were reviewed due to requests from various petitioners: French Creek by Green Valleys Association; Sutton Creek by Keep Sutton Creek Clean Committee; Cedar Run and Slate Run by the Pennsylvania Environmental Defense Foundation; Cove Creek by Friends of Cove Creek; and Trout Run by Greg McCarren and Jackie Greenfield.

The physical, chemical and biological characteristics and other information on these waterbodies were evaluated to determine the appropriateness of the current designations. Aquatic surveys of these streams were conducted by the Department's Bureau of Watershed Conservation and others. In reviewing whether waterbodies are subject to the Special Protection Waters Program the Department utilizes applicable State and Federal regulatory criteria and definitions. Based upon the data collected in these surveys and information gathered from Department records and other sources, the Board has made the designations set forth in Annex A.

Copies of the Department's stream evaluation reports referred to in this Preamble are available from Edward R. Brezina whose address and telephone number are listed in Section B of this Preamble.

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

The Board approved the proposed rulemaking on January 21, 1997. The proposal was published at 27 Pa.B. 1449 (March 22, 1997), with provisions for a 45-day public comment period. Several persons requested that public hearings be scheduled during this public comment period to receive additional comments on the Browns Run and Trout Run proposals. While the regular public comment period concluded on May 6, 1997, as was scheduled, the public comment period was extended for Browns and Trout Runs to allow for the public hearings. The Browns Run public hearing was held on July 1, 1997, at the Warren County Courthouse in Warren, and the Trout Run public hearing was held on July 2, 1997, at the Friendship Fire Company in Hellam Township, York County. This extended public comment period for Browns and Trout Runs concluded on July 2, 1997.

In response to the public comments and testimony received from 317 witnesses or commentators on the Browns Run and Trout Run proposals, the Department has determined that additional stream sampling and evaluations are needed to determine the appropriate recommendations for final rulemaking. Therefore, IRRC's and the EPA Region 3 (Region 3) comments and other public comments on Browns Run and Trout Run will be considered during the development of a separate final rulemaking which will address the Browns Run and Trout Run final recommendations.

In addition, in response to the Board's decision at its May 21, 1998, meeting, the lower section of Cove Creek,

from the T-433 Bridge downstream to the Mouth, was removed from the Part A package on the basis that further analysis of the lower basin is necessary due to the dominance of sensitive mayfly populations. The Department is proposing to retain the CWF designation for this stream segment. The Department plans to seek public comment on changing the interpretation of this metric to allow for a higher rapid bioassessment protocol (RBP) score when the dominant species is indicative of good water quality.

The Board also agreed to remove Grimes Run from the Part A package to further consider whether the stream was meeting its use as a HQ-CWF on the effective date of the Clean Water Act (November 28, 1975). The Department is proposing to reclassify Grimes Run to a CWF. The FBC has additional information which they believe indicates that these uses were being met, and plans to submit it to the Department.

Final recommendations will be considered by the Board as a Part B package following completion of the additional stream evaluations for Browns Run and Trout Run and following consideration of information to be obtained relevant to Grimes Run and the lower section of Cove Creek.

The Board received comments from 121 commentators during the public comment period on this Part A of the French Creek, et al proposed rulemaking. Three commentators, the Independent Regulatory Review Commission (IRRC) and Region 3 provided general comments on the entire proposed rulemaking package. In addition to the general comments on the proposed rulemaking package, IRRC also provided specific comments on Cove Creek and Grimes Run as part of its initial submission of comments on the French Creek, et al rulemaking. Also, Region 3 commented specifically on the French Creek, West Branch Brandywine, Cove Creek, Sutton Creek, Mill Creek and Toms Run proposals.

The following is a summary of comments submitted by IRRC, Region 3 and the public for the proposed stream redesignations for the Part A package. The House and Senate Standing Committees did not provide comments on the proposed rulemaking.

One commentator supported all of the proposed redesignations in the French Creek, et al proposed rulemaking. Region 3 asked for clarification as to which criteria were applied, and how the Federal promulgation was accommodated for the proposed stream redesignations. The EPA also indicated that the United States Fish and Wildlife Service was asked to provide input on the proposed changes. Two commentators and IRRC questioned Pennsylvania's authority to continue stream redesignations because of EPA's recent promulgation of Federal regulations for a portion of Pennsylvania's Special Protection Program and the appropriateness of these redesignations in light of the Commonwealth's proposal to amend its antidegradation program published at 27 Pa.B. 1459 (March 22, 1997). The two commentators expressed that the Department should not proceed with any stream redesignations, especially EV Waters redesignations, until a clear regulatory basis for these designations is established. IRRC suggested that if the proposed stream redesignations are consistent with the Federal provisions, it is appropriate for the Board to proceed to final-form regulations. Conversely, IRRC agreed that if the proposed stream redesignations are not consistent with the Federal promulgation, the Board should defer further action on these regulations until it has adopted its new antidegradation regulations and the Environmental Protection Agency (EPA) has withdrawn its overriding promulgation.

The Department believes that the current stream redesignations are consistent with the Federal provisions and implementation of the Commonwealth's Special Protection Program.

One commentator, representing the Chester County Water Resources Authority (CCWRA), expressed full support for the proposed designations for increased protection of more than 19 streams and stream segments in Chester County. The commentator referenced the redesignations for French Creek, Birch Runs and the mainstem segments of the West Branch Brandywine Creek and several tributary basins.

The 113 supportive commentators for the French Creek proposed redesignations included many local municipal officials, agencies, community organizations and local State Legislators.

Region 3 asked for several points of clarification on the French Creek redesignations. They were confused over the intended designation for the Beaver Run subbasin due to an inadvertently omitted entry. The Beaver Run basin designation is HQ-TSF, MF. They also questioned how several sampling scores were derived and how the downstream limit of several of the various designations were determined.

Region 3 suggested that the Board reconsider Special Protection for "Briar Run," an unnamed tributary in the West Branch Brandywine Creek basin. The Department explains that UNT #00130 ("Briar Run") was not recommended for HQ protection because it did not achieve the minimum score of 83% of the reference station score.

Region 3 expressed concerns that the low scores for Sutton Creek were due primarily to some habitat parameters being rated suboptimal. They suggested that the increased protection afforded an HQ stream could benefit the habitat. The Department does not believe the suboptimal conditions on Sutton Creek would benefit from HQ protection. The habitat parameters which rated suboptimal for all Sutton Creek stations included velocity/depth regimes, channel alterations, channel flow status, vegetative disruptive pressure and riparian vegetation zone width.

These regulatory changes allow wastewater treatment requirements for dischargers to these streams to be consistent with the water uses to be protected. These regulatory amendments do not contain any standards or requirements which exceed requirements of the companion Federal regulations.

F. *Summary of Changes to the Proposed Rulemaking*

In response to testimony and comments received during the public hearings and comment period, the Department decided to conduct additional stream sampling and evaluations before returning with final recommendations for Browns Run and Trout Run as a separate Part B final rulemaking package.

In response to the Board's decision at its May 21, 1998, meeting, Grimes Run and the lower section of Cove Creek were removed from the Part A package and will be reconsidered in the Part B package.

An entry that was inadvertently omitted from the proposed rulemaking has been added to Annex A for Beaver Run in the French Creek basin. This clarifies that the Beaver Run basin designation is HQ-TSF, MF.

The Department also discovered during development of this final rulemaking that a "Basin" descriptor was inadvertently omitted from the proposed rulemaking Annex A for the first Mill Creek entry. Therefore, a "Basin" entry was inserted in the Zone column to replace the "Main Stem" descriptor that was being deleted during proposed rulemaking.

G. *Benefits, Costs and Compliance*

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

1. *Benefits*—Overall, the citizens of this Commonwealth will benefit from these recommended changes because they reflect the appropriate designated use and maintain the most appropriate degree of protection for each stream in question.

2. *Compliance Costs*—Generally the changes should have no fiscal impact on, or create additional compliance costs for the Commonwealth or its political subdivisions. Except as noted, no costs will be imposed directly upon local government by this recommendation. However, indirect costs may result from revisions to Act 537 Sewage Facilities Plans due to consultant and other administrative fees. Political subdivisions which add a new sewage treatment plant or expand an existing plant in the basin may experience changes in cost as noted in discussion of impacts on the private sector.

Persons proposing activities or projects which result in discharges to streams must comply with the regulatory requirements relating to current stream designations. These persons could be adversely affected by the recommended changes that increase the level of protection provided to a stream, if they expand their discharge or add a new discharge point, since they may need to provide a higher level of treatment for their new or expanded discharge. These increased costs take the form of higher engineering, construction or operating costs for wastewater treatment facilities. Treatment costs are site-specific and may depend upon the size of the discharge in relation to the size of the stream, and many other factors. It is, therefore, not possible to precisely predict the actual change in costs. In addition, nonpoint source controls necessary to protect High Quality and Exceptional Value Waters may add to the cost of planning and development for new or expanded nonpoint source discharges. Economic impacts would primarily involve the potential for higher treatment costs for new or expanded discharges to streams which are upgraded, and potentially lower treatment costs for dischargers to streams which are downgraded.

3. *Compliance Assistance Plan*—The regulatory revisions have been developed as part of an established program that has been implemented by the Department since the early 1980's. The proposal is consistent with and based on existing Department programs and current policies. Therefore, no policy changes are anticipated. The proposal extends additional protection to selected waterbodies that exhibit exceptional water quality and is consistent with antidegradation requirements established under the Federal Clean Water Act and Pennsylvania Clean Streams Law. All surface waters in this Commonwealth are afforded a minimum level of protection through compliance with the water quality standards which prevent pollution and protect existing water uses.

The proposed amendments will be implemented through the National Pollution Discharge Elimination System (NPDES) permitting program since the stream use designation is a major basis for determining allowable stream discharge effluent limitations. These permit conditions are established to assure that the water quality criteria are achieved and the designated uses are protected. New and expanded dischargers with water quality-based effluent limitations are required to provide effluent treatment according to the water quality criteria associated with the revised designated water uses.

4. *Paperwork Requirements*—The regulatory revisions should have no direct paperwork impact on the Commonwealth, local governments and political subdivisions or the private sector. These regulatory revisions are based on existing Department programs and policies. There may be some indirect paperwork requirements for new or expanding dischargers to streams upgraded to Special Protection (HQ or EV). For example, NPDES general permits are not available for new or expanded discharges to Special Protection streams. Thus, an individual permit, and its associated additional paperwork, would be required. Additionally, paperwork associated with demonstrating social and economic justification (SEJ), and the nonfeasibility of nondischarge alternatives, may be required for new or expanded discharges to certain Special Protection waters.

H. *Pollution Prevention*

The antidegradation program is a major pollution prevention tool because its objective is to prevent degradation by maintaining and protecting existing water quality. Although new and expanded wastewater discharges are not prohibited by the antidegradation program, nondischarge alternatives are encouraged and required, when appropriate. Nondischarge alternatives, when implemented, remove impacts to surface water and reduce the overall level of pollution to the environment by remediation of the effluent through the soil.

I. *Sunset Review*

These amendments 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. In addition, these regulations are water quality standards subject to section 303(c)(1) of the Federal Clean Water Act (33 U.S.C.A. § 1313(c)(1)).

J. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on March 10, 1997, the Department submitted a copy of the notice of proposed rulemaking to IRRC and to the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment. The notice was published at 27 Pa.B. 1449. In compliance with section 5(b.1) of the Regulatory Review Act, the Department also provided IRRC and Committees with copies of the comments received, as well as other documentation.

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

This final-form regulation was deemed approved by the House and the Senate Committees on July 20, 1998. IRRC met on July 30, 1998, and approved the amendments in accordance with section 5(c) of the Regulatory Review Act.

K. *Findings*

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, 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 27 Pa.B. 1449.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this Preamble.

L. *Order*

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

(a) The regulations of the Department, 25 Pa. Code Chapter 93, are amended by amending §§ 93.9f, 93.9g, 93.9k, 93.9l, 93.9n—93.9p and 93.9r to read as set forth in Annex A, with ellipses referring to the existing text of the regulations. (*Editor's Note*: A proposal to amend §§ 93.9l and 93.9p, amended in this document, remains outstanding at 28 Pa.B. 1635 (April 4, 1998).

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval and review as to legality and form, as required by law.

(c) The Chairperson shall submit this order and Annex A to IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

JAMES M. SEIF,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4007 (August 15, 1998).)

Fiscal Note: 7-306A. 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 93. WATER QUALITY STANDARDS

§ 93.9f. Drainage List F.

Delaware River Basin in Pennsylvania

Schuylkill River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
3-French Creek	Basin, Source to Beaver Run	Chester	EV	None
4-Beaver Run	Basin	Chester	HQ-TSF, MF	None
3-French Creek	Basin, Beaver Run to Birch Run	Chester	HQ-TSF, MF	None
4-Birch Run	Basin	Chester	EV	None
3-French Creek	Basin, Birch Run to the Junction of West Vincent, East Vincent and East Pikeland Township Borders	Chester	HQ-TSF, MF	None
3-French Creek	Basin, Junction of West Vincent, East Vincent and East Pikeland Township Borders to Mouth	Chester	TSF, MF	None
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§ 93.9g. Drainage List G.

Delaware River Basin in Pennsylvania

Delaware River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
4-West Branch Brandywine Creek	Main Stem, T 437 Bridge to Dam at Valley Station	Chester	TSF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek	Basins, T 437 Bridge to Dam at Valley Station (except those in West Brandywine Township)	Chester	TSF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek	Basins, in West Brandywine Township	Chester	HQ-TSF, MF	None
5-Birch Run	Basin, Source to Hibernia Park Dam	Chester	HQ-CWF	None
5-Birch Run	Basin, Hibernia Park Dam to Mouth	Chester	TSF, MF	None
5-Unnamed Tributary to West Branch Brandywine Creek at RM 21.2 (UNT #00215)	Basin	Chester	HQ-CWF, MF	None
5-Rock Run	Basin	Chester	TSF, MF	None
4-West Branch Brandywine Creek	Main Stem, Dam at Valley Station to Dennis Run	Chester	WWF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek	Basins, Dam at Valley Station to Dennis Run	Chester	WWF, MF	None
5-Sucker Run	Basin	Chester	WWF, MF	None
5-Dennis Run	Basin	Chester	WWF, MF	None
4-West Branch Brandywine Creek	Main Stem, Dennis Run to Buck Run	Chester	WWF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek	Basins, Dennis Run to Buck Run, except unnamed Tributary to West Branch Brandywine at RM 12.3 (UNT #00193)	Chester	WWF, MF	None
5-Unnamed Tributary to West Branch Brandywine Creek at RM 12.3 (UNT #00193)	Basin, Source to Unnamed Tributary to UNT #00193 at RM 0.3 (UNT #00194)	Chester	CWF, MF	None
6-Unnamed Tributary to UNT #00193 at RM 0.3 (UNT #00194)	Basin	Chester	EV, MF	None
5-Unnamed Tributary to West Branch Brandywine Creek at RM 12.3 (UNT #00193)	Basin, Unnamed Tributary to UNT #00193 at RM 0.3 (UNT #00194) to Mouth	Chester	CWF, MF	None
5-Buck Run	Basin	Chester	TSF, MF	None
4-West Branch Brandywine Creek	Main Stem, Buck Run to Confluence with East Branch	Chester	WWF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek	Basins, Buck Run to Confluence with East Branch except Unnamed Tributaries to West Branch Brandywine at RM's 10.0, 9.48, 9.14, 8.0 & 5.2 (UNT's #00130, 00126, 00124, 00119, 00108)	Chester	WWF, MF	None
5-Unnamed Tributaries to West Branch Brandywine Creek at RM's 10.0, 9.48, 9.14 & 8.0 (UNT's #00130, 00126, 00124, 00119)	Basins	Chester	CWF, MF	None

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
5-Unnamed Tributary to West Branch Brandywine Creek at RM 5.2 (UNT #00108)	Basin	Chester	EV, MF	None
5-Broad Run	Basin	Chester	EV, MF	None

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§ 93.9k. Drainage List K.

Susquehanna River Basin in Pennsylvania

Susquehanna River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
3-Stony Brook	Basin	Columbia	EV	None
	* * * * *			

(*Editor's Note*: Final consideration of the appropriate designation of the Grimes Run basin will be part of a Part B final rulemaking action to be taken at a later date. A proposal which would have changed the designation from HQ-CWF to CWF was included in the proposed rulemaking at 27 Pa.B. 1449, 1455 (March 22, 1997).)

§ 93.9l. Drainage List L.

Susquehanna River Basin in Pennsylvania

West Branch Susquehanna River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
4-Cedar Run	Basin	Lycoming	EV	None
	* * * * *			
4-Slate Run				
5-Francis Branch Slate Run	Basin, Source to Confluence with Cushman Branch	Tioga	EV	None
5-Cushman Branch	Basin, Source to Slate Run	Tioga	EV	None
4-Slate Run	Basin, Confluence of Francis and Cushman Branches to Mouth	Lycoming	EV	None

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(*Editor's Note*: Final consideration of the appropriate designation for the lower reach of the Cove Creek basin, from the T-433 bridge to the mouth will be part of a Part B final rulemaking action to be taken at a later date. A proposal which would have retained CWF for the lower reach was included in the proposed rulemaking at 27 Pa.B. 1449, 1456 (March 22, 1997).)

§ 93.9n. Drainage List N.

Susquehanna River Basin in Pennsylvania

Juniata River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
4-Cove Creek	Basin, Source to T 433 Bridge	Bedford	EV	None
4-Cove Creek	Basin, T433 Bridge to Mouth	Bedford	CWF	None

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
5-South Branch Little Aughwick Creek	Basin, Source to Inlet of Cowans Gap Lake	Fulton	EV	None
5-South Branch Little Aughwick Creek	Basin, Inlet of Cowans Gap Lake to Confluence with North Branch	Fulton	HQ-CWF	None
	* * * * *			
3-West Licking Creek	Basin	Huntingdon	HQ-CWF	None
3-Sugar Valley Run	Basin	Mifflin	CWF	None
3-Beaverdam Run	Basin	Mifflin	HQ-CWF	None
	* * * * *			

(*Departmental Note*: Final consideration of the appropriate designation of the Trout Run basin will be part of a Part B final rulemaking action to be taken at a later date. A proposal which would have changed the designation from WWF to EV was included in the proposed rulemaking at 27 Pa.B. 1449, 1457 (March 22, 1997).)

§ 93.9o. Drainage List O.

Susquehanna River Basin in Pennsylvania

Susquehanna River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
3-Little Swatara Creek	Basin, Berks-Lebanon County Border to Mouth	Lebanon	WWF	None
3-Indiantown Run	Basin, Source to Inlet of Marquette Lake	Lebanon	CWF	None
3-Indiantown Run	Basin, Inlet of Marquette Lake to Inlet of Memorial Lake	Lebanon	TSF	None
3-Indiantown Run	Basin, Inlet of Memorial Lake to Mouth	Lebanon	WWF	None
3-Quittapahilla Creek	Basin	Lebanon	TSF	None
	* * * * *			

§ 93.9p. Drainage List P.

Ohio River Basin in Pennsylvania

Allegheny River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
3-Mill Creek	Basin, Source to North Hollow	Potter	HQ-CWF	None
3-Mill Creek	Basin, North Hollow to Mouth	Potter	CWF	None
3-Dingman Run	Main Stem	Potter	HQ-CWF	None
	* * * * *			
4-Cole Creek	Basin, Source to South Branch Cole Creek	McKean	CWF	None
5-South Branch Cole Creek	Basin	McKean	EV	None
4-Cole Creek	Basin, South Branch Cole Creek to Mouth	McKean	CWF	None

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			

(*Departmental Note*: Final consideration of the appropriate designation of the Browns Run basin in § 93.9q. will be part of a Part B final rulemaking action to be taken at a later date. A proposal to change the designation from CWF to EV was included in the proposed rulemaking at 27 Pa.B. 1449, 1458 (March 22, 1997).)

§ 93.9r. Drainage List R.

Ohio River Basin in Pennsylvania

Clarion River

Stream	Zone	County	Water Uses Protected	Exceptions To Specific Criteria
	* * * * *			
4-Toms Run	Basin, Source to Little Hefren Run	Clarion	EV	Add TON
5-Little Hefren Run	Basin	Clarion	CWF	*Add* TON
4-Toms Run	Basin, Little Hefren Run to Mouth	Forest	EV	*Add* TON
	* * * * *			

[Pa.B. Doc. No. 98-1439. Filed for public inspection September 4, 1998, 9:00 a.m.]

[25 PA. CODE CH. 94]
Municipal Wasteload Management

The Environmental Quality Board (Board) by this order adopts amendments to Chapter 94 (relating to the administration of the municipal wasteload management program). The amendments are the result of the Department of Environmental Protection's (Department) Regulatory Basics Initiative and Executive Order 1996-1 (Regulatory Review and Promulgation). This final rulemaking incorporates the goals of these initiatives. Among the more significant changes from the proposed rulemaking are elimination of provisions which would have required both influent and effluent metering; elimination of provisions which would have required additional flow meters in the collection and conveyance facilities, and the addition of provisions to encourage voluntary pollution prevention techniques.

The Board approved these final-form regulations at its June 16, 1998, meeting.

A. *Effective Date*

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

B. *Contact Persons*

For further information regarding these amendments, contact Glenn M. Maurer, Director, Bureau of Water Quality Protection, 11th Floor, Rachel Carson State Office Building, 400 Market Street, P. O. Box 8774, Harrisburg, PA 17105-8774, (717) 787-9666 or William S. Cumings, Jr., Assistant Counsel, Bureau of Regulatory Counsel, 9th Floor, Rachel Carson State Office Building, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. 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 final rule is available electronically through the Department's Web site (http://www/dep.state.pa.us).

C. *Statutory Authority*

The amendments are being promulgated under the authority of section 5 of The Clean Streams Law (35 P. S. § 691.5) and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510.20).

D. *Background and Purpose*

Chapter 94 establishes the framework for monitoring sewer system and sewage treatment plant loading rates; projecting future loads; limiting additional contributions of sewage to overloaded facilities; planning for necessary facility expansion and encouraging pollution prevention options.

The Department has conducted an overall review of Chapter 94 through its Regulatory Basics Initiative as outlined at 25 Pa.B. 3343 (August 19, 1995) and through Governor Ridge's Executive Order 1996-1 (Regulatory Review and Promulgation) dated February 6, 1996. These initiatives were designed with the goal of improving Department regulations. The proposed rulemaking for this chapter published at 27 Pa.B. 4334 (August 23, 1997) resulted from these initiatives. Comments received on the proposed rulemaking were reviewed and a Comment and Response document was developed. That document and the changes made in this final rulemaking were reviewed by the Water Resources Advisory Committee (WRAC) which represents a wide range of organizations with an interest in wastewater.

E. *Summary of Comments and Responses on the Proposed Rulemaking and Amendments to the Proposed Rule*

The proposed rulemaking was published with a 30-day public comment period. The Board received comments from ten commentators. Detailed summaries of all comments may be found in a Comment and Response Document which is available from the contact persons whose names and addresses are noted in Section B of this Preamble. Following are summaries and responses to the more significant comments which were received during the comment period.

1. *Significant Comments—§ 94.13 Relating to Measuring*

A majority of the comments concerned the proposed language of § 94.13(a) which would have required sewage treatment plants receiving flows in excess of 100,000 gallons per day to be equipped to measure the influent flow of the plant. Some commentators suggested that this was unnecessary because measurements of outflow accomplish the same result. In addition, some commentators noted that this would require approximately 20% of wastewater treatment plants in this Commonwealth to retrofit their facilities with new meters. The costs for a new meter could range from $5,000 to $50,000 per treatment plant. Accordingly, the term "influent" is being deleted in the final rule.

Proposed § 94.13(a) provided that "[a] sewage treatment plant or other part of a facility which receives or will receive within the next 5 years flows exceeding 100,000 gallons per day shall be equipped to continuously measure, indicate and record the . . . flow." A number of commentators felt that the phrase "or other part of a facility" was ambiguous. It was asserted that since there is no definition of facility, it is unclear exactly what areas of the wastewater system would have to have flow meters installed. Others felt it was also unclear if organic loading should also be monitored from facilities that are not wastewater treatment facilities. In light of these comments, the phrase "or other part of a facility" is being deleted in this final rule.

2. *Section 94.1—Definitions*

One commentator noted that the terms "facility," "plant" and "POTW" were used in the proposal somewhat interchangeably and without clear distinction. The Board agrees and the defined terms "plant" and "treatment facilities" have replaced these other terms throughout the regulation, where appropriate. The definition of "POTW" has been deleted because it was initially intended to be used in the context of the pretreatment regulations outlined in Chapter 97 (relating to industrial waters). The Department has not accepted delegation from the Environmental Protection Agency (EPA) for the administration of a pretreatment program and does not intend to do so.

The existing definition of "average daily flow" was not proposed to be changed; however, since the phrase is not used in Chapter 94 as a result of the final rule, it is being deleted.

The term "bypass" was also not proposed to be changed. The existing definition is inconsistent with the definition and use of the term under the NPDES program and 40 CFR 122.41(m) (relating to conditions applicable to all permits (applicable to state programs)). To ensure consistency, a new definition of "bypass" is being provided. The term is defined as "[t]he intentional diversion of wastewater either at or after the headworks of the plant."

A minor grammatical change has been made to the definition of "combined sewer system."

A new term which was not noted in the proposal, "CAP—corrective action plan," is defined. This term was added to more accurately reflect the type of plan which must be submitted to the Department to address an existing or projected overload as provided under §§ 94.21 and 94.22 (relating to existing overload; and projected overload).

A new definition for "headworks" was added to clarify the use of this term in the definitions of "bypass" and "sanitary sewer overflow."

The definition of "hydraulic design capacity" has been clarified. The proposal defined the term, in relevant part, as "[t]he highest monthly average flow, expressed in millions of gallons per day, at which a sewage treatment plan is expected to consistently provide the required treatment . . . ." This part of the definition has been revised to make it clear that it applies to the maximum monthly design flow rather than the highest monthly average flow. A sentence has been added at the end of the definition explaining that the maximum monthly design flow is specified in the water quality management (Part II) permit issued under Chapter 91 (relating to general provisions). Information regarding the maximum monthly design flow is an important tool in determining if there is an overload and the permit is the only place where the design flow is indicated. In addition, the term "sewage treatment facility" has been changed as explained.

The definition of "hydraulic overload" has also been clarified. The proposal defined the term, in part, as "[t]he condition that occurs when the monthly average flow of the sewage treatment facility or other portion of the sewage system exceeds the hydraulic design capacity for 3-consecutive months out of the preceding 12 months. . . ." The final rule clarifies this portion of the definition as "[t]he condition that occurs when the monthly average flow entering a plant exceeds the hydraulic design capacity for 3-consecutive months out of the preceding 12 months."

The term "industrial user" is changed to make it clear that it applies to an establishment which discharges or introduces industrial wastes into a sewerage facility rather than a POTW as currently provided. This change is necessitated because the term "POTW" has been deleted throughout the chapter, as discussed previously.

A new term, "monthly average organic loading," has been added and is defined as "[t]he total organic load received at a plant during any 1-calendar month divided by the number of days in that month. This value is expressed in pounds per day of BOD_5." This term was added to provide consistency with the definition of "average monthly flow" and to provide a clear definition of how this loading is to be calculated.

The term "organic overload" has been revised to make it clear that it applies when the "average daily organic load exceeds the organic design capacity" rather than the load capacity.

Two terms relating to pollution prevention activities have been added to encourage pollution prevention activities. The terms are "pollution prevention" and "PPP—Pollution Prevention Plan."

Two terms relating to pretreatment program, "pretreatment" and "pretreatment program" were proposed for deletion in the proposal. During its review of these final-form regulations, the Department discerned that the deletion of these terms would affect the applicability of § 94.15 (relating to pretreatment program development).

Accordingly, the terms are reinserted with slight modifications which eliminate sections of the regulations which are no longer applicable.

The definition of "Regional Administrator" is being deleted because the term is no longer used in the chapter.

The definition of "sanitary sewer overflow" was proposed to be deleted because the term would not have been applicable if the proposal were adopted. However, the term is used in these final-form regulations in § 94.12(a)(6), and the term has, therefore, been reinserted. The definition has been changed to make it consistent with the application of the term as used under the NPDES Program administered in accordance with Chapter 92 (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance).

The definition of "separate sanitary sewer system" has been clarified to make it clear that the system is intended to carry sanitary sewage separate from stormwater as specified in the permit. The proposal did not contain a reference to the phrase "as specified in the permit."

The definition of "sewerage facilities" has been clarified so that the term is applicable to a plant and sewer system "owned by or serving a municipality." This is intended to address those situations where privately-owned sewerage facilities are connected to municipally-owned sewerage facilities.

3. *Section 94.2—Purpose*

This section outlines the purpose of Chapter 94, which is to reduce pollution. The proposal provided that Chapter 94 is intended to prevent pollution by requiring owners and operators of sewerage facilities to manage wasteloads entering the sewerage facilities to accomplish certain enumerated objectives. The language has been revised to explain that the purpose of Chapter 94 is to "prevent unpermitted and insufficiently treated wastewater from entering waters of this Commonwealth by requiring the owners and operators of sewerage facilities to project, plan and manage future hydraulic, organic and industrial waste loadings to their sewerage facilities." Owners and operators of sewerage facilities are encouraged to apply pollution prevention practices to avoid overloads.

Among the current objectives is the prevention of the introduction of pollutants into POTWs "which will interfere with the operation of the plant or pass through or otherwise be incompatible with the plant." This objective, outlined in paragraph (3), is being deleted because this provision applies to pretreatment programs. The Department has not accepted delegation from the EPA for the administration of a pretreatment program.

Another current objective, outlined in paragraph (4) is to "improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludges." This subsection is renumbered as paragraph (3) and is revised to highlight pollution prevention and source reduction opportunities. Thus, paragraph (3) provides that one of the pollution prevention objectives is to "improve opportunities to prevent or reduce the volume and toxicity of industrial wastes generated and discharged to sewerage facilities and where prevention and reduction opportunities have been maximized and to recycle and reuse municipal and industrial wastewaters and sludges."

4. *Section 94.12—Annual Report*

Among other things, the proposal would have required that annual reports required to be submitted by March 31 of each year be prepared using "a brief summary form provided by the Department." This language has been replaced by language providing that the report be signed by the preparer and by the permittee of the plant. This phrase was added to clearly identify what signatures are required for the Department to accept the report as an official document of the permittee.

Subsection (a)(2) of the proposal provided that the information to be included in the annual report is to include a line graph depicting 5-year past and projected average daily organic loading for each month expressed as pounds per day of BOD_5. In this final rulemaking, the information is to depict the monthly average organic loading rather than average daily loading. This change was made to provide consistency with defined terms.

Subsection (a)(3) of the existing regulation provides that 5-year projections are to include data supporting the projections. The language has been revised to clarify that the information in the annual report is also to include calculations and tables used to support the projections, as well as historic monthly data in tabular form.

Subsection (a)(4) of the proposal provided that the annual report is to also include a map showing, among other things, all sewer extensions approved in the past year in accordance with the Pennsylvania Sewage Facilities Act (35 P. S. §§ 750.1—750.20). This portion of the subsection has been clarified to provide that the map also include sewer extensions exempt from the planning requirements of that act.

Subsection (a)(8) of the existing regulation (subsection (a)(6) of this final rulemaking) outlines certain types of sewer system problems which must be discussed in the annual report. The final-form regulations clarifies that these problems relate to combined sewer overflows and sanitary sewer overflows.

Subsection (a)(9) of the existing regulation (subsection (a)(7) of this final-form regulations) provides that a discussion in the annual report relating to the condition of sewage pumping stations include a comparison of "available capacity" with present and projected maximum flows for each station. The phrase "available capacity" has been changed to "the maximum pumping rate." This change is intended to enable the Department to determine the maximum flows which a pump station can put out without overflowing.

Subsection (a)(8) of the proposal outlined other types of information relating to ordinances and industrial waste which should be submitted with the annual report. Language has been added designed to encourage the utilization of pollution prevention measures.

5. *Section 94.13—Measuring, Indicating and Recording Devices*

Most of the changes to this section have been outlined in Part 1 of Section E of this Preamble. However, the flows threshold for measurements required in this section has been clarified to make it clear that it applies to monthly average flows rather than flows.

6. *Sections 94.21 and 94.22—Existing and Projected Overload*

These sections require the permittee of a sewerage facility to prepare a written plan setting forth actions the permittee will undertake to address either a hydraulic or organic overload at its facility. The type of plan required is more accurately a corrective action plan. Accordingly, the phase "corrective action plan" has been inserted in lieu of existing terms referring to the plan.

7. *Section 94.31—Organic or Hydraulic Overload (Imposition of Ban)*

This section outlines the conditions which will result in the imposition of a ban on connections. Bans will be imposed whenever the Department determines that the sewerage facilities or a portion of a facility are either hydraulically or organically overloaded or that the discharge from the plant causes pollution and one or more other conditions prevail. Among the other conditions specified is that the "[f]ailure of the permittee to provide facilities to prevent an organic or hydraulic overload was not caused solely by the unavailability of Federal construction grants under section 201 of the Clean Water Act for which the permittee has applied and remains eligible." This Federal construction grants program no longer exists and the quoted language from paragraph (3) has accordingly been deleted in this final rulemaking.

F. *Benefits, Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the final-form regulations. It also requires a statement of the need for, and a description of forms, reports or other paperwork required as a result of the final-form regulations.

These final-form regulations are necessary to implement the Department's Regulatory Basics Initiative and the goals of Executive Order 1996-1. Sections of Chapter 94 were identified as obsolete, overly prescriptive or written in a way that causes significant noncompliance.

Benefits

Individuals, consultants and sewage treatment plant permittees will benefit from the final amendments. The simplified annual report requirements will make it easier for permittees to comply with the regulations and should increase compliance. Cost savings were estimated as $753,000 during the development of the Regulatory Basics Initiative. In addition, elimination of obsolete regulations and modifications of the proposed rulemaking in response to comments received during the public comment period has improved the clarity of the regulations and will promote compliance.

Compliance Costs

The final rulemaking does not create new regulatory requirements. Several amendments included in the proposed rulemaking relating to metering flows were eliminated in the final-form rulemaking because some commentators noted these changes would substantially increase the cost of compliance. The final rulemaking will not impose additional costs on anyone.

Compliance Assistance Plan

The Department does not intend to develop a compliance assistance plan because there is no adverse impact on compliance.

Paperwork Requirements

There are no additional forms, reports or other paperwork required as the result of this final rulemaking. This final rulemaking is intended to reduce and simplify paperwork requirements.

G. Pollution Prevention

Pollution prevention approaches to environmental management often provide environmentally sound and longer-term solutions to environmental protection because pollution is prevented at the source. Pollution prevention is defined by the EPA as measures taken to avoid or reduce generation of all types of pollution—solid/hazardous waste, wastewater discharges and air emissions—at their points of origin; however, it does not include activities undertaken to treat, control or dispose of pollution once it is created. The Federal Pollution Prevention Act of 1990 established a National policy and environmental management hierarchy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. The hierarchy is as follows:

(a) Pollution should be prevented or reduced at the source.

(b) Pollution that cannot be prevented should be recycled in an environmentally safe manner whenever possible.

(c) Pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible to render it less hazardous, toxic or harmful to the environment.

(d) Disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.

The short- and long-term health of the economy of this Commonwealth depends on clean air, pure water and the preservation of the natural, scenic, historic and aesthetic values of the environment. The Commonwealth spends over $1 billion per year in efforts to control pollutants through regulation of both industrial point source discharges and nonpoint sources. To meet the Commonwealth's economic development and environmental protection goals successfully, the Commonwealth needs to adopt programs like pollution prevention that not only protect the environment, but also significantly reduce costs and increase the competitiveness of the regulated community. When pollution is prevented up front, it can reduce a company's bottom-line costs and overall environmental liabilities. Sometimes a company can get out of the regulatory loop through a successful pollution prevention program. It also can get the Department out of the business of regulating pollution that may not need to be generated in the first place.

In keeping with Governor Ridge's interest in encouraging pollution prevention solutions to environmental problems, this rulemaking has incorporated the following provisions and incentives to meet that goal:

The final-form regulations require permittees of wastewater treatment facilities to project, through an annual evaluation of permitted facilities, the potential for either a hydraulic or organic overload 5 years into the future. When overloads are projected, the permittee is required to take appropriate action to either eliminate the source of the overload or to expand or upgrade the wastewater facilities to handle the projected increased loading. Therefore, Chapter 94 is a pollution prevention program to the extent that permittees are required to prevent overloads preferably by eliminating the source of the overload.

Section 94.12 of the final rulemaking retains a reporting requirement to identify industrial discharges to sewerage facilities and discuss actions taken to alleviate problems caused by these discharges. Section 94.15 requires that where pollutant contributions by an industrial user results in interference or pass through and the violation is likely to recur, the sewerage facility must develop local limits for these industrial users to assure compliance with NPDES permits or sludge use or disposal practices. These elements provide important opportunities to encourage pollution prevention/source reduction programs and practices at sewage treatment facilities and at industries which discharge to these facilities.

In addition, the final rulemaking incorporates definitions of "pollution prevention" and "pollution prevention plan." Specific references to pollution prevention were added to §§ 94.2, 94.3 and 94.12(a) (relating to the purpose of the regulation; scope of the regulation; industrial wastewater discharges to municipal facilities and plans to reduce or eliminate overloads).

The Department's Office of Pollution Prevention and Compliance Assistance is available to provide assistance in identifying pollution prevention opportunities to applicants subject to these provisions. For more information, contact:

Department of Environmental Protection
Office of Pollution Prevention and Compliance Assistance
Rachel Carson State Office Building
P. O. Box 8772
Harrisburg, PA 17105-8772
(717) 787-0540

or contact the nearest Department Regional Office or access the Department's WEB site at http://www.dep.state.pa.us (Choose "Pollution Prevention").

H. *Sunset Review*

These final-form 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.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 12, 1997, the Department submitted a copy of the notice of proposed rulemaking, published at 27 Pa.B. 4334 (August 23, 1997), to IRRC and the Chairperson 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 all comments received, as well as other documentation.

In preparing these final-form regulations, the Department has considered all comments received from the Commission and the public. No comments were received from either of the Committees.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), these final-form regulations were deemed approved by the House and Senate Committees on July 31, 1998. IRRC met on August 11, 1998, and approved the final-form regulations in accordance with section 5.1(e) of the Regulatory Review Act.

J. *Findings*

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 final-form regulations do not enlarge the purpose of the proposal published at 27 Pa.B. 4334.

(4) These final-form regulations are necessary and appropriate for the administration and enforcement of the authorizing acts identified in Section C of this Preamble.

K. *Order*

The Board, acting under authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapter 94, are amended by amending §§ 94.1—94.3, 94.11—94.15, 94.21, 94.22, 94.31 and 94.57 and by deleting §§ 94.61—94.64 to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Senate and House Committees as required by the Regulatory Review Act.

(c) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(d) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

(*Editor's Note:* The following sections were not among the sections proposed to be amended at 27 Pa. B. 4334 (August 23, 1997): §§ 94.21, 94.22, 94.31 and 94.57.)

JAMES M. SEIF,
Chairperson

Fiscal Note: Fiscal Note 7-322 remains valid for the final adoption of the subject regulations.

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4215 (August 22, 1998).)

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart C. PROTECTION OF NATURAL RESOURCES

ARTICLE II. WATER RESOURCES

CHAPTER 94. MUNICIPAL WASTELOAD MANAGEMENT

GENERAL PROVISIONS

§ 94.1. Definitions.

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

Average daily organic load—The arithmetic mean of all samples of 5-day Biochemical Oxygen Demand, expressed in terms of pounds per day, collected over a calendar month.

Ban—A restriction placed by the Department on additional connections to an overloaded sewer system or a sewer system tributary to an overloaded plant and other necessary measures the Department may require to prevent or alleviate an actual organic or hydraulic overload or an increase in an organic or hydraulic overload.

Bypass—The intentional diversion of wastewater either at or after the headworks of the plant.

CAP—Corrective action plan—A plan and schedule developed by the permittee of a sewerage facility which has an existing or projected overload. A CAP establishes actions needed and a schedule to reduce the overload and provide needed capacity.

CSO—Combined sewer overflow—An intermittent overflow, or other untreated discharge from a municipal combined sewer system (including domestic, industrial

and commercial wastewater and stormwater) which results from a flow in excess of the dry weather carrying capacity of the system.

Capacity—The rated ability of the plant to receive and effectively treat a specified load. When the term is used in reference to a pump station or sewer system, the term refers to the rated ability to effectively convey a specified load.

Clean Water Act—33 U.S.C.A. §§ 1251, 1252, 1254—1256, 1259, 1262, 1263, 1281—1288, 1291, 1292, 1294—1297, 1311, 1314, 1315, 1317—1319, 1321—1324, 1328, 1341, 1342, 1344, 1345, 1362, 1364, 1375 and 1376.

Combined sewer system—A sewer system which has been designed to serve as both a sanitary sewer and a storm sewer.

Connection—The connection of a structure which generates or could generate hydraulic or organic loads to a sewer system.

Discharge—Wastewater flow which is or would be discharged to a sewer system.

Exception to a ban—An allowable connection to a sewer system even though a ban is in effect.

Extension—An addition to the sewer system to accommodate more than one connection.

Facilities of public need—Hospitals, health clinics, nursing care facilities, primary and secondary education facilities, fire and police stations and correctional institutions.

Headworks—For the purposes of this chapter, the first treatment unit or wetwell within the plant.

Hydraulic design capacity—The maximum monthly design flow, expressed in millions of gallons per day, at which a plant is expected to consistently provide the required treatment or at which a conveyance structure, device or pipe is expected to properly function without creating a backup, surcharge or overflow. This capacity is specified in the water quality management permit (Part II permit issued under Chapter 91) (relating to general provisions).

Hydraulic overload—The condition that occurs when the monthly average flow entering a plant exceeds the hydraulic design capacity for 3-consecutive months out of the preceding 12 months or when the flow in a portion of the sewer system exceeds its hydraulic carrying capacity.

Industrial user—An establishment which discharges or introduces industrial wastes into a sewerage facility.

Interference—A discharge which, alone or in conjunction with a discharge from other sources, does the following:

(i) Inhibits or disrupts the sewerage facility, its treatment processes or operations or its sludge processes, use or disposal.

(ii) Is a cause of a violation of a requirement of the sewerage facility's NPDES permit—including an increase in the magnitude or duration of a violation—or of the prevention of sewage sludge use or disposal in compliance with the following statutory provisions and regulations or permits issued thereunder—or more stringent State or local regulations:

(A) Section 405 of the Clean Water Act (33 U.S.C.A. § 1345).

(B) The Solid Waste Disposal Act (SWDA) (42 U.S.C.A. §§ 6901—6987), including Title II, more commonly referred to as the Resource Conservation and Recovery Act of 1976 (RCRA).

(C) State regulations contained in a State sludge management plan prepared under Subtitle D of the SWDA, the Clean Air Act (42 U.S.C.A. §§ 7401—7642), the Toxic Substances Control Act (15 U.S.C.A. §§ 2601—2629) and the Marine Protection, Research, and Sanctuaries Act of 1972 (16 U.S.C.A. §§ 1431—1434; 33 U.S.C.A. §§ 1401, 1402, 1411—1421 and 1441—1445).

Load—The rate of flow and organic strength of the wastewater, including infiltration, discharged to a plant, as measured at the influent of the plant or in the sewer system or a portion of it.

Monthly average flow—The total flow received at a sewerage facility or another portion of the sewer system during any 1-calendar month divided by the number of days in that month. This value is always expressed in millions of gallons per day (mgd).

Monthly average organic loading—The total organic load received at a plant during any 1 calendar month divided by the number of days in that month. This value is expressed in pounds per day of biological oxygen demand after 5 days (BOD_5).

NPDES permit—A permit or equivalent document or requirements issued by the EPA, or, if appropriate, by the Department, to regulate the discharge of pollutants under section 402 of the Clean Water Act (33 U.S.C.A. § 1342).

Official plan—A comprehensive plan for the provision of adequate sewage systems adopted by a municipality possessing authority or jurisdiction over the provision of the systems and submitted to and approved by the Department as provided by the Pennsylvania Sewage Facilities Act (35 P. S. §§ 750.1—750.20) and Chapter 71 (relating to administration of sewage facilities planning program).

Organic design capacity—The highest daily organic load at which a sewage treatment facility or a portion thereof is expected to provide a specific predetermined level of treatment. This capacity is normally specified in the water quality management permit (Part II permit issued under Chapter 91).

Organic overload—The condition that occurs when the average daily organic load exceeds the organic design capacity upon which the permit and the plant design are based.

PPP—Pollution Prevention Plan—A written document that guides a discharger in the reduction of pollutants at their source before they reach the wastewater treatment plant. The PPP shall, at a minimum, address the following elements:

(i) An explicit statement of top management support for implementation of the pollution prevention plan.

(ii) A process characterization that identifies and characterizes the input of raw materials, outflow of products and generation of wastes.

(iii) An estimate of the amount of each waste generated.

(iv) Development of pollution prevention alternatives based on an estimate of reductions in the amount and toxicity of waste from each pollution prevention activity.

(v) An identification of pollution prevention opportunities to be implemented and an implementation timetable with interim and final milestones and periodic review of implemented recommendations.

Pass through—A discharge which exits the plant into waters of this Commonwealth in quantities or concentra-

tions which, alone or in conjunction with a discharge from other sources, is a cause of a violation of a requirement of the plant's NPDES permit—including an increase in the magnitude or duration of a violation.

Permit—A permit required by section 202 or 207 of the act (35 P. S. §§ 691.202 and 691.207).

Permittee—A person who possesses or is required to possess a permit.

Plant—Devices, systems or other works installed for the purpose of treating, recycling or disposing of sewage.

Pollution prevention—Source reduction and other practices—for example: direct reuse or in-process recycling—that reduce or eliminate the creation of pollutants through increased efficiency in the use of raw materials, energy, water or other resources, or protection of natural resources by conservation.

Pretreatment—The reduction of the amount of pollutants, the elimination of pollutants or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing the pollutants into a sewerage facility.

Pretreatment program—A program administered by a sewerage facility that has been approved by the EPA under 40 CFR 403.11 (relating to approval procedures for pretreatment programs and granting of removal credits).

Prohibition—A restriction placed by a permittee on additional connections to an overloaded sewer system or a sewer system tributary to an overloaded plant.

Sanitary sewer overflow—An intermittent overflow of wastewater, or other untreated discharge from a separate sanitary sewer system (which is not a combined sewer system), which results from a flow in excess of the carrying capacity of the system or from some other cause prior to reaching the headworks of the plant.

Separate sanitary sewer system—A sewer system or part thereof which is specifically designed and intended to carry sanitary sewage separate from stormwater as specified in the permit.

Sewerage facilities—The term used to collectively describe a plant and sewer system owned by or serving a municipality.

Sewer system—The pipelines or conduits, pumping stations and force mains, and other appurtenant constructions, devices and facilities used for conveying sewage to a plant.

(b) A word or phrase which is not defined in this chapter but which is defined in Chapter 92 (relating to National Pollutant Discharge Elimination System) has the meaning as defined therein.

§ 94.2. Purpose.

This chapter is intended to prevent unpermitted and insufficiently treated wastewater from entering waters of this Commonwealth by requiring the owners and operators of sewerage facilities to project, plan and manage future hydraulic, organic and industrial waste loadings to their sewerage facilities. Reductions in wastewater volume and pollutant mass loadings through the application of pollution prevention practices are encouraged to avoid hydraulic, organic and industrial wastewater overloads at sewerage facilities to accomplish the following objectives:

(1) Prevent the occurrence of overloaded sewerage facilities.

(2) Limit additional extensions and connections to an overloaded sewer system or a sewer system tributary to an overloaded plan.

(3) Improve opportunities to prevent or reduce the volume and toxicity of industrial wastes generated and discharged to sewerage facilities and where prevention and reduction opportunities have been maximized, and to recycle and reuse municipal and industrial wastewaters and sludges.

§ 94.3. Scope.

This chapter requires owners of sewerage facilities to properly plan, manage and maintain sewerage facilities in a manner which will do the following:

(1) Anticipate and prevent overloading sewerage facilities.

(2) Limit additional extensions and connections to an overloaded sewer system or a sewer system tributary to an overloaded plant.

(3) Prevent the introduction into sewerage facilities of pollutants which will interfere with the operation of the plant or pass through or otherwise be incompatible with the treatment process or sewerage facility.

(4) Improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludges.

GENERAL REQUIREMENTS

§ 94.11. Sewer extensions.

(a) A sewer extension may not be constructed if the additional flows contributed to the sewerage facilities from the extension will cause the plant, pump stations or other portions of the sewer system to become overloaded or if the flows will add to an existing overload unless the extension is in accordance with an approved CAP submitted under § 94.21 or § 94.22 (relating to existing overload; and projected overload) or unless the extension is approved under § 94.54 (relating to sewer line extension).

(b) The Department may issue a permit for the construction of a capped sewer, which would be tributary to an overloaded sewerage facility where the capped sewer would not be placed into service until adequate conveyance and treatment capacity becomes available under all of the following conditions:

(1) The proposed project is consistent with the approved official plan of the municipality.

(2) The municipality or municipal authority which owns the sewer system to which the capped sewer would connect has an approved program for providing adequate conveyance and treatment capacity within 5 years of the date of issuance of a capped sewer permit by the Department.

(3) Other Department requirements for sewer design and construction are met.

§ 94.12. Annual report.

(a) To provide for annual review of sewerage facilities and ensure that there is sufficient time to address existing operational or maintenance problems or to plan and construct needed additions, plant permittees shall submit a complete and accurate wasteload management annual report, in duplicate, by March 31 of each year to the appropriate regional office of the Department. The report shall be signed by the preparer and by the permittee of the plant and include the following:

(1) A line graph depicting the monthly average flows (expressed in millions of gallons per day) for each month

for the past 5 years and projecting the flows for the next 5 years. The graph shall also include a line depicting the hydraulic design flow (also expressed in millions of gallons per day) of the plant included in the water quality management permit (Part II permit issued under Chapter 91 (relating to general provisions)).

(2) A line graph depicting the monthly average organic loading (expressed as pounds per day of BOD_5) for each month for the past 5 years and projecting the monthly average organic loading for the next 5 years. The graph shall also include a line depicting the organic loading design (also expressed in pounds per day of BOD_5) of the plant included in the water quality management permit (Part II permit issued under Chapter 91).

(3) A brief discussion of the basis for the projections referred to in paragraphs (1) and (2), as well as a description of the time needed to expand the plant to meet the load projections, if necessary. Data used to support those projections should be included in an appendix to the annual report.

(4) A map showing all sewer extensions constructed within the past calendar year, sewer extensions approved or exempted in the past year in accordance with the Pennsylvania Sewage Facilities Act (35 P. S. §§ 750.1—750.20) and Chapter 71 (relating to administration of the sewage facilities program), but not yet constructed, and all known proposed projects which require public sewers but are in the preliminary planning stages. The map shall be accompanied by a list summarizing each extension or project and the population to be served by the extension or project. If a sewer extension approval or proposed project includes schedules describing how the project will be completed over time, the listing should include that information and the effect this build-out-rate will have on population served.

(5) A discussion of the permittee's program for sewer system monitoring, maintenance, repair and rehabilitation, including routine and special activities, personnel and equipment used, sampling frequency, quality assurance, data analyses, infiltration/inflow monitoring, and, where applicable, maintenance and control of combined sewer regulators during the past year.

(6) A discussion of the condition of the sewer system including portions of the system where conveyance capacity is being exceeded or will be exceeded in the next 5 years and portions where rehabilitation or cleaning is needed or is underway to maintain the integrity of the system and prevent or eliminate bypassing, combined sewer overflow, sanitary sewer overflow, excessive infiltration and other system problems.

(7) A discussion of the condition of sewage pumping stations, including a comparison of the maximum pumping rate with present maximum flows and the projected 2-year maximum flows for each station.

(8) A report, if applicable, of industrial wastes discharged into the sewer system. This report shall include the following:

(i) A copy of any ordinance or regulation governing industrial waste discharges to the sewer system or a copy of amendments adopted since the initial submission of the ordinance or regulation under this chapter, if it has not previously been submitted. Ordinances, regulations or fee structures may provide incentives to industrial waste dischargers to use pollution prevention techniques to reduce or eliminate the generation of industrial wastewater discharges to the sewer system.

(ii) A discussion of the permittee's or municipality's program for surveillance and monitoring of industrial waste discharges into the sewer system during the past year.

(iii) A discussion of specific problems in the sewer system or at the plant, known or suspected to be caused by industrial waste discharges and a summary of the steps being taken to alleviate or eliminate the problems. The discussion shall include a list of industries known to be discharging wastes which create problems in the plant or in the sewer system and action taken to eliminate the problem or prevent its recurrence. The report may describe pollution prevention techniques in the summary of steps taken to alleviate current problems caused by industrial waste dischargers and in actions taken to eliminate or prevent potential or recurring problems caused by industrial waste dischargers.

(9) A proposed plan to reduce or eliminate present or projected overloaded conditions under §§ 94.21 and 94.22 (relating to existing overload; and projected overload).

(b) Permittees of sewer systems which contribute sewage flows to the plant shall submit information to the permittee of the plant as required to facilitate preparation of the annual report.

§ 94.13. Measuring, indicating and recording devices.

(a) A plant which receives or will receive within the next 5 years, monthly average flows exceeding 100,000 gallons per day shall be equipped to continuously measure, indicate and record the flow. The permittee of the plant shall install equipment necessary for these measurements within 6 months after the date when such a flow becomes evident.

(b) Flow measuring, indicating and recording equipment shall be calibrated annually, and the calibration report shall be included in the annual report submitted under § 94.12 (relating to annual report).

§ 94.14. Approval of official plans and revisions.

No official plan, official plan revision or supplement will be approved by the Department or delegated agency, nor will an exemption from the planning requirements be granted under Chapter 71 (relating to administration of the sewage facilities planning program) that is inconsistent with this chapter.

§ 94.15. Pretreatment program development.

In cases where pollutants contributed by industrial users result in interference or pass through, and the violation is likely to recur, a permittee shall develop and implement specific local limits for industrial users and other users, as appropriate, that together with appropriate sewerage facility or operational changes, are necessary to ensure renewed or continued compliance with the plant's NPDES permit or sludge use or disposal practices.

ACTION ON OVERLOAD FACILITIES

§ 94.21. Existing overload.

(a) If the annual report establishes or if the Department determines that the sewerage facilities or any portions thereof are either hydraulically or organically overloaded, the permittee of the sewerage facilities shall comply with the following program:

(1) Prohibit new connections to the overloaded sewerage facilities except as approved by the permittee under the standards for granting exceptions contained in §§ 94.55—94.57 (relating to building permit issued prior

to ban; replacement of a discharge; and other exceptions). No building permit may be issued by a governmental entity which may result in a connection to overloaded sewerage facilities or increase the load to those sewerage facilities from an existing connection. The permittee shall retain records of exceptions granted and make the records available to the Department upon request.

(2) Immediately begin work for the planning, design, financing, construction and operation of the sewerage facilities that may be necessary to provide required capacities to meet anticipated demands for a reasonable time in the future and resulting in a project that is consistent with the applicable official plans approved under the Pennsylvania Sewage Facilities Act (35 P. S. §§ 750.1—750.20) and the regulations thereunder in Chapter 71 (relating to administration of the sewage facilities planning program) and consistent with the requirements of the Department and the Federal Government regarding areawide planning and sewerage facilities.

(3) Submit to the Regional Office, for the review and approval of the Department, a written CAP to be submitted with the annual report or within 90 days of notification of the Department's determination of overload, setting forth the actions to be taken to reduce the overload and to provide the needed additional capacity. The written CAP shall include, but not be limited, to limitations on and a program for control of new connections to the overloaded sewerage facilities and a schedule showing the dates each step toward compliance with paragraph (2) shall be completed.

(b) Upon receipt of an acceptable CAP submitted in accordance with subsection (a)(3), the Department may modify or lift the requirement to prohibit new connections and the issuance of building permits contained in subsection (a)(1). In determining whether the requirement to prohibit new connections shall be modified or lifted, the Department will consider the extent to which the permittee plans to limit new connections; the timing for provisions of additional capacity and reduction of the existing overload; and the impact of the overload on treatment plant effluent quality, water quality degradation and public health.

(c) The Department may approve permits for extensions to overloaded sewerage facilities when the following conditions are met:

(1) The proposed extension is consistent with an acceptable CAP submitted under subsection (a)(3).

(2) The proposed extension is consistent with the applicable official plan approved under the Pennsylvania Sewage Facilities Act and the regulations adopted thereunder at Chapter 71.

(3) The additional load from the proposed extension will not have a significant adverse impact on the water quality of the receiving waters.

(4) The proposed extension is in accordance with any other applicable requirement of this title.

(5) The connections to the extension are controlled in accordance with the CAP submitted in accordance with subsection (a)(3); provided that, no connections to extension may be allowed when the approved CAP is not being implemented in accordance with the schedule contained therein.

§ 94.22. Projected overload.

If the annual report shows or if the Department determines that the sewerage facilities or any portion thereof will, within the next 5 years, become hydraulically or organically overloaded, the permittee of the sewerage facilities shall comply with the following:

(1) Submit a report or CAP to the regional office, with the annual report or within 90 days of notification of the Department's determination, setting forth steps to be taken by the permittee to prevent the sewerage facilities from becoming hydraulically or organically overloaded. If the steps to be taken include planning, design, financing, construction and operation of sewerage facilities, the facilities shall be consistent with an official plan approved under the Pennsylvania Sewage Facilities Act (35 P. S. §§ 750.1—750.20) and the regulations thereunder in Chapter 71 (relating to administration of the sewage facilities planning program) and consistent with the requirements of the Department and the Federal government regarding areawide planning and sewerage facilities.

(2) Limit new connections to and extensions of the sewerage facilities based upon remaining available capacity under a plan submitted in accordance with this section.

IMPOSITION OF BAN

§ 94.31. Organic or hydraulic overload.

A ban on connections will be imposed by the Department whenever the Department determines that the sewerage facilities or any portion thereof are either hydraulically or organically overloaded or that the discharge from the plant causes actual or potential pollution of the waters of this Commonwealth and, in addition, that one or more of the following conditions prevail:

(1) The Department determines that a ban is necessary to prevent or alleviate endangerment of public health.

(2) The permittee has failed to submit a satisfactory plan or has failed to implement the program as required by § 94.21 (relating to existing overload).

EXCEPTIONS TO BANS

§ 94.57. Other exceptions.

Connections which are necessary to eliminate a public health hazard or which are necessary for the operation of a facility of public need as the term is defined in § 94.1 (relating to definitions) shall constitute an exception to a ban.

§§ 94.61—94.64. (Reserved).

[Pa.B. Doc. No. 98-1440. Filed for public inspection September 4, 1998, 9:00 a.m.]

[25 PA. CODE CHS. 128, 129, 131 AND 139]
Air Quality Amendments (RBI 2)

The Environmental Quality Board (Board), by this Order, amends Chapters 128, 129, 131 and 139 to read as set forth in Annex A.

These amendments delete portions of Chapter 128 (relating to alternative emission reduction limitations) which established alternative emission reduction limitations for certain air contamination sources. Section 129.56 (relating to storage tanks greater than 40,000 gallons capacity containing VOCs) is amended to allow owners and operators of floating roof storage tanks with capacities greater than 40,000 gallons up to 45 days to complete repairs on defective storage tank seals. An additional

30-day extension may be granted by the Department of Environmental Protection (Department) if the storage tank vessel cannot be emptied or repaired within the 45-day time frame. Section 129.67(b)(2) (relating to graphic arts systems) is amended to include the term "less water," which was erroneously deleted in a previous rulemaking. Section 129.70 is amended to delete the Department's perchloroethylene (PCE) requirements for dry cleaning facilities because PCE is no longer regulated as a volatile organic compound (VOC). The rulemaking also deletes the sulfates (as H_2SO_4) ambient air quality standard in § 131.3 (relating to ambient air quality standards) and the sampling and analytical procedures in § 139.32 (relating to sampling and analytical procedures) for sulfates (as H_2SO_4).

This final rulemaking was adopted by the Board at its meeting of June 16, 1998.

A. *Effective Date*

These amendments will be effective immediately upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. *Contact Persons*

For further information, contact Terry Black, Chief, Regulation and Policy Development Section, Division of Compliance and Enforcement, Bureau of Air Quality, Rachel Carson State Office Building, 12th Floor, P. O. Box 8468, Harrisburg, PA 17105-8468 (717) 787-1663, or Joyce E. Epps, Assistant Counsel, Bureau of Regulatory Counsel, Office of Chief Counsel, Rachel Carson State Office Building, 9th Floor, P. O. Box 8464, Harrisburg, PA 17105-8464 (717) 787-7060.

C. *Statutory Authority*

This final rulemaking is being made under the authority of section 5 of the Air Pollution Control Act (35 P. S. § 4005), which grants to the Board the authority to adopt rules and regulations for the prevention, control, reduction and abatement of air pollution in this Commonwealth.

D. *Background and Purpose*

On August 4, 1995, Secretary Seif issued the "Directive on Review of Existing Regulations and Technical Guidance." This directive mandated an extensive review of the Department's regulations and technical guidance and provided an opportunity for public comments on the results of this Regulatory Basics Initiative (RBI). The goals of the RBI included identifying those regulations that were more stringent than Federal requirements, obsolete or redundant or no longer necessary. The RBI also required the Department to identify regulations which inhibited new green technologies and failed to encourage pollution prevention approaches.

Subsequently, the Governor signed Executive Order 1996-1 entitled "Regulatory Review and Promulgation" on February 6, 1996. The Executive Order establishes procedures for the review of existing regulations and the drafting and promulgation of new regulations. General requirements of Executive Order 1996-1 include the promulgation of regulations which have a compelling public interest, regulatory costs which do not outweigh their benefits and regulations that are no more stringent than standards imposed by Federal law unless justified by a compelling State interest.

This final rulemaking is consistent with the principles of Executive Order 1996-1 and the Department's RBI, and deletes the obsolete alternative emission limitations in Chapter 128 as well as the redundant PCE requirements for dry cleaners in § 129.70. The volatile organic storage tank requirements in § 129.56 (relating to storage tanks greater than 40,000 gallons capacity containing VOCs) are being revised to conform to Federal requirements for repairing defective floating roof seals in volatile organic storage tanks. These amendments also delete the sulfates (as H_2SO_4) ambient air quality standard and sampling and analysis techniques codified in Chapters 131 and 139 (relating to ambient air quality standards; and sampling and testing) which are no longer necessary and not required by Federal law.

The Department consulted with the Air Subcommittee of the Air Quality Technical Advisory Committee (AQTAC) during the development of the final amendments to Chapters 128, 129, 131 and 139. On January 16, 1998, AQTAC voted to support the Department's recommendation to submit this final rulemaking to the Board for consideration.

E. *Summary of Regulatory Requirements*

These final amendments delete portions of Chapter 128. Under the existing regulations, the owners and operators of air contamination sources at 12 facilities, including Andre Greenhouses, Inc., United States Steel Corporation, Scott Paper, Bethlehem Steel Corporation and Sun Refining and Marketing Company, submitted proposals to the Department to implement alternative emission reduction limitations for certain air contamination sources. Alternative emission reduction limitations for those sources were incorporated in revised operating permits, codified in the *Pennsylvania Code* and submitted to the United States Environmental Protection Agency (EPA) as revisions to the State Implementation Plan (SIP). Eleven of the 12 alternative emission reduction limitations are no longer necessary due to changes in processes and equipment or the closing of the affected facility. Consequently, the final amendments delete the alternative emission reduction limitations for 11 of the 12 facilities.

These amendments include revisions to several provisions in Chapter 129 (relating to standards for sources). Final revisions to § 129.56 will allow the owners and operators of volatile organic liquid storage tanks to empty the tanks and repair the seals within 45 days if the floating roof seals are defective. A 30-day extension may be requested from the Department if the request includes a demonstration that alternative storage capacity is unavailable. Section 129.56 does not presently include a time frame for repairing or emptying of defective organic liquid storage tanks. This revision ensures that § 129.56 is consistent with the Federal procedures in 40 CFR 60.113b(b)(4)(iii) (relating to testing and procedures).

The amendment to § 129.67(b)(2) revises the graphic arts systems requirements by adding the term "less water." This term was inadvertently omitted during a previous rulemaking (22 Pa.B. 2720 (May 23, 1992)). The addition of the term "less water" clarifies that water is not to be considered when demonstrating compliance with the requirements.

This final rulemaking deletes § 129.70. In 1981, as part of its ozone strategy, the Department adopted PCE requirements for certain dry cleaning facilities which emitted more than 100 tons per year of VOCs. The EPA no longer considers PCE to be a photochemically reactive compound and removed the compound from its listing of

VOCs. Consequently, § 129.70 is no longer necessary as a result of EPA's finding. However, new and existing dry cleaning facilities in this Commonwealth with the potential to emit more than 10 tons of PCE a year must comply with the National Emission Standards for Hazardous Air Pollutants (NESHAP) for PCE dry cleaning facilities published at 58 FR 49354 (September 22, 1993). The NESHAP for those PCE dry cleaning facilities specifies control of PCE emissions to the level of the maximum achievable control technology (MACT) required under section 112 of the Clean Air Act.

The final rulemaking also deletes the sulfate (as sulfuric acid [H_2SO_4]) ambient air quality standard in § 131.3 and the related sampling and analysis techniques in § 139.32. The Department has retained the ambient air quality standards for beryllium because of its extreme toxicity and the total settled particulates (TSP) standard because of its usefulness Statewide as an investigative tool to address citizen complaints. With the exception of beryllium, there are no Federal ambient standards for those air contaminants for which maximum ambient air concentrations were established in September 1971.

In the final rulemaking, the Department has also retained the hydrogen fluoride standard and related sampling and analysis techniques due to concerns raised by representatives for the South and Southwest Philadelphia communities. Although the ambient air quality standard for hydrogen fluoride is not specifically required by the Clean Air Act, the Department is authorized under section 4.2(f) of the Air Pollution Control Act to retain regulations approved by the Board prior to July 9, 1992. The Department may also retain any ambient air quality standards adopted by the Board where no standard has been approved by the EPA (35 P. S. § 4004.2(f)).

The ambient air quality standard for hydrogen sulfide and associated sampling and analytical procedures in §§ 131.3 and 139.32 are also retained. The sampling of hydrogen sulfide has been used to investigate malodor complaints. During the past year, the Department's Southeast Regional Office received complaints concerning odors and hydrogen sulfide emissions from mushroom composting operations in London Grove Township, Chester County. To determine hydrogen sulfide concentrations and health effect measurements in the West Grove/Avondale area, the Department, in cooperation with the Pennsylvania Health Department, is currently conducting hydrogen sulfide monitoring and health assessments. Following the completion of the hydrogen sulfide monitoring by the Department and assessments by the Department of Health, the Department will evaluate whether the ambient air quality standard for hydrogen sulfide will be deleted in a subsequent rulemaking.

The Department will submit these amendments to the EPA as a revision to the SIP.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

The Board held three public hearings on the proposed rulemaking published at 27 Pa.B. 3058 (June 28, 1997). The hearings were held in Pittsburgh on July 28, 1997; Harrisburg on July 30, 1997; and Conshohocken on August 5, 1997. The Board did not receive any testimony during the public hearings. During the public participation process, persons interested in providing written comments were invited to submit comments, suggestions or objections on the proposal to the Board by September 4, 1997.

The Board reviewed written comments from eight individuals and organizations concerning the proposed deletion of the ambient air quality standards for sulfates, hydrogen fluoride and hydrogen sulfide in § 131.3 and the sampling and analysis techniques for those contaminants in § 139.32. One commentator, Air Products and Chemicals, Inc. supported the proposed deletion of those standards. However, the Board received written comments from seven organizations opposed to the deletion of the ambient air standard for hydrogen fluoride. These commentators stated that retention of the hydrogen fluoride standard and sampling techniques is required for public health and safety reasons in the South and Southwest Philadelphia communities because of their proximity to a facility which uses hydrogen fluoride. Because of their concerns, the hydrogen fluoride ambient air quality standard in § 131.3 and the sampling and analysis techniques in § 139.32 have been retained.

Although the Department did not receive any comments concerning the proposed deletion of the 1-hour and 24-hour hydrogen sulfide ambient air quality standard in § 131.3 and the sampling and analytical procedures in § 139.32, these provisions are retained pending the outcome of ongoing hydrogen sulfide sampling in Chester County.

G. *Benefits and Costs*

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

Benefits

Persons affected by this rulemaking will benefit from the deletion of obsolete or redundant air quality regulations. The revisions to § 129.56 will establish a time frame, consistent with Federal law, for the owners and operators of large organic liquid storage tanks to empty the storage tanks and make repairs on defective seals. The inclusion of a time frame for emptying the storage tanks and repairing the seals will also allow safer completion of repairs to defective seals on the floating roof tank.

The deletion of the PCE requirements for dry cleaning facilities in § 129.70 would allow the owners and operators of PCE dry cleaning facilities to eliminate duplicate recordkeeping to demonstrate compliance with Chapter 129 requirements and the Federal NESHAP requirements for PCE dry cleaning facilities.

Compliance Costs

These amendments are not expected to result in additional costs or savings to the regulated community or the general public. The Bureau of Air Quality will save an estimated $34,000 to $43,000 after sulfate analyses are no longer required for the estimated 1,281 sulfate filters analyzed each year.

Compliance Assistance Plan

The changes to § 129.67 will allow the owners and operators of storage tanks of greater than 40,000 gallons capacity up to 45 days to repair the floating roof seals or empty the storage vessels. The owners and operators of the tanks may request an additional 30 days to correct defective seals in the floating storage tanks. The regulated community, generally owners and operators of large storage tanks at petroleum terminals, chemical plants and refineries, will be advised of the compliance schedule included in the regulation for emptying and repairing large storage tanks.

Paperwork Requirements

This final rulemaking is not expected to result in increased paperwork requirements. Deletion of the sampling and analytical procedures for ambient air quality standard for sulfates (as sulfuric acid) will reduce paperwork requirements for the regulated community since monitoring reports required under § 139.53 will not be necessary. In addition, elimination of the PCE requirements for dry cleaning facilities will also reduce paperwork requirements for the owners and operators of PCE dry cleaning facilities.

H. *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.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 16, 1997, the Department submitted a copy of the proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In compliance with section 5(b.1) of the Regulatory Review Act, the Department also provided IRRC and the House and Senate Committees with copies of the comments as well as other documentation.

In preparing these final-form regulations, the Department has considered the comments received from the public. The Committees and IRRC had no objections, comments or suggestions to offer on these amendments.

These final-form regulations were deemed approved by the House and Senate Committees on July 20, 1998. IRRC met on July 30, 1998, and approved the final-form regulations in accordance with section 5(c) of the Regulatory Review Act.

J. *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 and public hearings were provided as required by law and all comments were considered.

(3) These final-form regulations do not enlarge the purpose of the proposal published at 27 Pa.B. 3058.

(4) These final-form regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of the Preamble and are reasonably necessary to achieve and maintain the National Ambient Air Quality Standards.

K. *Order of the Board*

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

(a) The regulations of the Department, 25 Pa. Code Chapters 128, 129, 131 and 139, are amended by amending §§ 129.56, 129.67, 131.3 and 139.32 and deleting §§ 128.11—128.20, 128.22 and 129.70 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form as required by law.

(c) The Chairperson shall submit this order and Annex A to IRRC and the Senate and House Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect immediately upon publication.

JAMES M. SEIF,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4007 (August 15, 1998).)

Fiscal Note: Fiscal Note 7-317 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart C. PROTECTION OF NATURAL RESOURCES

ARTICLE III. AIR RESOURCES

CHAPTER 128. ALTERNATIVE EMISSION REDUCTION LIMITATIONS

SPECIFIC LIMITATIONS

§ 128.11—128.20. (Reserved).

§ 128.22. (Reserved).

CHAPTER 129. STANDARDS FOR SOURCES

SOURCES OF VOCs

§ 129.56. Storage tanks greater than 40,000 gallons capacity containing VOCs.

* * * * *

(h) If a failure is detected during inspections required in this section, the owner or operator, or both, shall repair the items or empty and remove the storage vessel from service within 45 days. If this failure cannot be repaired within 45 days and if the vessel cannot be emptied within 45 days, a 30-day extension may be requested from the Department. A request for an extension shall document that alternate storage capacity is unavailable and specify a schedule of actions the owner or operator will take that will assure that the equipment will be repaired or the vessel will be emptied as soon as possible but within the additional 30-day time requested.

§ 129.67. Graphic arts systems.

(a) This section applies to facilities whose rotogravure and flexographic printing presses by themselves or in

combination with a surface coating operation subject to § 129.52 (relating to surface coating processes) have the potential to emit or have emitted VOCs into the outdoor atmosphere in quantities greater than 1,000 pounds (460 kilograms) per day or 100 tons (90,900 kilograms) per year during any calendar year since January 1, 1987.

(b) A person may not permit the emission into the outdoor atmosphere of VOCs from a rotogravure or flexographic printing press subject to this section unless one of the following limitations is met:

(1) The volatile fraction of the ink, as applied to the substrate, contains 25% or less by volume of VOC and 75% or more by volume of water.

(2) The ink, as applied to the substrate, less water, contains 60% by volume or more of solid material.

(3) The owner or operator installs and operates a carbon adsorption system, an incineration system or an alternative VOC emission reduction system which recovers or destroys at least 90% of the VOCs entering the system. The overall level of emission recovery or destruction may not be less than that necessary to comply with subsection (c).

(c) A capture system shall be used in conjunction with the emission control systems in subsection (b)(3). The design and operation of the capture and control system shall be consistent with good engineering practice and shall be designed to provide for a contemporaneous, overall reduction in VOC emission from each ink/press of at least the following:

(1) Seventy-five percent where a publication rotogravure process is employed.

(2) Sixty-five percent where another rotogravure process is employed.

(3) Sixty percent where a flexographic printing process is employed.

(d) Presses used only to check the quality of the image formation of newly etched or engraved printing cylinders are exempted from this section if the aggregate emissions from the presses do not exceed 400 pounds in a 30-day running period.

(e) To determine applicability under this section, emissions of VOCs used in clean-up operations shall be summed with emissions from surface coating and printing.

§ 129.70. (Reserved).

CHAPTER 131. AMBIENT AIR QUALITY STANDARDS

§ 131.3. Ambient air quality standards.

The following standards apply and, unless otherwise stated, are maximum values that may not be exceeded:

		Concentrations Averaged Over		
Contaminant	*1-Year*	*30-Days*	*24-Hours*	*1-Hour*
Settled particulate (total)	.8 mg./cm.^{2}/mo.	1.5 mg./cm.^{2}/mo.	—	—
Beryllium	—	.01 µg./m.^{3}	—	—
Fluorides (total soluble, as HF)	—	—	5 µg./m.^{3}	—
Hydrogen sulfide	—	—	.005 p.p.m.	.1 p.p.m.

CHAPTER 139. SAMPLING AND TESTING

Subchapter A. SAMPLING AND TESTING METHODS AND PROCEDURES

AMBIENT LEVELS OF AIR CONTAMINANTS

§ 139.32. Sampling and analytical procedures.

(a) Sampling and analytical techniques which may be used directly or employed as reference standards against which other methods may be calibrated shall be as follows:

Contaminant	*Sampling Method*	*Analytical Method*
Settled particulates (total)	Open top cylinder (6)	Gravimetric (6)
Beryllium	High-volume filtration (7)	Spectrographic (7)
Flourides (total soluble, as HF)	Filtration plus gas absorption (9)	Thorium-alizarin lake titration (9)
Hydrogen sulfide	Gas absorption (18)	Methylene blue method (18)

(b) The numbers following the reference standards in subsection (a) refer to the references contained in § 139.4 (relating to references).

[Pa.B. Doc. No. 98-1441. Filed for public inspection September 4, 1998, 9:00 a.m.]

Title 31—INSURANCE

INSURANCE DEPARTMENT

[31 PA. CODE CH. 41]

Fraternal Beneficial Societies Administration

The Insurance Department (Department) deletes § 41.1 (relating to extension of waiver of meetings) to read as set forth in Annex A. This rulemaking is made under the authority of sections 206, 506, 1501 and 1502 of The Administrative Code of 1929 (71 P. S. §§ 66, 186, 411 and 412); and the Fraternal Benefit Societies Code (40 P. S. §§ 1142-101—1142-701). Section 41.1 sets forth requirements that must be met in a request for waiver or extension of a meeting of a domestic fraternal beneficial society.

Purpose

The purpose of the rescission of § 41.1 is to eliminate an obsolete, unnecessary regulation. Section 41.1 was adopted May 18, 1943, under the authority of section 3 of the act of July 17, 1935 (P. L. 1092, No. 357) (Act 357) (40 P. S. § 1053) (now repealed). The regulation required that a request for waiver or extension of a meeting of a fraternal beneficial society shall be made by resolution of the board of directors or similar managing body. The resolution is required to contain six items of information listed in the regulation, including a certification that the request for waiver or extension has been approved by a majority of the subordinate lodges or bodies of the fraternal beneficial society.

Act 357 which initially authorized the regulation was transferred to 15 P. S. §§ 8501—8543 and later repealed by section 5(a)(9) of the act of November 15, 1972 (P. L. 1063, No. 271) (Act 271), 40 Pa.C.S. §§ 6501—6701. Act 271 was subsequently replaced by the act of July 29, 1977 (P. L. 105, No. 38) (Act 38) (40 P. S. §§ 1141-101—1141-1001). Finally, Act 38 was replaced by section 701 of the Fraternal Benefit Societies Code (40 P. S. § 1142-701).

Section 202 of the Fraternal Benefit Societies Code (40 P. S. § 1142-202) contains requirements relating to meetings of domestic fraternal benefit societies. The current statutory requirements relating to meetings of fraternal benefit societies are consistent with requirements relating to other types of insurers. However, § 41.1 contains additional requirements beyond those contained in current law, which requirements are not imposed on other types of insurers. Imposing special requirements on fraternal benefit societies regarding their meetings serves no compelling public interest. The statutory requirements are sufficient. Therefore, the regulation has been superseded by the existing statutory requirements in the Fraternal Benefit Societies Code (40 P. S. §§ 1142-101—1142-616) and are no longer needed.

Statutory Authority

The regulation is being deleted under the authority of sections 206, 506, 1501 and 1502 of The Administrative Code of 1929; and the Fraternal Benefit Societies Code. The regulation was adopted under the authority of section 3 of Act 357.

Comments

Notice of this rescission was published at 27 Pa.B. 3063 (June 28, 1997) as a proposed rulemaking with a 30-day public comment period.

No comments were received from the standing committees, industry trade associations or other parties during the 30-day public comment period. On August 27, 1997, the Independent Regulatory Review Commission (IRRC) submitted notice to the Department that IRRC had no objections, comments or suggestions to offer on the deletion of the regulation.

Fiscal Impact

The deletion of the regulation has no fiscal impact because of the obsolescence of the regulation.

Paperwork

The deletion of the regulation will impose no additional paperwork requirements on the Department or fraternal benefit societies.

Affected Parties

The deletion of the regulation affects fraternal benefit societies.

Effectiveness/Sunset Date

This rulemaking will become effective upon final publication in the *Pennsylvania Bulletin*. Because the rulemaking rescinds an obsolete, unnecessary regulations, no sunset date has been assigned.

Contact Person

Questions or comments regarding this final rulemaking may be addressed in writing to Peter J. Salvatore, Regulatory Coordinator, Office of Special Projects, 1326 Strawberry Square, Harrisburg, PA 17120, (717) 787-4429.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 18, 1997, the Department submitted a copy of the proposed rulemaking to IRRC, the Chairpersons of the House Insurance Committee and the Senate Banking and Insurance Committee. In addition to the submitted rulemaking, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of the material is available to the public upon request.

The final rulemaking was deemed approved by the House and Senate Committees on August 2, 1998, in accordance with section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)). The amendment was deemed approved by IRRC on August 4, 1998, under section 5(g) of the Regulatory Review Act.

Findings

The Insurance Commissioner finds that:

(1) Public notice of intention to adopt this rulemaking as amended by this order has been 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 the regulation thereunder, 1 Pa. Code, §§ 7.1 and 7.2.

(2) The adoption of this rulemaking in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statutes.

Order

The Insurance Commissioner, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 31 Pa. Code, are amended by deleting § 41.1 to read as set forth in Annex A.

(b) The Commissioner shall submit this order and Annex A to the Office of General Counsel and Office of Attorney General for approval as to form and legality as required by law.

(c) The Commissioner shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) The regulation deleted by this order shall be abolished upon publication in the *Pennsylvania Bulletin*.

M. DIANE KOKEN,
Insurance Commissioner

Fiscal Note: Fiscal Note 11-153 remains valid for the final adoption of the subject regulation.

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4215 (August 22, 1998).)

Annex A

TITLE 31. INSURANCE

Subpart D. FRATERNAL BENEFICIAL SOCIETIES

CHAPTER 41. (Reserved)

§ 41.1. (Reserved).

[Pa.B. Doc. No. 98-1442. Filed for public inspection September 4, 1998, 9:00 a.m.]

[31 PA. CODE CH. 57]

Publication of Citations and Notice of Hearings

The Insurance Department (Department) amends § 57.1 (relating to general requirements) to read as set forth in Annex A. This rulemaking is promulgated under the authority of sections 206, 506, 1501 and 1502 of The Administrative Code of 1929 (71 P. S. §§ 66, 186, 411 and 412). Notice of proposed rulemaking is omitted in accordance with section 204(1)(iii) and (3) of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204 (1)(iii) and (3)) (CDL).

Purpose

The purpose of this final omitted rulemaking is to delete obsolete language referring to a nonexistent practice. This rulemaking pertains to Departmental practice concerning publication of notice in the *Pennsylvania Bulletin*. Section 57.1 was adopted March 23, 1973.

Under section 204(1)(iii) and (3) of the CDL, notice of proposed rulemaking may be omitted if the agency finds that the notice procedures are unnecessary because the regulation pertains to agency procedure or practice or the agency finds that the regulation is contrary to the public interest.

Explanation of Regulatory Requirements

The title of Chapter 57, "Publication of Citations and Notice of Hearings," will be amended by deleting reference to "citations."

Section 57.1 will be amended by deleting a reference to an obsolete practice. The amendment will more narrowly tailor the language to reflect actual practice.

Fiscal Impact

The amendment will not have any impact on costs associated with the Department, insurance companies, political subdivisions or the general public.

Paperwork

The amendment will not impose additional paperwork requirements on the Department, insurers or the general public.

Persons Regulated

The amendment applies only to Departmental practice concerning publication of notices in the *Pennsylvania Bulletin*.

Effective/Sunset Date

This order is effective upon publication in the *Pennsylvania Bulletin*. No sunset date has been assigned.

Contact Person

Questions or comments regarding the rulemaking may be addressed in writing to J. Salvatore, Regulatory Coordinator, 1326 Strawberry Square, Harrisburg, PA 17120, (717) 787-4429.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on July 14, 1998, the Department submitted a copy of this amendment with the proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate Banking and Insurance Committee and the House Insurance Committee. On the same date, the rulemaking was submitted to the Office of Attorney General for review and approval under section 204(b) of the Commonwealth Attorneys Act (71 P. S. § 732-204(b)).

In accordance with section 5.1(d) of the Regulatory Review Act, the amendment was deemed approved by the Senate Banking and Insurance Committee and the House Insurance Committee on August 3, 1998. The amendment was deemed approved by IRRC on August 4, 1998, when section 5(g) of the Independent Regulatory Review Act.

Findings

The Insurance Commissioner finds that:

There is good cause under section 204 of the CDL, to amend the regulation effective upon publication, because this regulation pertains only to agency procedure and practice. An immediate effective date should best serve the public interest.

Order

The Insurance Commissioner, acting under the statutory authority, orders that:

(a) The regulations of the Department, 31 Pa. Code Chapter 57, are amended by amending § 57.1 to read as set forth in Annex A.

(b) The Department shall submit this order and Annex A to the Office of the Attorney General and Office of General Counsel for approval as to form and legality as required by law.

(c) The Department shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon its publication in the *Pennsylvania Bulletin*.

M. DIANE KOKEN,
Insurance Commissioner

Fiscal Note: 11-174. No fiscal impact; (8) recommends adoption.

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4215 (August 22, 1998).)

Annex A

TITLE 31. INSURANCE

PART I. GENERAL PROVISIONS

Subpart F. RULES OF PROCEDURE

CHAPTER 57. PUBLICATION OF NOTICE OF HEARINGS

§ 57.1. General requirements.

All notices of hearing pertaining to alleged violations of the insurance laws of the Commonwealth will hereafter be published in the *Pennsylvania Bulletin* for the purpose of informing the respondents, the insurance industry and the public of pending actions.

[Pa.B. Doc. No. 98-1443. Filed for public inspection September 4, 1998, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

General Revisions

The State Board of Pharmacy (Board) amends Chapter 27 (relating to State Board of Pharmacy) to read as set forth in Annex A. The amendments delete dated and redundant language and clarify standards of practice and licensure requirements.

A. *Effective Date*

The amendments will be effective upon publication in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

The amendments are authorized under sections 3(f), 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P. S. §§ 390-3(f), 390-4(j) and 390-6(k)(1) and (9)).

C. *Background and Purpose*

The amendments are designed to maintain health and safety standards in the delivery of pharmacy services to Pennsylvanians consistent with current business and professional practices.

The amendments generally revise, clarify and update various provisions of the Board's regulations. Outdated language has been deleted, as has redundant language. Amendments define a "pharmacy technician" and enlarge the scope of technician utilization. They define a "satellite pharmacy" and clarify when institutions will be required to obtain separate permits for pharmacies in the system. Amendments further clarify and update provisions pertaining to sanitary standards, construction and equipment requirements and standards of practice. Provisions related to pharmacy internships and licensure by reciprocity are also clarified.

D. *Summary of Comments on Proposed Rulemaking and Board Responses*

Notice of proposed rulemaking was published at 26 Pa.B. 1032 (March 9, 1996). The Board received comments from 25 public commentators, including the Pennsylvania Society of Health-System Pharmacists, the Hospital and Healthsystem Association of Pennsylvania, individual community, chain and hospital pharmacies and pharmacists, health system pharmacists, educators and Legislators. The House Professional Licensure Committee (House Committee) and the Independent Regulatory Review Commission (IRRC) also provided comments and recommendations which the Board has considered in final rulemaking.

Pharmacy Technicians

The vast majority of commentators expressed concern that the proposed amendments would unduly restrict the utilization of pharmacy technicians in the delivery of cost-effective pharmaceutical services. Specifically, commentators objected to the requirement in proposed rulemaking that a pharmacist supervise no more than two pharmacy technicians at any time. (§ 27.12(d)(5)). Commentators suggested that certain dispensing functions involving automation and remote order entries could be safely performed with ratios higher than two-to-one, while other functions could require one-to-one supervision. The commentators recommended that a pharmacist be permitted the latitude to exercise professional judgment in determining the number of technicians the pharmacist may effectively supervise. They further contended that the use of more technicians to perform routine functions such as counting pills, stocking pharmacy shelves, preparing prescription labels and certain recordkeeping, will free pharmacists for other important activities requiring professional judgment. These activities include verifying the accuracy and appropriateness of a prescription or drug order prior to its being dispensed and providing patient counseling services. Concurring with these comments, IRRC recommended that the ratio in § 27.12(d)(5) be deleted in final rulemaking.

The Board notes that the purpose of the proposed ratio was a recognition that public health and safety issues are implicated when unlicensed persons such as technicians are performing pharmacy services. Indeed, most jurisdictions limit the number of pharmacy technicians a pharmacist may supervise at any given time. However, in view of the objections raised, and in light of the fact that the ratio represents only one factor in determining appropriate supervision of pharmacy technicians, the Board in final rulemaking has deleted § 27.12(d)(5). The Board is satisfied that other provisions in the regulation which outline the parameters of technician practice, list prohibited duties, set out supervisory responsibilities of pharmacists and require written protocols in various pharmacy settings provide adequate notice to pharmacists of their supervisory responsibilities over technicians and ultimate responsibility for all pharmacy services rendered.

Several commentators objected to the requirement that a pharmacist review a prescription or drug order prior to its preparation and again prior to its being dispensed. The commentators suggested that the review by a pharmacist of a prescription or drug order only prior to its being dispensed to verify the accuracy of the preparation would provide more efficient management of the pharmacist's time. Likewise, the commentators perceived the proposed rulemaking to require a pharmacist to be "hovering" over a technician to direct the technicians every move. This, the commentators suggested, was an ineffi-

cient and costly proposition. IRRC, on the other hand, suggested that the act requires the Board to adopt a more stringent standard than that proposed.

The Board has reviewed sections 5(a)(7) and 8(2) of the act (63 P. S. §§ 390-5(a)(7) and 390-8(2)), which provide that "other authorized personnel . . . may assist the pharmacist in the pharmacy under the direct and immediate personal supervision of a licensed pharmacist . . ." The Board does not agree that the act requires constant pharmacist supervision of all technician activities. Rather, the Board agrees with the public commentators that an "on-premises" supervision standard is not only consistent with consumer safety and efficient practice, but also tracks the language of the statute. The Board also agrees that a review of a prescription or drug order prior to its being dispensed to verify the final product is cost-effective and sufficient to satisfy consumer safety concerns. Accordingly, in final rulemaking, § 27.12(b)(1)—(3) has been amended to accomplish this goal.

Two commentators as well as IRRC acknowledged that written protocols are appropriate to define the duties of a pharmacy technician because the technician is an unlicensed person assisting in the practice of pharmacy, but sought more specific guidance as to what the contents of a written protocol should include. The Board notes that § 27.12 outlines the duties which a pharmacy technician may perform and identifies the responsibilities of the supervising pharmacist. The Board suggests that the written protocol identify the specific tasks which the pharmacy technician will be permitted to perform in the particular pharmacy practice, the supervision which the pharmacist will provide, the training the technician must have and the tasks which the technician may not perform. The Board likens the written protocol to a training or operations manual currently utilized in pharmacy practice. The Board declines to further expand upon the relatively detailed provisions already contained in § 27.12 in an effort to avoid unnecessary regulation inconsistent with Executive Order 1996-1.

A commentator representing hospital pharmacists expressed concern that proposed § 27.12(d)(3)(ii), prohibiting pharmacy technicians from assisting in the preparation of Schedule II controlled substances, would result in significant additional costs to institutions where technicians perform such tasks as delivering controlled drugs to nursing unit stock, stocking automated dispensing machines and performing some inventory functions. The Board has reviewed this provision, and has determined that the prohibition is unnecessary to safe pharmacy practice. The written protocols required in § 27.12(d)(4), together with the supervising pharmacist's acceptance of responsibility for prescriptions and drug orders which are dispensed, are sufficient to provide safe and efficient pharmaceutical care. Accordingly, in final rulemaking, the Board has deleted § 27.12(d)(3)(ii).

With regard to public comments, IRRC suggested that uniform certification of pharmacy technicians by the National Pharmacy Technician Certification Board could satisfy many concerns. Although the Board believes that the registration of pharmacy technicians may aid in tracking and reviewing technician utilization, State recognition of both certification and registration would require authorization from the General Assembly.

Errata

IRRC pointed out that § 27.18(d)(7)(v) as published requires a drug dispensed in unit dose to be labeled to indicate the patient's name, drug name, drug strength, dosing instructions and lot number. IRRC agreed with several commentators that this labeling requirement is simply not practical because unit doses are prepackaged single dosages often no larger than 1 square inch. The Board has noted that a drafting error changed the language which should have read "a drug NOT in unit dose shall be labeled to indicate the patient name, drug name, drug strength, dosing instructions and lot number." The Board has made the correction and added further clarifying language in this section in final rulemaking.

Pharmacy Internships

IRRC suggested that the Board's qualifications for pharmacy internship registration exactly track the statutory provisions in section 3(e) of the act. The Board has, in final rulemaking, amended § 27.26(b) and (b)(2) as recommended.

The House Committee questioned why the Board proposed to allow a pharmacist desirous of becoming a preceptor to seek a waiver of the prohibition against his having once been convicted of "an offense with respect to observance of Federal, State and municipal statutes and ordinances relating to the practice of pharmacy." (§ 27.26(h)(1)). The waiver provision was intended to allow the Board some flexibility in registering as a preceptor a pharmacist whose only infraction had been a minor recordkeeping, facility or building code violation, or the like. Upon reflection, however, the Board has determined that a waiver procedure could prove unwieldy and generate potential equal protection concerns absent specific standards. Likewise, the Board finds that the requirements for registration as a pharmacist preceptor need further clarification.

In final rulemaking, § 27.26(h) has been amended to clarify that a pharmacist seeking to serve as a preceptor: (1) may not have been convicted of a criminal offense relating to the practice of pharmacy; (2) currently holds a license without restriction to practice pharmacy in this Commonwealth; and (3) is working full-time in a pharmacy approved for intern training. In this way, the public health and safety will continue to be protected through the exclusion from service as preceptors those pharmacists convicted of criminal activity involving the practice of pharmacy, while preserving the Board's ability to register as preceptors pharmacists who have been the subject of minor civil or administrative infractions.

Satellite Pharmacies

Commentators expressed confusion over the provisions in proposed rulemaking in §§ 27.1 and 27.11(i) related to satellite pharmacies. The Board has clarified these provisions to codify in regulatory form its longstanding policy that nonsatellite pharmacies must be separately permitted.

Sections 2(12) and 4(e) of the act (63 P. S. §§ 390-2(12) and 390-4(e)) require that any place where drugs are stored, compounded or dispensed must hold a pharmacy permit, have a designated pharmacist in charge and meet the drug safety and security requirements of the Board.

The Board intends by its definition of a "satellite pharmacy" in § 27.1 (relating to definitions) to refer to places in large multidisciplinary hospitals where drugs are routinely stored from the inventory of the central institutional pharmacy for the convenience of various medical departments of the hospital. Satellite pharmacies are not required to be separately permitted. § 27.11(i) (relating to pharmacy permit and pharmacist manager). Satellites are not, however, pharmacies established by hospitals to sell pharmaceuticals to the public in the

nature of retail sales. Furthermore, satellites are not institutional pharmacy activities occurring in multiple geographic locations within a health care system. These two categories of pharmacy activity require separate permits.

The purpose of the rule is twofold. First, it notifies hospitals and other institutions that if they intend to function as retail pharmacies, they must be regulated as such. In other words, they must have facilities physically separate from the institutional pharmacy and must separately meet the drug safety and security requirements and practice standards of the Board. Second, it notifies health systems that satellites are permissible only on the premises of a hospital which has a permitted institutional pharmacy. Separate permits are required for separate hospitals because the pharmacy activities which take place there require separate security, separate drug safety measures and separate clinical supervision.

With respect to the first category, Federal law at 15 U.S.C.A. § 13 prohibits institutions from unfairly competing with retail pharmacies by reselling to consumers pharmaceuticals purchased for institutional use. Institutional uses include drugs for inpatients, emergency patients, outpatients (when the drug is to be used on the premises), discharged patients (when the drug is for personal use and the prescription cannot be refilled), hospital employes, students or staff physicians and their dependents. Sales to former patients through renewal or refill of prescriptions, to staff physicians for dispensing in the course of their clinical private practices, or to walk-in customers do not constitute institutional uses. *See*, *Abbott Labs v. Portland Retail Druggist*, 425 U. S. 1 (1976).

The second category is grounded in the Board's primary responsibility to protect the health and safety of the public. The Board has determined that a pharmacist manager located in one facility of a health system with several institutions where acute care is provided, cannot adequately maintain supervision over drug dispensing, inventory and other pharmacy services throughout the entire system. Accordingly, remote institutional pharmacy activities, even if operated by the same entity which operates an institution's central pharmacy, must be separately permitted.

To the extent that further refinements can be made to the satellite pharmacy provisions following their adoption without compromising public health and safety, the Board pledges to work cooperatively with the Department of Health and other interested parties to develop overall standards and policies for health system-wide pharmaceutical care delivery. The amendments are not meant to inhibit innovation in the delivery of pharmaceutical care. The Board intends the amendments to establish outside parameters for public health and safety. It will continue to make judgment calls in conjunction with the Department of Health on the basis of individual institutional needs. For example, by these amendments, the Board does not intend to require a pharmacy in a long term care facility where the population is residential, where patient conditions are stable and where routine maintenance drug therapy is involved. On the other hand, where two or more acute care institutions are located miles apart and where patient conditions may change dramatically and intensive drug monitoring is necessary, a single shared pharmacy would not likely protect the public health.

Pharmacies in Retail Establishments

IRRC and the House Committee also suggested that the provisions related to a self-contained pharmacy be reorganized in the amendments. The Board has considered this comment and reviewed the entire section concerning self-contained pharmacies, and determined that the phrase "self-contained" does not accurately identify the provisions in question. Accordingly, the Board has revised entirely § 27.16(b)(2) (relating to construction and equipment requirements) to accurately reflect the Board's intent that pharmacies located within retail establishments whose business hours differ from the pharmacies' hours are required to maintain certain standards of security.

Miscellaneous

In accordance with the suggestions of IRRC and the House Committee, the Board has amended § 27.11(g) to specify a 30-day time limit within which changes in name or ownership or controlling interest of a pharmacy must be reported to the Board and an application for new permit filed.

The House Committee questioned why the Board has deleted the requirement in § 27.14(c)(3) (relating to supplies) that a pharmacy refrigerator be used exclusively for the storage of drugs. The deletion relates to sanitary considerations which would not prohibit, for example, a sealed beverage or food container from being stored in the pharmacy refrigerator.

In addition to adopting a number of recommendations made by IRRC and the House Committee to clarify provisions of the regulations, the Board has also attempted, in final rulemaking, to remove redundancies and clarify, where possible, language unnecessary to the understanding of the regulations consistent with Executive Order 1996-1 and within the scope of proposed rulemaking. For the same reason, the Board has declined to unduly burden the regulation in § 27.25(a) (relating to licensure by reciprocity) by reiterating the requirements of section 3(g) of the act.

E. *Compliance with Executive Order 1996-1*

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), the Board has sought in final rulemaking to achieve clear and, where possible, nontechnical language. The Board has also refined the regulations to achieve cost effective methods of addressing compelling public health and safety concerns in the delivery of pharmaceutical services in this Commonwealth. Likewise, it has reviewed and incorporated many of the comments received on proposed rulemaking from various individuals and organizations representing the regulated community.

F. *Fiscal Impact and Paperwork Requirements*

The amendments will have a positive fiscal impact on Commonwealth institutions and institutions operated by political subdivisions. Pharmacies which utilize pharmacy technicians will be required to prepare written protocols if they have not already done so. The expanded ability of pharmacies to utilize technicians will reduce overall costs. The cost for a new permit when changes in controlling interests of a pharmacy occur will increase only by the cost of the permit. Pharmacies should achieve overall savings in monetary cost and paperwork through the implementation of practice standards which recognize technological advances in drug distribution and electronic data collection and maintenance.

G. *Sunset Date*

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

H. *Regulatory Review*

Under section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), on April 6, 1998, the Board submitted within the required 2-year period from the conclusion of the public comment period, the text of these final-form regulations together with the Board's responses to comments received on proposed rulemaking, a copy of the notice of proposed rulemaking, published at 26 Pa.B. 1032 and other required documentation, to IRRC and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee for review and comment. In compliance with section 5(c) of the Regulatory Review Act, the Board also provided IRRC and the Committees with copies of all comments received, as well as other documentation. Under section 5.1(b) of the Regulatory Review Act, the Board copied all commentators with the final-form regulations and this explanation of changes to proposed rulemaking on the same date.

In preparing these final-form regulations the Board has considered comments received from IRRC, the Committees and the public.

The final-form regulations were reviewed by the House Committee on April 22, 1998, and tabled with a recommendation for revision concerning pharmacist preceptor registration requirements. The Board requested disapproval from IRRC to allow it to make revisions consistent with the House Committee's recommendation. On May 7, 1998, IRRC disapproved the final-form regulations under section 5.1(e) of the Regulatory Review Act. The disapproval order was received by the Board on May 8, 1998. In addition to the reason for which the Board sought disapproval, the order also cited concerns about satellite pharmacy provisions raised by representatives of health systems on May 7, 1998.

On May 14, 1998, the Board submitted written notice to the Governor, the House and Senate Committees and IRRC, under section 7(a) of the Regulatory Review Act (71 P. S. § 745.7(a)), of its intention to resubmit the regulation with modifications in accordance with section 7(c) of the Regulatory Review Act. Modifications were made to § 27.26(h) relating to requirements for registration as a pharmacy preceptor as outlined in Paragraph D of this Preamble.

On June 15, 1998, the Board delivered the modified final-form regulations, together with the section 7(c) report, to the Governor, the House and Senate Committees and IRRC. On July 9, 1998, IRRC disapproved the report, barring publication of the final-form regulations, on the grounds that the definition of a "satellite pharmacy" "violates [IRRC's] criteria of clarity, and raises serious questions of need, cost-effectiveness and economic impact." The disapproval order was delivered to the House and Senate Committees on July 16, 1998.

The Board's final-form regulations were subsequently deemed approved by the House and Senate Committees on July 30, 1998, clearing the way to final promulgation under section 7(d) of the Regulatory Review Act.

I. *Public Information*

Interested persons may obtain information regarding the amendments by writing to State Board of Pharmacy, 116 Pine Street, P. O. Box 2649, Harrisburg, PA 17105-2649.

J. *Findings*

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 the 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 amendments do not enlarge the purpose of proposed rulemaking published at 26 Pa.B. 1032.

(4) These amendments are necessary and appropriate for administration and enforcement of the authorizing act identified in Part B of this Preamble.

K. *Order*

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended by amending §§ 27.1, 27.11, 27.12, 27.14—27.16, 27.18, 27.25 and 27.26, to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

PAULA L. CASTOR, R.Ph.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 3558 (July 25, 1998).)

Fiscal Note: Fiscal Note 16A-542 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL REVISIONS

§ 27.1. Definitions.

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

ACPE—The American Council of Pharmaceutical Education.

Act—The Pharmacy Act (63 P. S. §§ 390-1—390-13).

Board—The State Board of Pharmacy.

CEU—Continuing Education Units—The unit of measuring contact hours of continuing education provided by ACPE accredited providers. Ten contact hours are equivalent to 1.0 CEU.

Commissioner—The Commissioner of Professional and Occupational Affairs in the Department.

Contact hours—Continuing education units of measure equivalent to 50 to 60 minutes of participation in an

approved organized learning experience, including home study with approved educational materials.

Continuing education—Professional education obtained to maintain, improve or expand current skills or knowledge, or to develop new skills or knowledge.

DEA—The Federal Drug Enforcement Administration.

Department—The Department of State of the Commonwealth.

Drug order—An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient. The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

Institutions—Extended care facilities, nursing homes, nursing care facilities, convalescent homes, resident care facilities, hospitals or another place which offers medical treatment to patients who require food, board and overnight sleeping facilities and care.

Long-term care facility—A nursing home, retirement care, mental care or other institution that provides extended health care to resident patients.

Medical practitioner—A physician, dentist, veterinarian or other individual authorized and licensed by law to prescribe drugs.

Nonproprietary drug—A drug containing any quantity of a controlled substance or a drug which is required by an applicable Federal or state law to be dispensed only by prescription.

Pharmacist manager—The pharmacist named in the permit to operate a pharmacy who is in charge of a pharmacy and responsible for operations involving the practice of pharmacy under section 4 of the act (63 P. S. § 390-4).

Pharmacy—The place licensed by the Board where the practice of pharmacy is conducted.

Pharmacy intern—A person registered by the Board as a pharmacy intern under section 3(e) of the act (63 P. S. § 390-3(e)) and § 27.26 (relating to pharmacy internship).

Pharmacy technician—An unlicensed person working in a pharmacy to assist a pharmacist in the practice of pharmacy in accordance with § 27.12 (relating to practice of pharmacy and delegation of duties). The term does not include a pharmacy intern or clerical or housekeeping personnel.

Practice of pharmacy—The practice of that profession concerned with the art and science of preparing, compounding and dispensing drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or sold directly to the ultimate consumer. The term includes the proper and safe storage and distribution of drugs, the maintenance of proper records therefor and the responsibility of relating information as required concerning the drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.

Prescription—A written or oral order issued by a licensed medical practitioner in the course of professional practice for a controlled substance, other drug or device or medication which is dispensed for use by a consumer.

Prescription area—That area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term does not include waiting counters or display space attached to the waiting counters.

Proprietary drug—A nonprescription, nonnarcotic medicine or drug which may be sold without a prescription and which is prepackaged for use by the consumer and labeled in accordance with the requirements of Federal and State statutes and regulations.

Satellite pharmacy—A pharmacy in an institution which provides specialized services for the patients of the institution and which is dependent upon the centrally located pharmacy for administrative control, staffing and drug procurement. The term does not include a pharmacy serving the public on the premises of the institution nor does it include a pharmacy located off premises from the centrally located pharmacy of the institution regardless of whether the pharmacy is owned by the same person or entity which owns the institution.

STANDARDS

§ 27.11. Pharmacy permit and pharmacist manager.

(a) A permit to conduct a pharmacy issued under section 4 of the act (63 P. S. § 390-4) shall show the name and address of the pharmacy, the name of the current owner and the name of the current pharmacist manager.

(b) A pharmacy may not display, advertise or use any name other than the name in which it is registered.

(c) A pharmacy may not be open without a licensed pharmacist on duty at all times.

(d) A change in name or ownership or controlling interest of the pharmacy shall require a new permit. Applications for new permits shall be filed within 30 days of the change in name, ownership or controlling interest.

(e) A person or entity holding a certificate, license, permit or registration as a licensed pharmacist or pharmacy may not post or display in public view a current certificate, license, permit, registration or renewal of a person not lawfully employed by the licensee.

(f) A pharmacy which closes or otherwise ceases operation shall immediately return to the Board its current permit and shall immediately inform the Board of the disposition of the prescription files and nonproprietary drugs. After 30 days, neither prescription files nor nonproprietary drugs may be sold, transferred or disposed of without prior permission from the Board. When a pharmacy closes or ceases operation, signs, symbols or other indications of a pharmacy shall immediately be removed from both the interior and exterior of the premises.

(g) If the pharmacist manager ceases to hold that position, the pharmacy permit holder shall inform the Board in writing of this fact and of the new pharmacist manager not more than 15 days later. If the Board does not object within 30 days of notification, the new pharmacist manager may be deemed approved. If the permit holder is unable to replace the pharmacist manager within those 15 days, the permit holder may request in writing an extension of up to 30 additional days to obtain a replacement. A pharmacy may not operate without a pharmacist manager for more than 15 days unless the pharmacy first obtains from the Board an extension of time for obtaining a replacement.

(h) A pharmacist may not serve as the pharmacist manager of more than one pharmacy at any given time.

The holder of a permit to operate a pharmacy which has lost the services of a pharmacist manager and cannot obtain a suitable replacement may apply in writing to the Board for a temporary waiver of this subsection. The Board may grant a waiver which would authorize a pharmacist manager to serve as pharmacist manager of more than one pharmacy for up to 60 days after the initial 15 days permitted under subsection (g).

(i) Each pharmacy in this Commonwealth will require a separate permit regardless of ownership unless the pharmacy is a satellite pharmacy as defined in § 27.1 (relating to definitions).

§ 27.12. Practice of pharmacy and delegation of duties.

(a) *General.* It is unlawful for a person not licensed as a pharmacist by the Board to engage or allow another person to engage in the practice of pharmacy as defined in § 27.1 (relating to definitions) and section 2 of the act (63 P. S. § 390-2) except in accordance with this section.

(b) *Delegation.* A pharmacist may delegate aspects of the practice of pharmacy to a pharmacy intern or pharmacy technician, as defined in § 27.1, subject to the following conditions:

(1) The pharmacist shall review every prescription or drug order prior to its being dispensed to determine the name of the drug, strength, dosage, quantity, permissible refills and other information required under § 27.18(b) (relating to standards of practice) to verify the accuracy of the preparation.

(2) The pharmacist shall provide direct, immediate and personal supervision to pharmacy interns and pharmacy technicians working with the pharmacist. Direct, immediate and personal supervision means that the supervising pharmacist has reviewed the prescription or drug order prior to its being dispensed, has verified the final product and is immediately available on the premises to direct the work of interns and technicians and respond to questions or problems.

(3) The pharmacist shall ensure that the label of the container in which a nonproprietary drug is dispensed or sold pursuant to a prescription complies with the labeling requirements of § 27.18(d).

(c) *Pharmacy interns.*

(1) A pharmacy intern may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) A pharmacy intern may neither accept nor transcribe an oral order or telephone prescription.

(3) A pharmacy intern may neither enter nor be in a pharmacy if a pharmacist is not on duty.

(4) A pharmacy intern working under the direct, immediate, personal supervision of a pharmacist may perform procedures which require professional skill and training. Examples of these procedures include: verifying ingredients, weighing ingredients, compounding ingredients and other similar processing of ingredients.

(d) *Pharmacy technicians.*

(1) A pharmacy technician may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) The following are examples of the types of activities which a pharmacy technician may perform:

(i) Carry containers of drugs in and around the pharmacy.

(ii) Count pills, tablets and capsules and put them in a container.

(iii) Type or print, or both, labels.

(iv) Maintain records which are related to the practice of pharmacy.

(v) Assist the pharmacist in preparing and reconstituting parenteral products and other medications. After the parenteral product or other medication has been prepared, the supervising pharmacist shall initial the label of the product or medication to document his final inspection and to accept total responsibility for its preparation.

(vi) Enter prescription, drug order or patient information in a patient profile.

(3) A pharmacy technician may not:

(i) Accept or transcribe an oral order or telephone prescription.

(ii) Enter or be in a pharmacy if a pharmacist is not on duty.

(iii) Perform any act within the practice of pharmacy that involves discretion or independent professional judgment.

(iv) Perform a duty until the technician has been trained and the duty has been specified in a written protocol.

(4) The pharmacist manager shall create and maintain a written protocol for each pharmacy technician employed in the pharmacy. The protocol shall specify each duty which the pharmacy technician may perform. The pharmacist manager and the pharmacy technician shall date and sign the protocol and each amendment to the protocol. The pharmacist manager shall make the protocol available to agents of the Board upon demand.

§ 27.14. Supplies.

(a) A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve. The applicant for a pharmacy permit shall show proof by affidavit that the applicant has ordered or possesses and shall continue to maintain an inventory of nonproprietary drugs, devices and equipment appropriate to the practice of that pharmacy. The inventory shall include at least $5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer. The inventory may not go below this figure at any time.

(b) Drugs which must be removed from active stock shall be removed in accordance with the following provisions:

(1) The pharmacist manager is responsible for removing from the active stock of the pharmacy and disposing of the following:

(i) A drug whose expiration date has passed.

(ii) A drug which does not meet legal standards of strength and purity.

(iii) A drug which varies from the strength and purity indicated on the label of the commercial container.

(iv) A drug which has been improperly stored.

(v) A drug which has deteriorated.

(vi) A drug which is unfit, misbranded or adulterated under Federal or State statutes.

(2) Drugs which have been removed from active stock in accordance with this subsection may not be sold or given away. The drugs shall be returned to the wholesaler or manufacturer for disposal or disposed of by the pharmacy according to Federal or State statutes or regulations.

(3) A pharmacy desiring to or required to dispose of a controlled substance shall contact the nearest DEA office for authority and instructions to dispose of the substance.

(4) The pharmacist manager shall be responsible for keeping proper records of controlled substances which have been disposed of. These records shall include the name of the substance, the number of units or the volume of the substance or the number of commercial containers and the date and manner of disposal.

(c) A pharmacy shall maintain at least the following equipment and supplies:

(1) A Class A prescription balance or other scale with a no-load sensitivity of 6 milligrams or less.

(2) Both an apothecary set of weights from 1/2 grain to 1 ounce and a set of metric weights from 10 milligrams to 50 grams.

(3) A mechanical refrigerator having the appropriate temperature control for the storage of the drugs, vaccines, biologicals or medicaments which require specific temperatures for their stability. The refrigerator shall be kept within the prescription area.

(4) At least four graduates assorted to measure 1 ml to 500 ml.

(5) At least two mortars and pestals, glass or wedgewood.

(6) At least three spatulas of assorted sizes, metallic-rust resistant and rubber or nonmetalic composition.

(7) At least two funnels, one 120 ml and the other 480 ml.

(8) One glass or tile slab or specially treated paper for use in compounding ointments.

(9) A book to record sales and transfers of Schedule V controlled substances and poisons. This paragraph does not apply to an institutional pharmacy servicing only inpatients.

(10) An adequate supply of filter paper and powder papers and an adequate supply of empty capsules, prescription containers, prescription and poison and other applicable identification labels used in dispensing of prescription drugs and medication.

(11) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, the regulations of the DEA at 21 CFR 1304.04(h) (relating to maintenance of records and inventories). The original prescription shall be retained for 2 years. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like, if the system has safeguards to prevent accidental erasure and the information can be transferred to hard copy within 72 hours.

(12) Current copies of the act and this chapter.

(13) Federal and Commonwealth statutes and regulations pertaining to the practice of pharmacy.

(14) An adequate reference library including two or more of the latest editions of the following, including current supplements:

(i) The United States Pharmacopeia, *The National Formulary.*

(ii) *Physicians Desk Reference.*

(iii) *Drug Facts and Comparisons.*

(iv) *Remington's Pharmaceutical Sciences.*

(v) *The United States Dispensatory.*

(vi) *Physicians' Generix.*

(vii) *USPDI* (United States Pharmacopeia Dispensing Information).

(viii) *American Drug Index.*

(ix) Goodman and Gilman's *Pharmacological Basis of Therapeutics.*

(x) *AHFS Drug Information.*

(xi) *Radiological Health Handbook.*

(xii) *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals.*

(xiii) *Martindale: The Extra Pharmacopeia.*

§ 27.15. Sanitary standards.

(a) The pharmacy and equipment shall be maintained in a clean and orderly condition and in good repair.

(b) The pharmacy shall comply with the health and sanitation statutes of the Commonwealth and of the municipality and county in which the pharmacy is located.

(c) Waste material may not be permitted to collect upon the floor, counter or other area of the pharmacy. The pharmacy shall have a waste removal system adequate to maintain clean and sanitary conditions.

(d) The prescription area shall be dry and well ventilated, free from rodents, insects, dirt and foreign material, and well lighted.

(e) Plumbing shall be in good repair and working order.

(f) The prescription area shall contain only appliances, instruments, equipment, materials, drugs, medicines, chemicals and supplies necessary for the practice of pharmacy, as set forth in section 2(11) of the act (63 P. S. § 390-2(11)), and other equipment and supplies deemed reasonable for the operation and management of a pharmacy as established by the Board.

(g) Persons working in the prescription area shall be required to keep themselves and their apparel in a clean, sanitary and professional manner.

§ 27.16. Construction and equipment requirements.

(a) *Approval of plans.* The following requirements are applicable to approval of plans:

(1) *New pharmacy or change-of-location.* Plans for construction of a new pharmacy or new location for an existing pharmacy may be submitted to the Board for approval prior to proceeding with construction. Within 90 days of receiving the plans, the Board will notify the applicant of its approval of the planned pharmacy or of its disapproval and the reasons for disapproval. The plans, including dimensions, shall demonstrate compliance with applicable regulations and shall show the layout and fixtures for the prescription area and the immediately adjacent area.

(2) *Alterations.* The practice of pharmacy shall cease while substantial alterations in the layout or fixtures of an approved pharmacy are being made unless:

(i) The pharmacy makes the alterations and takes adequate precautions so that the health and safety of professionals, employes and the public is protected during the continuing operation of the pharmacy.

(ii) The plans for the alterations and a description of the precautions are submitted to the Board at least 30 days before the beginning of alteration work. If the Board raises no objection during that time, the pharmacy is authorized to proceed with the alterations as planned.

(b) *Building standards.* The following apply to building standards:

(1) *Minimum size.* The minimum size of the prescription area shall be at least 250 square feet, and shall be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employes and the public. Within the prescription area, there shall be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(2) *Pharmacies in retail establishments.* Pharmacies located within retail establishments whose business hours differ shall adhere to the following standards:

(i) The pharmacy can be securely sealed off from the remainder of the retail establishment.

(ii) The barrier devices which seal off the pharmacy shall be capable of providing security for the pharmacy. The barrier devices shall reach from floor to ceiling, shall be impenetrable by hand or the use of a reach extender, and shall be securely locked whenever a licensed pharmacist is not present and on duty.

(iii) The pharmacy shall be closed whenever a licensed pharmacist is not present and on duty.

(iv) Safes, electrical equipment or other facilities of the retail establishment may not be located in or approached through the pharmacy unless a pharmacist is on duty whenever staff from the retail establishment need access to these facilities.

(v) The hours of the pharmacy shall be posted at all points of public access.

(vi) Protocols for access to the pharmacy when it is closed by nonpharmacist staff for bona fide emergencies, such as fires, natural disasters or police matters, shall include notification to the pharmacist manager.

(3) *Locked compartment.* Space shall be provided in the prescription area for a substantially constructed cabinet or safe to contain controlled substances unless the pharmacy disperses controlled substances throughout the stock of noncontrolled substances in a manner that obstructs the theft of controlled substances. If the pharmacy stocks Schedule I controlled substances, these substances shall be stored in a securely locked, substantially constructed cabinet or safe.

(4) *Telephone.* At least one telephone shall be accessible in the prescription area, and the telephone number shall be the telephone number printed on the prescription label.

(5) *Sanitary facilities.* Pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink shall measure at least 200 square inches exclusive of drainboard area. The sink shall be connected properly to supply hot and cold water. Restroom facilities for employes of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

(7) *Lighting and ventilation.* The pharmacy shall be well lighted and ventilated.

(7) *No television set.* A television set may not be placed within the prescription area or so situated in the pharmacy that its viewing screen may be seen when looking at it from within the prescription area.

(8) *Physical arrangement.* The prescription area shall be arranged so that prescription drugs and devices are inaccessible to an unlicensed or unauthorized person. The prescription area may not be used for storage of merchandise or other items other than those used in the preparation, dispensing or delivery of drugs. No animals may be allowed in a prescription area except for security reasons.

(9) *Existing pharmacies.* Existing pharmacies licensed by the Board prior to the effective date of this chapter may continue if they reasonably conform, or are made to reasonably conform, to the intent of this chapter. The Board will determine what constitutes reasonable conformity consonant with the public interest, health, safety and welfare.

§ 27.18. Standards of practice.

(a) A pharmacist shall dispense a new prescription in a new and clean container or in the manufacturer's original container. In refilling a prescription, the pharmacist may reuse the original container of that prescription if the container is clean and reuseable. The refill requires a new label containing the information specified in subsection (d). Pharmacies and pharmacists shall comply with the Poison Prevention Packaging Act of 1970 (15 U.S.C.A. §§ 1471—1476) which includes the use of child resistant containers.

(b) Prescriptions kept on file in the pharmacy shall meet the following requirements:

(1) Prescriptions on file shall show the name and address of the patient; the name and address or other identifier of the prescriber; the date the prescription was issued, if the prescription is for a controlled substance or if it was written with a PRN or ad lib refill designation; the name and quantity of the drug prescribed; directions for its use; cautions communicated to the ultimate consumer by means of auxiliary labels or other means when dispensed to the ultimate consumer; the date the prescription was compounded and dispensed; and the name or initials of the dispensing pharmacist.

(2) Prescriptions for controlled substances shall show the DEA number of the prescriber. Prescriptions for Schedule II controlled substances shall be written with ink, indelible pencil, typewriter, word processor or computer printer and shall be manually signed by the prescriber. The pharmacist is responsible for compounding and dispensing nonproprietary drugs consistent with the Federal Controlled Substances Act (21 U.S.C.A. §§ 801—904), The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) and the regulations promulgated under these acts.

(3) If a prescription for a nonproprietary drug is refilled, a record of the refill shall show the date of the refill, the name or initials of the dispensing pharmacist

and the quantity dispensed. If the pharmacist dispenses a quantity different from that of the original prescription, the pharmacist shall indicate the changes on the back of the original prescription or shall enter the changes in the computerized files of the pharmacy.

(4) Original prescriptions shall be kept for 2 years.

(5) In an institution, Schedule II controlled substances which the pharmacy dispensed and which were ultimately received by the patient shall be recorded and the record kept for 2 years.

(c) A pharmacist may decline to fill or refill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent or unlawful, or that it is tendered by a patient served by a public or private third-party payor who will not reimburse the pharmacist for that prescription. A pharmacist may not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug or device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused or misused. In addition, a pharmacist may decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled. The pharmacist shall explain the decision to the patient. If necessary the pharmacist shall attempt to discuss the decision with the prescriber.

(d) The container in which a prescription drug or device is sold or dispensed to the ultimate consumer shall bear a label which shall be written in ink, typed or computer generated and shall contain the following information:

(1) The name, address, telephone number and DEA number of the pharmacy.

(2) The name of the patient.

(3) Full directions for the use of its contents.

(4) The name of the prescriber.

(5) The serial number of the prescription and the date originally filled.

(6) The trade or brand name of the drug, strength, dosage form and quantity dispensed. If a generic drug is dispensed, the manufacturer's name or suitable abbreviation of the manufacturer's name shall also be shown.

(7) On controlled substances, the statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

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(j) Prescriptions for Schedule II controlled substances may not be refilled. No controlled substance in Schedule III, IV or V may be filled or refilled more than five times in the 6-month period from the date of the prescription. Other nonproprietary drugs which may be renewed for a longer period of time or for a greater number of refills shall be in specific numbers, such as, "may be renewed ten times" and shall be in the original handwriting of the prescriber. A nonproprietary drug which is refillable by statute may not be refilled on the basis of preprinted designations or "ad lib," P.R.N., or similar instructions more than five times in the 6-month period from the date of the prescription.

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(r) The following provisions apply to the advertisement and sale of drugs:

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(7) The patient has the right to request a copy of an original prescription. The copy shall clearly indicate on its face that it is a copy and may not be used to obtain a new prescription or refill. Before a pharmacist provides a copy of a written prescription to a patient or an authorized agent of the patient, the person requesting the copy shall show the pharmacist acceptable authorization and identification, such as a driver's license. The pharmacist shall record in writing the date, to whom and by whom the copy was given.

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(v) A drug order in an institution is not required to conform to the labeling requirements of subsection (d) as long as the drug is dispensed in unit dose. A drug not in unit dose shall be labeled to indicate the patient name, drug name, drug strength, dosing instructions and lot number. The label of a parenteral, enteral or total parenteral nutrition product shall contain the name of the patient; the ingredients, including the name, strength, quantity of each, the diluent and expiration date; and the initials of the pharmacist.

PHARMACISTS

§ 27.25. Licensure by reciprocity.

(a) An applicant for licensure by reciprocity shall comply with section 3(g) of the act (63 P. S. § 390-3(g)).

(b) An applicant for licensure by reciprocity who received a license to practice pharmacy in any other state, territory or possession of the United States after January 26, 1983, shall be required to demonstrate that he passed the FDLE.

§ 27.26. Pharmacy internship.

(a) Pharmacy internship means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide a registered intern with the knowledge and practical experience necessary for functioning competently under the act and this chapter.

(b) A certificate of registration as a pharmacy intern will be available to an individual of good moral character who has completed at least 2 years of pharmacy college or an accredited program leading to transfer into the third year of a pharmacy college in which the individual is enrolled or accepted. A person desiring to register as a pharmacy intern shall do the following:

(1) Apply to the Board for registration including the fee specified in § 27.91 (relating to schedule of fees) for registering as a pharmacy intern.

(2) Forward to the Board a letter or transcript certifying that the applicant has successfully completed 2 years of pharmacy college or an accredited program leading to transfer into the third year of a pharmacy college in which the applicant is enrolled or accepted.

(c) The Board will register an applicant after it receives a completed application and other items in subsection (b). A pharmacy intern certificate is valid for 6 years from the date of issue exclusive of time spent in the military.

(d) The following applies to internship credit:

(1) An intern shall serve at least 1,500 hours.

(2) A maximum of 50 hours may be credited in 1 week.

(3) An intern shall serve at least 750 of the 1,500 hours in a pharmacy.

(4) An intern may earn up to 750 of the 1,500 hours in an internship program sponsored or approved by the pharmacy college subject to the following conditions:

(i) The Board will determine the maximum number of hours available for each internship program sponsored or approved by a pharmacy college.

(ii) The Board will grant internship credit to an individual in an internship program sponsored or approved by a pharmacy college only if the following applies:

(A) The internship program is full-time.

(B) There is no concurrent academic courseload.

(C) The individual achieves a passing grade in the program.

(iii) A pharmacy college which desires to sponsor or approve an internship program shall request approval from the Board.

(iv) The Board will monitor internship programs which are sponsored or approved by a pharmacy college.

(5) The Board may grant internship credit for hours that an individual served in a pharmacy before the individual registered as an intern only if the individual shows good cause for failing to register in timely fashion.

(6) The Board will not grant internship credit for hours which an individual served in a pharmacy if the supervising pharmacist was not registered as a preceptor. An exception to the requirement that the supervising pharmacist register as a preceptor will be made for internship hours acquired in an internship program sponsored or approved by a pharmacy college.

(e) The Board will grant internship credit only for activities related to the practice of pharmacy. The following are examples of these activities: scrutinizing prescriptions or drug orders, compounding medications and filling prescriptions. The Board will not grant internship credit for activities which are not related to the practice of pharmacy. The following are examples of these activities: retail sales unrelated to pharmacy items, shelving or clerical functions unrelated to pharmacy.

(f) A person may not be eligible to become a candidate for registration to practice pharmacy unless the person receives instruction in practical pharmacy and pharmaceutical technique from an instructor, professor, or faculty member who is a registered pharmacist or from a faculty member who is a registered pharmacist at a pharmacy college.

(g) The following requirements are applicable to a pharmacy approved for intern training:

(1) A pharmacy may not have been or be in violation of Federal, State or municipal statutes and ordinances governing any phase of activity in which it is engaged. A pharmacy may appeal to the Board for a waiver of this provision.

(2) A pharmacy shall be managed so that the emphasis is on activities connected with the distribution of articles and services pertaining to medical care, including drugs, medicines, prescriptions, medical supplies and materials.

(3) A pharmacy shall be kept in a sanitary, orderly and clean condition, and the prescription department shall meet the requirements in the statutes and regulations as they affect prescription departments.

(4) A pharmacy shall compound and dispense a sufficient number of prescriptions including renewals so as to provide the pharmacy intern with ample opportunity to scrutinize prescriptions and to compound and dispense under the supervision of a licensed pharmacist.

(5) A pharmacy shall have in its employ a licensed pharmacist who is registered as a pharmacist preceptor.

(6) A pharmacy which meets the qualifications of this section shall be approved by the Board after proper notification by the owner or manager of willingness to cooperate in the development of the internship program. Whenever a new intern is accepted for training in the pharmacy, the pharmacist preceptor shall notify the Board of the name of the intern and his anticipated period of internship in the pharmacy.

(h) The requirements for registration as a pharmacist preceptor are as follows:

(1) A pharmacist preceptor may not have been convicted of a criminal offense relating to the practice of pharmacy.

(2) An applicant shall hold a license without restriction to practice pharmacy in this Commonwealth and shall be engaged in the active practice of pharmacy in this Commonwealth.

(3) The applicant shall be working on a full-time basis in a pharmacy approved for intern training.

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