PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 93]

Blue Eye Run, et al. (Water Quality Network (WQN) Package); Stream Redesignations

The Environmental Quality Board (Board) proposes to amend 25 Pa. Code §§ 93.9b, 93.9d, 93.9f, 93.9g, 93.9i, 93.9l, 93.9p and 93.9q to read as set forth in Annex A.

This proposal was adopted by the Board at its meeting on April 21, 2009.

A. *Effective Date*

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

B. *Contact Persons*

For further information, contact Richard H. Shertzer, Chief, Division of Water Quality Standards, Bureau of Water Standards and Facility Regulation, 11th Floor, Rachel Carson State Office Building, P. O. Box 8467, 400 Market Street, Harrisburg, PA 17105-8467, (717) 787-9637 or Michelle Moses, 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 proposal is available electronically through the Department of Environmental Protection's (Department) web site (http://www.depweb.state.pa.us).

C. *Statutory and Regulatory Authority*

This proposed rulemaking is being made under the authority of sections 5(b)(1) and 402 of The Clean Streams Law (35 P. S. §§ 691.5(b)(1) and 691.402), which authorize the Board to develop and adopt rules and regulations to implement the provisions of The Clean Streams Law (35 P. S. §§ 691.1—691.1001), and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which grants to the Board the power and duty to formulate, adopt and promulgate rules and regulations for the proper performance of the work of the Department. In addition, section 303 of the Federal Clean Water Act (33 U.S.C. § 1313) sets forth requirements for water quality standards and the Federal regulation in 40 CFR 131.32 (relating to Pennsylvania) sets forth certain requirements for portions of the Commonwealth's antidegradation program.

D. *Background of the Proposed Amendments*

Water quality standards are in-stream water quality goals that are implemented by imposing specific regulatory requirements (such as, treatment requirements and effluent limits) on individual sources of pollution. The Department may identify candidates for redesignation during routine waterbody investigations. Requests for consideration may also be initiated by other agencies. Organizations, businesses or individuals may submit a rulemaking petition to the Board.

The Department considers candidates for High Quality (HQ) or Exceptional Value (EV) Waters and all other designations in its ongoing review of water quality standards. In general, HQ and EV waters must be maintained at their existing quality and permitted activities shall ensure the protection of designated and existing uses.

Existing use protection is provided when the Department determines, based on its evaluation of the best available scientific information, that a surface water attains water uses identified in §§ 93.3 and 93.4 (relating to protected water uses; and Statewide water uses). Examples of water uses protected include the following: Cold Water Fishes (CWF), Warm Water Fishes (WWF), HQ and EV. A final existing use determination is made on a surface water at the time the Department takes a permit or approval action on a request to conduct an activity that may impact surface water quality or uses. If the determination demonstrates that the existing use is different than the designated use, the water body will immediately receive the best protection identified by either the attained uses or the designated uses. A stream will then be "redesignated" through the rulemaking process to match the existing uses with the designated uses. For example, if the designated use of a stream is listed as protecting WWF but the redesignation evaluation demonstrates that the water attains the use of CWF, the stream would immediately be protected for CWF, prior to a rulemaking. Once the Department determines the water uses attained by a surface water, the Department will recommend to the Board that the existing uses be made "designated" uses, through rulemaking, and be added to the list of uses identified in § 93.9 (relating to designated water uses and water quality criteria).

The Department operates the Surface Water Quality Network (WQN), which is a long-term, fixed station network of monitoring stations on rivers and streams throughout this Commonwealth. This network was initially designed to monitor water quality conditions on a broad scale. Most stations are located on major streams with large drainage areas. However, recent water quality monitoring trends emphasize the importance of identifying and defining biological reference conditions characteristic of no or minimal disturbance. As part of the process to establish biological reference conditions, smaller watersheds with minimal land disturbance were added to the water quality network to collect data representative of reference water quality conditions and to support biological metric protocol development. WQN streams are selected from various areas across this Commonwealth and monitored for 5 years. Following the close of the 5-year inventory period, the studied sites are replaced with a new set of stations.

After reviewing the WQN monitoring data, several of the stations displayed existing use stream conditions indicative of EV waters. Physical, chemical and biological characteristics along with other information on these waterbodies were considered to determine the appropriateness of the current and recommended designations using applicable regulatory criteria and definitions. In reviewing whether waterbodies qualify as HQ or EV waters, the Department considers the criteria in § 93.4b (relating to qualifying as High Quality or Exceptional Value Waters). According to the Department's regulatory criteria, a Biological Condition Score (BCS) greater than or equal to 92% of the reference station score supports an EV designation. See § 93.4(b)(1)(v).

All reference streams were selected because they were representative of excellent EV conditions based on the macroinvertebrate community and were of similar stream types, comparable geologic settings, and reasonable proximity with respect to their compared candidate stream. Both the candidate stream and the reference streams were sampled within a similar time frame to minimize the effects of seasonal variation.

All of the recommended redesignations in these proposed amendments for the WQN stations are candidates for EV, based upon data and appropriate regulatory criteria. All of the waterbodies in this regulatory package which are being recommended for EV qualify based on their BCS being greater than or equal to 92% of the reference station score. Copies of the Department's stream evaluation report for these waterbodies is available on the Department's web site or from the contacts whose addresses and telephone numbers are listed in Section B. The Department recommends the Board adopt these proposed amendments as described in this preamble and as set forth in Annex A.

Also note that a basinwide migratory fishes (MF) designation to drainage lists A—O and Z, currently has been added as part of the Triennial Review of Water Quality Standards final-form rulemaking at 39 Pa.B. 2523 (May 16, 2009). The MF designated use has been added to those waters that appear in the Annex A of this proposed rulemaking to be consistent with the Triennial Review final-form rulemaking.

The following is a brief explanation of the recommendations for each waterbody:

East Branch Dyberry Creek. East Branch Dyberry Creek is a tributary to Dyberry Creek in the Delaware River drainage basin. The basin is located in Dyberry and Lebanon Townships, Wayne County. The majority of East Branch Dyberry Creek basin is located in State Game Land (SGL) 159. Land use in the floodplain is mostly deciduous forest with a dirt road. There is some agriculture and low-density residential development in the surrounding hillsides. East Branch Dyberry Creek basin is currenty designated HQ-CWF, MF and the Department recommends that the basin be redesignated EV, MF. Three stations on the East Branch Dyberry Creek were compared to Little Bush Kill and all three stations scored 100% of the reference station.

Unnamed Tributary (UNT) 29200 to Tunkhannock Creek. UNT 29200 to Tunkhannock Creek lies in the Susquehanna River watershed. The basin lies in Ararat, Gibson, Jackson and Thompson Townships, Susquehanna County. The UNT Tunkhannock Creek basin is a mixture of deciduous forest along with agriculture, low-density residential development, and several roads. A small portion of the headwaters of one of the tributaries is located in SGL 236. UNT 29200 to Tunkhannock Creek mainstem is classified by the Fish and Boat Commission as Class A wild trout waters. The Department recommends that the basin be redesignated from CWF, MF to EV, MF. Wild Creek was the reference station for UNT 29200 to Tunkhannock Creek. UNT 29200 to Tunkhannock Creek scored 93% of the reference station score.

Young Womans Creek. Young Womans Creek is also a tributary to the West Branch Susquehanna River and flows through Chapman, Stewardson and Brown Townships in Clinton, Potter and Lycoming Counties, respectively. Most of the Young Womans Creek watershed is located within the Sproul State Forest. Land use in this basin is almost entirely forested with several roads and seasonal camps. Young Womans Creek basin is currently designated HQ-CWF, MF. Two stations on Young Womans Creek were compared to Cross Fork Kettle Creek and scored 93 and 100% of the reference station. The Department recommends that Young Womans Creek basin, from its source to and including Left Branch Young Womans Creek, be redesignated EV, MF.

Muncy Creek. Muncy Creek is a tributary to the West Branch Susquehanna River within the Susquehanna River basin. The Muncy Creek mainstem from its source to the second SR 2002 Bridge upstream of Sonestown at RM 26.4 is currently designated as CWF, MF. Elklick Run is a tributary to Muncy Creek in the affected area and is currently designated EV, MF. All of the other tributaries (both named and unnamed) to the Muncy Creek from the source to the second SR 2002 Bridge upstream of Sonestown at RM 26.4 are currently designated HQ-CWF, MF. This portion of the Muncy Creek basin lies in Davidson and Laporte Townships in Sullivan County and is mostly forested except for a narrow corridor that runs along the main stem. This area contains a paved road and low-density residential development. The headwaters of Muncy Creek originate in SGL 13. Muncy Creek was compared to Little Fishing Creek and scored 100% of the reference station. The Department recommends that the headwaters of the Muncy Creek basin, from the source to the second SR 2002 Bridge upstream of Sonestown at RM 26.4, be redesignated as EV, MF.

Spruce Run. Spruce Run flows through or along the boundaries of Hartley, Lewis, West Buffalo, White Deer and Buffalo Townships in Union County and then enters Buffalo Creek which is a tributary to the West Branch Susquehanna River. Nearly the entire watershed of Spruce Run is located in Bald Eagle State Forest. Land use in this basin is almost entirely forested with several roads and seasonal camps. The Spruce Run basin is currently designated HQ-CWF. Wild Creek was the reference station for Spruce Run. Spruce Run scored 100% of the reference station score. The Department recommends that Spruce Run basin, from its source to the eastern boundary of Bald Eagle State Forest at RM 5.09, be redesignated as EV, MF.

Blue Eye Run. Blue Eye Run flows through Columbus, Spring Creek and Pittsfield Townships in Warren County and is a tributary to the Brokenstraw Creek in the Ohio River Drainage basin. Blue Eye Run basin is currently designated CWF. Roughly one-half of the Blue Eye Run watershed is located in SGL 143. West Branch Caldwell Creek was the reference station for Blue Eye Run. Blue Eye Run scored 95% of the reference station score. The Department recommends that the Blue Eye Run basin from its source to SR 0027 Bridge be redesignated EV.

East Hickory Creek. East Hickory Creek is a tributary to the Allegheny River in the Ohio River watershed. East Hickory Creek basin from the source to Middle Hickory Creek has a designated use of EV. The remainder of the East Hickory Creek basin from and including the Middle Hickory Creek basin to the mouth is currently designated HQ-CWF. The East Hickory Creek basin from and including the Middle Hickory Creek basin to Forest Highway 119 is a candidate for redesignation to EV. The candidate portion of the basin flows through Watson and Limestone Townships in Warren County and is located in the Allegheny National Forest. Middle Hickory Creek enters East Hickory Creek in Limestone Township. The portion of the basin which is a candidate for redesignation is mostly forested with very little human disturbance except

for hiking trails. East Hickory Creek was compared to West Branch Caldwell Creek. The two stations in East Hickory Creek basin scored 95 and 100% of the reference station. The Department recommends that the East Hickory Creek basin from and including the Middle Hickory Creek basin to Forest Highway 119 should be redesignated from HQ-CWF to EV.

Other Changes. In addition to these recommended redesignations, the Department proposes corrections to eight stream names as they currently appear in §§ 93.9b, 93.9d, 93.9g, 93.9l and 93.9p. Tadyuskung Creek, a tributary to the Lackawaxen River in Drainage List B, will be corrected to Teedyuskung Creek. In Drainage List D, the stream names for Upper Tunkhanna and Hokendagua Creeks, both in the Lehigh River basin, will be corrected to Upper Tunkhannock Creek and Hokendauqua Creek. The current spelling of Mahanhon Creek, a tributary to the Schuylkill River in Drainage List F, will be corrected to Mahannon Creek. The Department is proposing to replace the stream name listing for UNT to East Branch Chester Creek at RM 0.4 ("Goose Creek") in Drainage List G with the correct name for this stream, which is Westtown Run. Three corrections are proposed in the West Branch Susquehanna River watershed in Drainage List L. Woodley Hollow, a tributary to Drury Run, is proposed to be corrected to Woodley Draft. Harrington Hollow and Burdie Run, both tributaries to Pine Creek will be corrected to Herrington Hollow and Burdic Run. In Drainage List P, Bayer Brook will be corrected to Boyer Brook. Boyer Brook is a tributary to Potato Creek.

E. *Benefits, Costs and Compliance*

1. *Benefits*. Overall, the Commonwealth, its citizens and natural resources will benefit from these recommended changes because they provide the appropriate level of protection to preserve the integrity of existing and designated uses of surface waters in this Commonwealth. Protecting water quality provides economic value to present and future generations in the form of clean water for drinking, recreational opportunities and aquatic life protection. It is important to realize these benefits to ensure opportunity and development continue in a manner that is environmentally, socially and economically sound. Maintenance of water quality ensures its future availability for all uses.

2. *Compliance Costs*. The proposed amendments to Chapter 93 may impose additional compliance costs on the regulated community. These regulatory changes are necessary to improve total pollution control. The expenditures necessary to meet new compliance requirements may exceed that which is required under existing regulations.

Persons conducting or proposing activities or projects must comply with the regulatory requirements relating to designated and existing uses. Persons expanding a discharge or adding a new discharge point to a stream could be adversely affected if they need to provide a higher level of treatment to meet the designated and existing uses of the stream. These increased costs may take the form of higher engineering, construction or operating cost for wastewater treatment facilities. Treatment costs are site-specific and 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. Economic impacts would primarily involve the potential for higher treatment costs for new or expanded discharges to streams that are redesignated. The initial costs resulting from the installation of technologically advanced wastewater treatment processes may be offset by potential savings from and increased value of improved water quality through more cost-effective and efficient treatment over time.

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 1980s. The revisions are consistent with and based on existing Department regulations. The revisions extend additional protection to selected waterbodies that exhibit exceptional water quality and are consistent with antidegradation requirements established by the Clean Water Act (33 U.S.C.A. §§ 1251—1376) and The 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 Department's permit and approval actions. For example, the National Pollutant Discharge Elimination System (NPDES) permitting program bases effluent limitations on the use designation of the stream. These permit conditions are established to assure water quality criteria are achieved and designated and existing 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 existing uses and 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 regulations and simply mirror the existing use protection that is already in place for these streams. There may be some indirect paperwork requirements for new or expanding dischargers to streams upgraded to HQ or EV. For example, NPDES general permits are not currently available for new or expanded discharges to these streams. Thus an individual permit, and its associated paperwork, would be required. Additionally, paperwork associated with demonstrating social and economic justification may be required for new or expanded discharges to certain HQ Waters, and consideration of nondischarge alternatives is required for all new or expanded discharges to EV and HQ Waters.

F. *Pollution Prevention*

The water quality standards and antidegradation program are major pollution prevention tools because the objective is to prevent degradation by maintaining and protecting existing water quality and existing uses. Although the antidegradation program does not prohibit new or expanded wastewater discharges, nondischarge alternatives are encouraged, and required when environmentally sound and cost effective. 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.

G. *Sunset Review*

These proposed 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.

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 5, 2009, the Department submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees (Committees). In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed regulations within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of these issues by the Department, the General Assembly and the Governor prior to final-form publication of the regulations.

I. *Public Comments*

Written Comments. Interested persons are invited to submit comments, suggestions or objections regarding the proposed amendments to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments must be received by the Board by August 4, 2009. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by August 4, 2009. The one page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the proposed amendments will be considered. If sufficient interest is generated as a result of this publication, a public hearing will be scheduled at an appropriate location to receive additional comments.

Electronic Comments. Comments may be submitted electronically to the Board at RegComments@state.pa.us and must also be received by the Board by August 4, 2009. A subject heading of the proposal and return name and address must be included in each transmission. If an acknowledgement of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JOHN HANGER,
Chairperson

Fiscal Note: 7-436. No fiscal impact; (8) recommends adoption.

(*Editor's Note*: A basinwide migratory fishes (MF) designation was added to drainage lists A—O and Z at 39 Pa.B. 2523 (May 16, 2009). This additional MF designation to the waters in drainage lists A—O and Z became effective May 16, 2009. The MF designation will apply to all waters within the respective basins unless there are specific exceptions already noted for certain waterbodies or stream segments within one of these drainage lists. Drainage lists A—G are located within the Delaware River Basin. Drainage lists H—O are located within the Susquehanna River Basin. Drainage list Z is located within the Potomac River Basin. The MF designated use has been added to those waters which appear in Annex A to be consistent with the action in the Triennial Review final rulemaking at 39 Pa.B. 2523.)

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

§ 93.9b. Drainage List B.

Delaware River Basin in Pennsylvania
Lackawaxen River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
4—Van Auken Creek	Basin	Wayne	HQ-TSF, MF	None
3—Dyberry Creek	**[Basin, Source to Big Brook**	**Wayne**	**HQ-CWF, MF**	**None]**
4—West Branch Dyberry Creek	**Basin**	**Wayne**	**HQ-CWF, MF**	**None**
4—East Branch Dyberry Creek	**Basin**	**Wayne**	**EV, MF**	**None**
3—Dyberry Creek	**Basin, Confluence of West Branch Dyberry Creek and East Branch Dyberry Creek to Big Brook**	**Wayne**	**HQ-CWF, MF**	**None**

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
4—Big Brook	Basin	Wayne	EV, MF	None
3—Dyberry Creek	Basin, Big Brook to **[Confluence with West Branch Lackawaxen River] Mouth**	Wayne	HQ-CWF, MF	None
	* * * * *			
3—**[Tadyuskung] Teedyuskung** Creek	Basin	Pike	HQ-CWF, MF	None
	* * * * *			

§ 93.9d. Drainage List D.

Delaware River Basin in Pennsylvania
Lehigh River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
4—Upper **[Tunkhanna] Tunkhannock** Creek	Basin	Monroe	HQ-CWF, MF	None
	* * * * *			
3—**[Hokendagua] Hokendauqua** Creek	Basin	Northampton	CWF, MF	None
	* * * * *			

§ 93.9f. Drainage List F.

Delaware River Basin in Pennsylvania
Schuylkill River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
3—**[Mahanhon] Mahannon** Creek	Basin	Schuylkill	CWF, MF	None
	* * * * *			

§ 93.9g. Drainage List G.

Delaware River Basin in Pennsylvania
Delaware River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
2—Chester Creek	Basin, Source to East Branch Chester Creek	Chester	TSF, MF	None
3—East Branch Chester Creek	Basin, Source to **[UNT at RM 0.4 ("Goose Creek")] Westtown Run**	Chester	TSF, MF	None
4—**[UNT to East Branch Chester Creek at RM 0.4 ("Goose Creek")] Westtown Run**	Basin	Chester	WWF, MF	None

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
3—East Branch Chester Creek	Basin, **[UNT at RM 0.4] Westtown Run** to Mouth	Chester	TSF, MF	None
2—Chester Creek	Basin, East Branch Chester Creek to Rocky Run	Delaware	TSF, MF	None

* * * * *

§ 93.9i. Drainage List I.

Susquehanna River Basin in Pennsylvania
Susquehanna River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
2—Taques Creek	Basin	Wyoming	CWF, MF	None
2—Tunkhannock Creek	**[Main Stem, Source to Susquehanna-Wyoming County Border] Basin, Source to UNT 29200 at RM 36.08**	Susquehanna**[- Wyoming]**	CWF, MF	None
[3—Unnamed Tributaries to Tunkhannock Creek	**Basins, Source to Susquehanna-Wyoming County Border**	**Susquehanna**	**CWF, MF**	**None**
3—Bear Swamp Creek	**Basin**	**Susquehanna**	**CWF, MF**	**None**
3—Bell Creek	**Basin**	**Susquehanna**	**CWF, MF**	**None**
3—Leslie Creek	**Basin**	**Susquehanna**	**CWF, MF**	**None**
3—Partners Creek	**Basin**	**Susquehanna**	**CWF, MF**	**None**
3—Tower Branch	**Basin**	**Susquehanna**	**CWF, MF**	**None**
3—Millard Creek	**Basin**	**Susquehanna**	**CWF, MF**	**None]**
3—UNT 29200 to Tunkhannock Creek at RM 36.08	**Basin**	**Susquehanna**	**EV, MF**	**None**
2—Tunkhannock Creek	**Basin, UNT 29200 to East Branch Tunkhannock Creek**	**Susquehanna**	**CWF, MF**	**None**
3—East Branch Tunkhannock Creek	Basin, Source to Dundaff Creek	Susquehanna	CWF, MF	None
	* * * * *			
3—East Branch Tunkhannock Creek	Basin, Dundaff Creek to Mouth	Susquehanna	CWF, MF	None
2—Tunkhannock Creek	**Basin, East Branch Tunkhannock Creek to Susquehanna-Wyoming County Border**	**Susquehanna-Wyoming**	**CWF, MF**	**None**
2—Tunkhannock Creek	Main Stem, Susquehanna-Wyoming County Border to Mouth	Wyoming	TSF, MF	None

* * * * *

§ 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—Sandy Run	Basin	Clinton	HQ-CWF, MF	None
3—Drury Run	Basin, Sandy Run to Woodley **[Hollow] Draft**	Clinton	HQ-CWF, MF	None

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
4—Woodley **[Hollow] Draft**	Basin	Clinton	CWF, MF	None
3—Drury Run	Basin, Woodley **[Hollow] Draft** to Mouth	Clinton	CWF, MF	None
	* * * * *			
3—Boggs Hollow	Basin	Clinton	EV, MF	None
3—Young Womans Creek	**Basin, Source to Left Branch Young Womans Creek**	**Clinton**	**EV, MF**	None
3—Young Womans Creek	Basin, **Left Branch Young Womans Creek to Mouth**	Clinton	HQ-CWF, MF	None
3—Caldwell Run	Basin	Clinton	HQ-CWF, MF	None
	* * * * *			
4—**[Harrington] Herrington** Hollow	Basin	Tioga	HQ-CWF, MF	None
	* * * * *			
4—**[Burdie] Burdic** Run	Basin	Tioga	HQ-CWF, MF	None
	* * * * *			
3—Carpenters Run	Basin	Lycoming	WWF, MF	None
[3—Muncy Creek	**Main Stem, Source to US 220 Bridge at Muncy Valley**	**Sullivan**	**CWF, MF**	**None**
4—Unnamed Tributaries to Muncy Creek	**Basins, Source to US 220 Bridge at Muncy Valley**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Lopez Pond Brook	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—South Brook	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Rock Run	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Tublick Run	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Peters Creek	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Big Run	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Cherry Run	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Elklick Run	**Basin**	**Sullivan**	**EV, MF**	**None**
4—Long Brook	**Basin**	**Sullivan**	**HQ-CWF, MF**	**None]**
3—Muncy Creek	**Basin, Source to second SR 2002 Bridge upstream of Sonestown at RM 26.4**	**Sullivan**	**EV, MF**	**None**
3—Muncy Creek	**Main Stem, Second SR 2002 Bridge upstream of Sonestown at RM 26.4 to US 220 Bridge at Muncy Valley**	**Sullivan**	**CWF, MF, MF**	**None**
4—UNTs to Muncy Creek	**Basins, Second SR 2002 Bridge upstream of Sonestown at RM 26.4 to US 220 Bridge at Muncy Valley**	**Sullivan**	**HQ-CWF, MF**	**None**
4—Slip Run	Basin	Sullivan	HQ-CWF, MF	None
	* * * * *			
4—Beaver Run	Basin	Union	CWF, MF	None

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
4—Spruce Run	**Basin, Source to eastern boundary of Bald Eagle State Forest at RM 5.09**	**Union**	**EV, MF**	**None**
4-Spruce Run	Basin**, Eastern boundary of Bald Eagle State Forest at RM 5.09 to Mouth**	Union	HQ-CWF, MF	None
4—Little Buffalo Creek	Basin	Union	CWF, MF	None

* * * * *

§ 93.9p. Drainage List P.

Ohio River Basin in Pennsylvania
Allegheny River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
4—Walcott Brook	Basin	McKean	CWF	None
4—**[Bayer] Boyer** Brook	Basin	McKean	HQ-CWF	None
4—Daly Brook	Basin	McKean	HQ-CWF	None

* * * * *

§ 93.9q. Drainage List Q.

Ohio River Basin in Pennsylvania
Allegheny River

Stream	*Zone*	*County*	*Water Uses Protected*	*Exceptions to Specific Criteria*
	* * * * *			
4—Gar Run	Basin	Warren	CWF	None
4—Blue Eye Run	**Basin, Source to SR 0027 Bridge**	**Warren**	**EV**	**None**
4—Blue Eye Run	Basin, **SR 0027 Bridge to mouth**	Warren	CWF	None
4—Little Brokenstraw Creek	Basin (all sections in PA)	Warren	CWF	None
	* * * * *			
3—Jones Run	Basin	Forest	CWF	None
3—East Hickory Creek	Basin, Source to **[Middle Hickory Creek] Forest Highway 119**	**[Forest] Warren**	EV	None
[4—Middle Hickory Creek	**Basin**	**Warren**	**HQ-CWF**	**None]**
3—East Hickory Creek	Basin, **[Middle Hickory Creek] Forest Highway 119** to Mouth	Forest	HQ-CWF	None
3—Siggens Run	Basin	Forest	CWF	None

* * * * *

[Pa.B. Doc. No. 09-1102. Filed for public inspection June 19, 2009, 9:00 a.m.]

[25 PA. CODE CH. 252]
Environmental Laboratory Accreditation

The Environmental Quality Board (Board) proposes to amend Chapter 252 (relating to environmental laboratory accreditation). The proposal clarifies existing requirements, eliminates unnecessary requirements and proposes additional requirements necessary for laboratory accreditation. The proposal also revises the current fee structure found in 25 Pa. Code § 252.204 (relating to fees).

This proposal was adopted by the Board at its meeting of April 21, 2009.

A. *Effective Date*

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

B. *Contact Persons*

For further information contact Aaren S. Alger, Chief, Laboratory Accreditation Program, P. O. Box 1467, Harrisburg, PA 17105-1467, (717) 346-8212 or Scott Perry, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) web site, http://www.dep.state.pa.us.

C. *Statutory Authority*

This proposed rulemaking is being made under the authority of 27 Pa.C.S. § 4103(a) (relating to establishment of program), which directs the Department of Environmental Protection (Department) to establish an accreditation program for environmental laboratories, 27 Pa.C.S. § 4104 (relating to powers and duties) which directs the Department to establish, administer and enforce an environmental Laboratory Accreditation Program (Program) which shall include the standards necessary for a State certification program, 27 Pa.C.S. § 4105 (relating to powers and duties of Environmental Quality Board), delegating the Board the power to adopt the regulations of the Department to implement the act, and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Purpose*

The regulations governing environmental laboratory accreditation at Chapter 252 became effective on January 28, 2006. While completing the first round of laboratory assessments under these regulations, the Program discovered various provisions that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. The Program also determined that several necessary standards for accreditation were missing.

Under 27 Pa.C.S. § 4104(6), the accreditation fees must be "in an amount sufficient to pay the Department's cost of implementing and administering the accreditation program." In addition, § 252.204(b) (relating to fees) requires the Department to recommend to the Board regulatory changes to the accreditation fees every 3 years to address any disparity between the program income generated by the fees and program costs. In accordance with this requirement, the Program staff performed a workload analysis to evaluate the costs associated with the Program. Based on this workload analysis, the Department determined that the accreditation fees contained in § 252.204 were not sufficient to recover the Department's costs to implement to the program. These proposed amendments provide a new fee structure to cover the costs of the Laboratory Accreditation Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department and the LAAC ensured that the interests, concerns, and needs of the regulated community were considered and implemented as appropriate. The LAAC met throughout 2008 to review and comment on the draft Chapter 252 amendments presented by the Department. On December 1, 2008, the LAAC unanimously voted to recommend the Chapter 252 amendments for presentation to the Board.

E. *Summary of Regulatory Requirements*

Subchapter A. General Provisions

§ 252.1 (relating to definitions). The definitions section was changed to eliminate references to the now defunct "National Environmental Laboratory Accreditation Conference (NELAC)" and replace this term with "The NELAC Institute," or "TNI." The term accrediting authority was changed to accreditation body. The term "laboratory notebook" was deleted, the definition for nonpotable water was changed, and the term "action level" was added.

§ 252.4. The provision for interim accreditation was deleted.

§ 252.5 (relating to NELAP/TNI equivalency). The proposed TNI Standard does not include requirements for environmental laboratories to respond to an onsite evaluation and/or submit a corrective action report. The requirement of NELAP laboratories to adhere to the provisions of Subchapter F (relating to onsite assessment requirements) was included. Additionally, clarification was made that laboratories choosing to become accredited in the National Environmental Laboratory Accreditation Program (NELAP) shall comply with the currently approved and effective edition of either the NELAC Standard or TNI Standard, as appropriate.

§ 252.6 (relating to accreditation-by-rule). The accreditation-by-rule section was amended to specify that all laboratories performing testing or analysis for compliance with a Department statute must be registered with the Department in accordance with 27 Pa.C.S. § 4107(a).

Subchapter B. Application, Fees and Supporting Documents

§ 252.202 (relating to application for transfer of laboratory accreditation). The phrase "open or pending" was removed from subsection (b).

§ 252.204. An environmental laboratory shall pay an initial application fee and annual renewal fees based on the appropriate accreditation categories sought. Under the act, the fees provided in this section must be sufficient to pay the Department's cost of implementing and administering the accreditation program including processing applications for certificates of accreditation, the issuance, renewal, modification, or other action relating to the certificate. Laboratories pay fees based on the number and complexity of the categories for which they request accreditation. The cost of each fee category is

based on the number of assessor hours necessary to accredit an environmental laboratory for that given category.

To appropriately distribute the cost of the implementation of the Program, the fee structure was amended to include fees for a requested change in administrative information, to perform a supplemental onsite assessment when requested by the applicant laboratory to add fields of accreditation, and an additional fee for NELAP accreditation. The changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure also allows for a laboratory performing a combination of matrices to pay a lower fee.

§ 252.205 (relating to out-of-State laboratories). The term "accrediting authority" was changed to "accreditation body" to be consistent with the terms used by TNI. The requirement for secondarily accredited laboratories to submit copies of their proficiency testing studies was deleted.

Subchapter C. General Standards for Accreditation

§ 252.301 (relating to laboratory supervisor). Subsection (a) was added to clarify that the Department considers only individuals named on the application for accreditation and approved by the Department as the laboratory supervisors of an environmental laboratory.

§ 252.302 (relating to qualifications of the laboratory supervisor). The requirements for a laboratory supervisor of an environmental laboratory performing microbiological testing were amended to require biology credits rather than microbiology.

§ 252.304 (relating to personnel requirements). The initial demonstration of capability requirements from § 252.307(j) (relating to methodology) were moved to this section to have the demonstration of capability requirements in one location within the regulation.

§ 252.306 (relating to equipment, supplies and reference materials). Clarification was made to the requirements for weights and thermometers used in the laboratory. Specific acceptance criteria were added to the verification requirements of volumetric dispensing devices and non-Class A glassware used for sample, reagent and standard reference material measurements. The requirements of subsection (h) were amended and rearranged to better explain the requirements of reference materials, reagents, media and laboratory supplies.

§ 252.307. The requirements for the Scope section of the laboratory's standard operating procedures have been expanded. The requirement to list or reference the quantitation range and drinking water MCL(s) or action levels for each Field of Accreditation was added.

Subchapter D. Quality Assurance and Quality Control Requirements

§ 252.401 (relating to basic requirements). Editorial changes and amendments have been made throughout this section. Subsection (a) now lists the items a quality manual must contain. Subsection (b) lists the policies and procedures that must be in the quality manual. These policies and procedures are not different from the previous version of Chapter 252; they were included here for reference and to aid the reader. Subsection (d) now includes the requirement for training in ethical and legal responsibilities within 2 months of employment for new employees and at least every 14 months thereafter for all employees. Subsection (f) now includes the minimum requirements for handling samples and documenting their receipt by the laboratory. Subsection (j) now includes the minimum requirements for an analytical test report issued by an accredited laboratory. Subsection (k) was added to allow a laboratory operated by a facility, as defined in § 252.1, to produce abbreviated reports. Subsection (m) was amended to include the requirement to qualify any analytical results that do not meet all analytical testing and sample acceptance criteria in addition to quality control measures.

§ 252.402 (relating to essential quality control—requirements). Editorial changes and amendments were made throughout this section. Subsection (d) now includes the required number of calibration standards that must be used when utilizing a second order calibration curve. Subsection (f) was amended. The requirement to alternate the concentrations of the calibration verification standards throughout the analytical batch has been changed to require verification of the calibration curve with a calibration verification standard at both a high and low concentration with each analytical batch. Subsection (m) was added to specify the requirements a laboratory must undertake when performing manual integrations. Subsection (n) was added to specify the confirmatory requirements a laboratory must undergo when performing organic chromatographic analysis with a detector other than a mass spectrometer. When a laboratory analyzes an environmental sample that has not been previously analyzed by the laboratory or has not previously yielded a detectable result for a particular compound, the laboratory must qualitatively confirm the result using a different detector, chromatographic column, or analytical technique. Subsection (o) was added to point the reader to the documentation requirements of § 252.306.

§ 252.403 (relating to essential quality control requirements—toxicity testing). Editorial changes were made to correct the subsection designations. Subsection (p) was added to point the reader to the documentation requirements of § 252.306.

§ 252.404 (relating to essential quality control requirement—microbiology). Editorial changes and amendments were made throughout this section. The documentation requirements for equipment, supplies and reference materials specifically listed in this section were removed and placed in § 252.306. Subsection (c) was amended to allow the use of pressure cookers in limited circumstances. Amendments were made to subsection (g) to add clarification to the requirements for membrane filtration units. Subsection (h) now clearly outlines that the applicant laboratory must perform the positive and negative control checks on the media used in the laboratory and specifies the requirements for maintenance of the control cultures. Subsection (j) was added to point the reader to the documentation requirements of § 252.306.

§ 252.405 (relating to essential quality control requirment—radiochemistry). Subsection (m) was added to point the reader to the documentation requirements of § 252.306.

Subchapter E. Proficiency Test Study Requirements

§ 252.501 (relating to proficiency test study requirements). Subsection (l) was amended to specify that the environmental laboratory shall have its proficiency testing study results submitted to the Department's Program.

Subchapter F. Onsite Assessment Requirements

§ 252.601 (relating to onsite assessment requirements). Subsection (a) was amended to specify that the Department will perform an onsite assessment of a laboratory prior to granting primary accreditation. Subsection (f) was added to supplement the proposed TNI Standard that does not include onsite assessment and corrective action report requirements for laboratories applying for NELAP accreditation. This subsection specifies that NELAP laboratories shall submit a corrective action report to the Department within 30 calendar-days from receipt of the onsite assessment report from the Department. This subsection also states that if TNI develops an alternate time line for submission of a corrective action report to an accreditation body, the laboratory shall follow the TNI-designated time frame. All NELAP applicant laboratories would be expected to adhere to the requirements of this section.

Subchapter G. Miscellaneous Provisions

§ 252.706 (relating to recordkeeping). Subsection (a) was amended to specify that records must be maintained in an organized fashion in a manner accessible by the Department. This means that the laboratory must have a recordkeeping system that allows ready access by the Department in a manner that can be readily understood and retrieved upon request.

§ 252.707 (relating to subcontracting). Subsection (b) was amended to require an accredited laboratory's final report to include the accreditation number of any laboratory performing subcontracted results.

§ 252.708 (relating to reporting and notification requirements). This regulation incorporates the reporting and notification requirements for the Safe Drinking Water regulations, Chapter 109, by reference. Since the Chapter 109 requirements are silent with regard to the time for which a laboratory must validate Safe Drinking Water Act (35 P. S. §§ 721.1—721.17) compliance results, amendments to subsection (a) were made to guide an accredited laboratory in how much time an analytical result can be held before the quality control associated with the analytical or preparation batch, or both, must be reviewed and validated. Subsection (b) was amended to require laboratories to notify the Department within 20 calendar days of a change in laboratory supervisor. Subsection (e) was added to require an environmental laboratory to promptly notify the Department any time a change in analytical capability occurs for more than 90 days. The Department requires this information to ensure that queries regarding a laboratory's analytical capability to produce accredited testing results can be accurately answered and that the laboratory's scope of accreditation is an accurate reflection of the laboratory's analytical capability. The laboratory's accreditation status would be listed as suspended until capability can be adequately demonstrated to justify reinstatement of the affected fields of accreditation.

F. *Benefits, Costs and Compliance*

Benefits

The most significant benefit of these proposed amendments will be the benefit of clear, concise and improved regulations for the regulated community. The proposed amendments will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories.

Improved data quality will allow the Department, the regulated community, and the citizens of this Commonwealth to make better decisions concerning the protection of the environment and the protection of public health, safety and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws.

Compliance Costs

The direct costs of the proposed amendments will be payment of the required fees. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit such as large commercial laboratories and NELAP laboratories will pay a higher accreditation fee. The proposed amendments contain a fee structure that is responsive to the needs of small laboratories. Categories of testing for basic drinking water parameters and for basic wastewater parameters have been increased by only $50 per category. These smallest environmental laboratories currently pay $1,200 annually and the proposed fee structure will require an annual fee of $1,250. In addition, changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure allows for a laboratory performing a combination of matrices to pay a lower fee.

Compliance Assistance Plan

The proposed amendments are minor and in most cases clarify existing requirements or eliminate unnecessary requirements. As such, the Department does not believe that a compliance assistance plan tailored to the proposed amendments is necessary. However, the Department will continue its ongoing compliance assistance efforts.

The ultimate goal of the compliance assistance effort will be improving an environmental laboratory's ability to produce valid and defensible data for use by the Department, the regulated community, and the public. Several areas where compliance assistance is necessary are general laboratory operation, correct performance of specific test procedures, and documentation of laboratory activities. Compliance assistance in these areas has been made available to all environmental laboratories regardless of size throughout this Commonwealth.

G. *Sunset Review*

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

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 5, 2009, the Department submitted a copy of the proposed rulemaking to the Legislative Reference Bureau for publication of notice of proposed rulemaking in the *Pennsylvania Bulletin*, to Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees (Committees). In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections on the proposed rulemaking within 30 days of the close of public comment period. The comments, recom-

mendations or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review by the Department, the General Assembly and the Governor prior to final publication of these regulations.

I. *Public Comments*

Written Comments. Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17105-2301). Comments submitted by facsimile will not be accepted. The Board must receive comments, suggestions or objections by July 20, 2009. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by July 20, 2009. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final-form rulemaking will be considered.

Electronic Comments. Comments may be submitted electronically to the Board at RegComments@state.pa.us and must also be received by the Board by July 20, 2009. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgement of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JOHN HANGER,
Chairperson
Environmental Quality Board

Fiscal Note: 7-434. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VI. GENERAL HEALTH AND SAFETY

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

§ 252.1. Definitions.

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

* * * * *

[***Accrediting authority*** **]** ***Accreditation body***—A territorial, state or Federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

* * * * *

***Action level*—The concentration of a contaminant which, if exceeded, triggers a treatment or other requirement which a water system must follow.**

* * * * *

[***Laboratory notebook*—A chronological record of observations, results of testing or analysis, equipment maintenance or calibration or other environmental laboratory data. A laboratory notebook may be maintained in an electronic format.]**

* * * * *

NELAP **[** ***accrediting authority*** **]** ***accreditation body***—An **[accrediting authority] accreditation body** that has been recognized as meeting the requirements of the NELAC **[standards] Standard or the TNI Standard** and has the authority to grant NELAP **or TNI** accreditation.

* * * * *

Nonpotable water—

(i) Any aqueous sample excluded from the definition of drinking water matrix.

(ii) The term includes wastewater, ambient water, surface water, groundwater, effluents, water treatment chemicals and **[toxicity characteristic leaching procedure or other extracts] leachates**.

* * * * *

Secondary accreditation—Accreditation received from the Department based upon the accreditation status granted by another **[accrediting authority] accreditation body**.

* * * * *

***TNI*—The NELAC Institute or its successor organization/Standard.**

* * * * *

§ 252.4. General requirements.

* * * * *

[(c) By July 28, 2006, an environmental laboratory testing or analyzing environmental samples within a matrix identified in § 252.3 and to comply with a statute listed in § 252.3 shall apply to the Department for accreditation in accordance with Subchapter B (relating to application, fees and supporting documents). An environmental laboratory that files an application within that time period shall have interim accreditation to continue operations until the Department takes final action on the application.

(d) After July 28, 2006, an environmental laboratory that seeks accreditation under this chapter shall apply in accordance with Subchapter B. Interim accreditation will not be granted to an environmental laboratory which submits an application for accreditation after July 28, 2006.]

§ 252.5. NELAP/TNI equivalency.

* * * * *

(b) An environmental laboratory seeking NELAP accreditation shall:

(1) Submit a complete application as provided in Subchapter B (relating to application, fees and supporting documents).

(2) **Comply with Subchapter F (relating to onsite assessment requirements).**

(3) Comply with Subchapter G (relating to miscellaneous provisions).

(4) Comply with the current edition of the NELAC Standard or TNI Standard.

* * * * *

§ 252.6. Accreditation-by-rule.

(a) *Purpose.* Environmental laboratories performing testing or analysis described in this section will be deemed to have accreditation-by-rule if the following general requirements are met:

(1) The environmental laboratory registers with the Department in accordance with 27 Pa.C.S. § 4107(a) (relating to interim requirements).

[(1)] (2) The environmental laboratory performs the testing or analysis in conformance with applicable State or Federal laws, regulations, promulgated methods, orders and permit conditions.

[(2)] (3) The environmental laboratory assures that samples for testing or analysis are properly preserved, are in proper containers, do not exceed maximum holding times between collection and analysis and are handled in accordance with applicable State or Federal Laws, regulations, promulgated methods, orders and permit conditions.

[(3)] (4) The environmental laboratory has the other necessary permits under the applicable environmental protection acts and is operating under the acts and regulations promulgated thereunder and the terms and conditions of permits.

[(4) (5) Records pertaining to the testing or analysis of environmental samples are retained onsite and in accordance with § 252.706 (relating to recordkeeping). Records shall be made available to the Department upon request.

[(5)] (6) The environmental laboratory is reporting the results of the testing or analysis of environmental samples in conformance with the applicable State or Federal laws, regulations, orders or permit conditions.

* * * * *

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.202. Application for transfer of laboratory accreditation.

* * * * *

(b) **[Open or pending enforcement] Enforcement** actions will be transferred with the accreditation.

* * * * *

§ 252.204. Fees.

(a) The appropriate fee in accordance with the following schedule must accompany an application for accreditation, renewal of accreditation, change of ownership, **[or] change in administrative information,** addition of fields of accreditation**, or supplemental onsite assessment**. A check must be payable to "Commonwealth of Pennsylvania." The fees are as follows:

Category	*Fee*
[Application fee—initial application	**$600**
Application fee—renewal application	**$500**
Application fee—ownership transfer	**$150**
Application fee—addition of fields of accreditation	**$250**
Basic drinking water category (one method for each of the following: total coliform bacteria, fecal coliform bacteria, E-coli bacteria, heterotropic bacteria, nitrate, nitrite, fluoride, cyanide)	**$600**
Asbestos—drinking water	**$350**
Microbiology—drinking water	**$450**
Trace metal category—drinking water	**$450**
Inorganic nonmetal category—drinking water	**$500**
Trace metal and inorganic nonmetal category—drinking water	**$800**
Volatile organic chemicals—drinking water	**$500**
Extractable and semivolatile organic chemicals—drinking water	**$750**
Dioxin—drinking water	**$600**
Radiochemical category—drinking water	**$700**
Basic nonpotable water category (one method for each of the following: fecal coliform bacteria, BOD, CBOD, nitrate, ammonia, total nitrogen, total kjeldahl nitrogen, nitrite, phosphorus and one method for each type of residue)	**$700**
Asbestos—nonpotable water	**$350**
Microbiology—nonpotable water	**$400**
Trace metal category—nonpotable water	**$450**
Inorganic nonmetal category—nonpotable water	**$550**
Trace metal and inorganic nonmetal category—nonpotable water	**$900**
Volatile organic chemicals—nonpotable water	**$500**
Extractable and semivolatile organic chemicals—nonpotable water	**$950**
Dioxin—nonpotable water	**$600**
Radiochemical category—nonpotable water	**$600**

Category	*Fee*
Whole effluent toxicity testing category	**$600**
Microbiology—drinking water and nonpotable water	**$750**
Trace metal category—drinking water and nonpotable water	**$800**
Inorganic nonmetal category—drinking water and nonpotable water	**$1,000**
Trace metal and inorganic nonmetal category—drinking water and nonpotable water	**$1,550**
Volatile organic chemicals—drinking water and nonpotable water	**$900**
Extractable and semivolatile organic chemicals—drinking water and nonpotable water	**$1,650**
Dioxin—drinking water and nonpotable water	**$1,050**
Radiochemical category—drinking water and nonpotable water	**$1,050**
Asbestos—solid and chemical materials	**$350**
Microbiology—solid and chemical materials	**$450**
Trace metal category—solid and chemical materials	**$450**
Inorganic nonmetal category—solid and chemical materials	**$550**
Volatile organic chemicals—solid and chemical materials	**$550**
Extractable and semivolatile organic chemicals—solid and chemical materials	**$1,200**
Dioxin—solid and chemical materials	**$600**
Radiochemical category—solid and chemical materials	**$600]**
Application fee—Initial Application for State Accreditation	**$750**
Application fee—Renewal Application for State Accreditation	**$500**
Application fee—Ownership Transfer or Change in Administrative Information	**$150**
Application fee—Initial Application for NELAP/TNI Accreditation	**$2,500**
Application fee—Renewal Application for NELAP/TNI Accreditation	**$2,000**
Application fee—Addition of Field of Accreditation	**$250**
Application fee—Supplemental Onsite Assessment	**$500**
Basic Drinking Water Category—Includes one method for each of the following: Total Coliform Bacteria, Fecal Coliform Bacteria, *E. coli* Bacteria, Heterotrophic Bacteria, Nitrate, Nitrite, Fluoride, Cyanide	**$650**
Basic Nonpotable Water Category—Includes one method for each of the following: Fecal Coliform Bacteria, BOD, CBOD, Nitrate, Ammonia, Total Nitrogen, Total Kjeldahl Nitrogen, Nitrite, Phosphorus, and one method for each type of residue including % Solids for land applied biosolids	**$750**
Asbestos—first matrix	**$400**
Microbiology—first matrix	**$500**
Trace Metal Category—first matrix	**$550**
Inorganic Nonmetal Category—first matrix	**$600**
Volatile Organic Chemicals—first matrix	**$650**
Extractable and Semivolatile Organic Chemicals—first matrix	**$1,500**
Dioxin—first matrix	**$650**
Radiochemical Category—first matrix	**$750**
Whole Effluent Toxicity Testing—first matrix	**$700**
Asbestos—second matrix	**$350**
Microbiology—second matrix	**$450**
Trace Metal Category—second matrix	**$500**
Inorganic Nonmetal Category—second matrix	**$550**
Volatile Organic Chemicals—second matrix	**$600**
Extractable and Semivolatile Organic Chemicals—second matrix	**$1,400**
Dioxin—second matrix	**$600**
Radiochemical Category—second matrix	**$700**
Asbestos—third matrix	**$300**

Category	*Fee*
Microbiology—third matrix	**$400**
Trace Metal Category—third matrix	**$450**
Inorganic Nonmetal Category—third matrix	**$500**
Volatile Organic Chemicals—third matrix	**$550**
Extractable and Semivolatile Organic Chemicals—third matrix	**$1,300**
Dioxin—third matrix	**$550**
Radiochemical Category—third matrix	**$650**

* * * * *

§ 252.205. Out-of-State laboratories.

(a) Out-of-State environmental laboratories may apply for primary accreditation or secondary accreditation from the Department.

* * * * *

(2) *Secondary accreditation.*

(i) The Department will recognize accreditation granted by a primary NELAP **[accrediting authority] /TNI accreditation body** for the same fields of accreditation for which the Department is a primary NELAP **[accrediting authority] /TNI accreditation body**.

* * * * *

(iii) An environmental laboratory seeking secondary accreditation from the Department shall:

* * * * *

(C) Submit a copy of a valid accreditation certificate from the primary **[accrediting authority] accreditation body**.

* * * * *

(E) [Submit copies of all proficiency test sample results reported to the primary accrediting authority within the past 12 months. (F)] Submit any other material relevant to accreditation, upon request of the Department.

* * * * *

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

(a) **The Department will consider the laboratory supervisor of an environmental laboratory as the individuals listed on the laboratory's application for accreditation for which the Department has reviewed and approved the individual's qualifications.**

(b) Testing, analysis and reporting of data by an environmental laboratory shall be under the direct supervision of a laboratory supervisor.

[(b)] (c) The laboratory supervisor shall certify that each test or analysis is accurate and valid and the test or analysis was performed in accordance with all conditions of accreditation. A laboratory supervisor may certify a test or analysis by signing the final laboratory report. A laboratory may use other mechanisms to certify a test or analysis, provided the mechanism is documented in the laboratory quality manual.

[(c)] (d) The laboratory supervisor shall ensure that the records required by this chapter are maintained.

[(d)] (e) The Department may disqualify a laboratory supervisor who is responsible for the submission of inaccurate test or analysis results.

[(e)] (f) The Department will disqualify a laboratory supervisor convicted of any crime or offense related to violations of State or Federal laws or regulations related to the provision of environmental laboratory services or reimbursement for the services.

[(f)] (g) An environmental laboratory may appoint one or more laboratory supervisors for the appropriate fields of accreditation for which they are seeking accreditation.

[(g)] (h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16 consecutive calendar days. If this absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

[(h)] (i) An individual may not be the laboratory supervisor of more than one environmental laboratory without authorization from the Department. Circumstances to be considered in the decision to grant the authorization will include at least the following:

(1) The extent to which operating hours of the laboratories to be supervised overlap.

(2) The adequacy of supervision in each laboratory.

§ 252.302. Qualifications of the laboratory supervisor.

* * * * *

(d) A laboratory supervisor of an environmental laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and **[heterotropic] heterotrophic** bacteria shall have the following qualifications:

* * * * *

(2) A minimum of 4-college semester credit hours in **[general microbiology] biology**.

(3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in **[general microbiology] biology**, may be substituted for the associate's degree.

* * * * *

§ 252.304. Personnel requirements.

* * * * *

(b) *Laboratory management responsibilities.* The environmental laboratory management shall be responsible for:

* * * * *

(3) Ensuring and documenting that the training and competency of each member of the environmental laboratory technical staff is kept up to date by maintaining records demonstrating the following:

* * * * *

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities**[.] has been performed. The initial demonstration of capability requirements are as follows:**

(A) An initial demonstration of capability is required prior to the use of any method.

(B) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel or method.

(C) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(D) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed; otherwise, an initial demonstration of capability shall be performed as follows:

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be approximately ten times the detection limit.

(II) At least four aliquots of the quality control sample must be prepared and analyzed according to the method.

(III) Using all of the results, calculate the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(IV) Compare the information from subclause (III) to the corresponding acceptance criteria for precision and accuracy in the method. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(E) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, the environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(F) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(G) The work cell as a unit shall meet the following requirements:

(I) When a member of a work cell changes, the new employee shall work with an experienced analyst in the work cell.

(II) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(III) If the entire work cell is changed, an initial demonstration of capability shall be completed.

* * * * *

§ 252.306. Equipment, supplies and reference materials.

* * * * *

(f) The following pieces of equipment shall be maintained according to this subsection.

* * * * *

(2) *Working thermometers.*

* * * * *

(ii) Working thermometers may be glass, dial or electronic and shall be calibrated against a certified NIST-reference thermometer as follows:

(A) Glass **[and electronic thermometers and continuous recording devices], liquid filled thermometers** shall be calibrated every 12 months at the temperature used.

(B) Dial **and electronic** thermometers shall be calibrated every 3 months at the temperature used. **[Dial thermometers that cannot be calibrated may not be used.] Electronic thermometers accompanied by a valid NIST traceable certificate of acceptance may be used for 12 months from the date of receipt before re-calibration.**

(C) An environmental laboratory shall maintain records **[in a laboratory notebook]** for each working thermometer that **[documents] document** the date of calibration, NIST reference thermometer identification, working thermometer identification, reference thermometer temperature reading, working thermometer temperature reading, correction factor and the initials of the individual conducting the calibration.

* * * * *

(iv) A working thermometer that differs by more than **[1.0C] 2.0°C** from the reference thermometer may not be used.

(3) *ASTM* ***[type] class*** *1, 2 or 3 (Class S or S-1****), or better*** *certified reference weights.*

(i) The mass of ASTM **[type] class** 1, 2 or 3 (Class S or S-1**), or better** certified reference weights shall be recertified at least once every 5 years.

* * * * *

(4) *Analytical or pan balances.*

* * * * *

(iv) Balance calibration shall be verified using a minimum of three ASTM **[type] class** 1, 2 or 3 (Class S or S-1) certified reference weights that bracket the effective range of the balance's use.

(v) An environmental laboratory shall maintain records **[in a laboratory notebook]** of balance calibrations that document the balance identification, date of calibration verification, reference weights used and initials of the individual performing the calibration. **[Correction factors shall be documented and used.]**

* * * * *

(5) *pH meter.*

* * * * *

(iii) The pH meter shall be **[standardized] calibrated** daily or before each use, whichever is less frequent, by one of the following:

* * * * *

(v) Records of pH meter standardization shall be maintained **[in a laboratory notebook]** that **[documents] document** the date of standardization, calibration buffers used and initials of the individual conducting the standardization.

(6) *Conductivity meter.*

* * * * *

(iv) Records of conductivity meter calibrations shall be maintained **[in a laboratory notebook]** that **[documents] document** the date of calibration, standards used, results of calibration or cell constant determined and the initials of the individual conducting the calibration.

* * * * *

(8) *Incubators, water baths* **[*and*],** *heating blocks* ***and ovens.***

(i) An environmental laboratory shall control and monitor the temperature of incubators, water baths **[and],** heating blocks **and ovens** in accordance with the method or as specified by regulations.

(ii) An environmental laboratory shall maintain a minimum of one thermometer per incubator, water bath **[or],** heating block **or oven** immersed in liquid **or sand for ovens** (except electronic thermometers) to the appropriate immersion line. When used as an incubation unit for microbiology, a minimum of one working thermometer shall be on the top and bottom shelf of the use area in each incubator.

* * * * *

(iv) Calibration-corrected temperatures for each incubator, water bath **[or],** heating block **or oven** shall be recorded once a day for each day in use for all laboratory activities. When used as an incubation unit for microbiology, the calibration-corrected temperature shall be recorded at least twice per day in use with the readings separated by at least 4 hours. The incubator, water bath or heating block identification, date, time, calibration corrected temperature and the initials of the responsible individual shall be recorded.

(9) *Volumetric dispensing devices.*

(i) Except for Class A glassware, mechanical volumetric dispensing devices including burettes, autopipetors and dilutors, must be of sufficient sensitivity for the application. Delivery volumes of mechanical volumetric dispensing devices shall be checked using **[a gravimetric] an appropriate** method at least once every 3 months.

(ii) Verification will be considered acceptable if the accuracy of the volumetric dispensing device is within 2.5% of expected values. Volumetric dispensing devices that do not meet this criterion may not be used.

(10) *Graduated sample containers.*

[When] (i) Except for Class A glassware, when graduation marks on **[clear glass or plastic] filter** funnels **[or],** sample bottles **or labware** are used to measure sample volume, an environmental laboratory shall verify and document the accuracy of the volume of **use for** each lot or at least once per year, whichever is more frequent.

(ii) Verification will be considered acceptable if the accuracy of the graduated sample container is within 2.5% of expected values. Graduated sample containers that do not meet this criterion may not be used to measure sample volumes.

[(11) *Spectrophotometer or colorimeter.* A spectrophotometer or colorimeter must be calibrated according to the manufacturer's specifications or test methods. An environmental laboratory shall maintain records of the calibrations.]

* * * * *

(h) **[Reference materials and reagents used for environmental testing must meet the following minimum requirements:**

(1) Analytical reagent grade chemicals or equivalent are acceptable, unless a method specifies other reagent purity grade requirements.

(2) Reagent and standard solutions shall be checked regularly for signs of decomposition, evaporation, and expiration. An environmental laboratory shall maintain standard and reagent preparation logs for all stack and working standards solutions in a laboratory notebook. Standards and reagent preparation logs must contain identification of the compound, concentration, date prepared, initials of the individual preparing the solution and expiration date.

(3) Reagent and standard solution containers shall be labeled with identification of the compound, concentration, date prepared, initials of the individual who prepared the solution and expiration date.

(4) Purchased chemicals, solutions and standards shall be labeled with date of receipt and the date when the container is opened. Purchased chemicals, solutions and standards without an expiration date on the original container shall be discarded after 10 years from the date of receipt.

(5) When reagents are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(6) Compressed gases must be of commercial grade, unless a method specifies other requirements.]

Reference materials, reagents, media and laboratory supplies that are essential to obtain analytical results (such as filters, solid-phase extraction disks/cartridges, presterilized filtration units, certified precleaned laboratory supplies, disposable volumetric equipment, prepreserved sample containers) must meet the following minimum requirements:

(1) Analytical reagent grade chemicals or equivalent are acceptable, unless a method specifies other reagent purity grade requirements.

(2) Standard, reagent and laboratory supply receipt records shall be maintained. These records must include vendor, lot number, amount received, date of receipt, expiration date and certificates of analysis or purity, if available.

(3) Purchased chemicals, solutions, standards, media and laboratory supplies shall be labeled with date of receipt, expiration date and the date when the container is opened. Purchased chemicals, solutions and standards without an expiration date on the original container shall be discarded after 10 years from the date of receipt.

(4) An environmental laboratory shall maintain records of standard, reagent and media preparation. Standard and reagent preparation records must contain identification of the compound, manufacturer, lot number, concentration, amount prepared, date prepared, final pH if used for microbiology testing, initials of the individual preparing the solution and expiration date.

(5) Reagent and standard solution containers shall be labeled with identification of the compound, traceability to the preparation record, such as unique identifier, and expiration date

(6) Standards, reagents and media may not be used past the date of expiration unless reevaluated and validated by a Department approved procedure.

(7) Reagent and standard solutions shall be checked regularly for signs of decomposition and evaporation. Reagent and standard solutions exhibiting signs of decomposition or evaporation shall be discarded.

(8) When reagents are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(9) Compressed gases must be of commercial grade, unless a method specifies other requirements.

* * * * *

§ 252.307. Methodology.

* * * * *

(d) An environmental laboratory shall develop and maintain written standard operating procedures for all fields of accreditation.

(1) The environmental laboratory's standard operating procedures must accurately reflect all aspects of the testing or analysis for the fields of accreditation, including the following:

* * * * *

(iii) Scope, including applicable matrix or matrices**, quantitation range, and for drinking water testing MCLs or action levels as appropriate**.

* * * * *

[(j) The initial demonstration of capability requirements are as follows:

(1) Prior to the use of any method, an initial demonstration of capability is required.

(2) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel, or method.

(3) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(4) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed, otherwise, an initial demonstration of capability shall be performed as follows:

(i) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be approximately ten times the detection limit.

(ii) At least four aliquots of the quality control sample must be prepared and analyzed according to the method.

(iii) Using all of the results, calculate the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(iv) Compare the information from subparagraph (iii) to the corresponding acceptance criteria for precision and accuracy in the method. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(5) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, an initial demonstration of capability is not required. An environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(6) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(7) The work cell as a unit shall meet the requirements of this paragraph.

(i) When a member of a work cell changes, the new employee shall work with an experienced analyst in the work cell.

(ii) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(iii) If the entire work cell is changed, an initial demonstration of capability shall be completed.]

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

(a) An environmental laboratory shall develop and maintain a quality manual appropriate to the type, range and volume of testing and analysis of environmental samples. The quality manual shall be available to and used by environmental laboratory personnel. **The quality manual must contain the following:**

(1) The full name and physical address of the laboratory.

(2) The name, address (if different from paragraph (1)), and telephone number of the laboratory supervisors.

(3) A revision number and effective date.

(4) A table of contents, and applicable lists of references, glossaries and appendices.

(b) The quality manual must state the environmental laboratory's policies, operational procedures, protocols and practices established to meet the requirements of this chapter. **These policies and procedures must include:**

(1) An ethics policy statement as specified in subsection (d).

(2) A document control system as specified in subsection (c).

(3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).

(4) The procedures for termination of operations and transfer of records as specified in § 252.706.

(5) The procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).

(6) The procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).

(7) The sample handling and acceptance procedures as specified in subsections (f) and (g).

(8) The reporting of analytical results as specified in subsection (j).

(9) The monitoring of the quality of analysis as specified in subsection (l).

* * * * *

(d) An environmental laboratory shall develop and maintain an ethics policy statement relevant to the employee's duties and responsibilities under the act.

(1) The laboratory shall **[have] implement** procedures for educating and training personnel in their ethical and legal responsibilities under the act.

(2) The laboratory shall provide training in ethical and legal responsibilities within 2 months of employment to the laboratory and at least every 14 months thereafter for all employees.

* * * * *

(f) An environmental laboratory shall establish procedures for handling environmental samples.

(1) The environmental laboratory shall implement procedures for checking the thermal or chemical, or both, preservation and the sample container. The results of these checks shall be recorded.

(2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:

(i) The client/project name.

(ii) The date, time and location of sample collection, name of sample collector and field identification code.

(iii) The date and time of laboratory receipt.

(iv) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

(v) A unique laboratory ID code that corresponds to the information required by this paragraph.

(vi) An identification of the person making the entries.

* * * * *

(j) An environmental laboratory shall develop procedures for reporting results of testing or analysis of environmental samples. **Each test report must include at least the following information, except as specified in subsection (k).**

(1) The name and address of the laboratory.

(2) The total number of pages in the report, including any addendums, in the format of Page x of y.

(3) The name and address of the client.

(4) An identification of the test method used.

(5) An identification of the samples including the client identification code.

(6) The date and time of sample collection.

(7) The date of sample analysis.

(8) The time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.

(9) The test results and units of measurement.

(10) The quantitation limit.

(11) The names, functions and signatures of the persons authorizing the test report.

(12) Results reported on a basis other than as received (for example, dry weight).

(13) An identification of testing or analysis results not covered by the laboratory's scope of accreditation.

(14) An identification of results that do not meet the requirements of this chapter.

(15) An identification of subcontracted results.

(k) **Tests performed by an environmental laboratory operated by a facility that provides results to the facility management for compliance purposes do not need to be reported under subsection (j) regarding laboratory sample handling procedures, provided the information required by subsection (j) is maintained under § 252.706**

(l) An environmental laboratory shall implement procedures or practices to monitor the quality of the laboratory's analytical activities. Examples of the procedures or practices are:

* * * * *

[(l)] (m) To the extent possible, results of testing or analysis of environmental samples shall be reported only if all quality control**, analytical testing and sample acceptance** measures are acceptable. If a quality control**, analytical testing and sample acceptance** measure is found to be out of control and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed quality control measure shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

[(m)] (n) Policies, procedures, protocols and practices specified in this section must be in writing and be followed.

§ 252.402. Essential quality control requirements—chemistry.

* * * * *

(c) Initial calibration requirements are as follows:

* * * * *

(6) **[Results not bracketed by the initial calibration standards shall be reported with appropriate qualifiers.**

(7)] The lowest standard used for initial calibration may not be below the detection limit. The lowest standard must be at or below the lower limit of the range of quantitation.

(d) Except for methods that explicitly allow initial calibration using a single concentration of standard, initial calibration shall be done using multiple concentrations of standards according to the requirements of this subsection.

(1) Unless otherwise specified in the method, the initial calibration must meet one of the following criteria:

* * * * *

(ii) A **[correlation]** coefficient **[(r)] of determination (r^2)** of 0.99 for a linear calibration curve.

(iii) A **[correlation]** coefficient **[(r)] of determination (r^2)** of 0.999 for a nonlinear calibration curve **determined with the use of at least 6 calibration standards** or as otherwise specified by the Department.

* * * * *

(6) If the method does not specify the number of calibration standards, the minimum number of calibration standards **for a response factor or linear calibration**, not including blanks or a zero standard, shall be determined as follows:

* * * * *

(f) Calibration verification requirements are as follows:

* * * * *

(3) At a minimum, the **[concentration of the] laboratory shall verify the calibration curve of each analytical batch with** calibration verification **[standard shall be alternated between] standards at** a low and a high level.

* * * * *

(h) Laboratory control sample requirements are as follows:

* * * * *

(2) **[The laboratory control sample must consist of a defined matrix containing known and verified concentrations of analytes. The Department will allow the use of an artificial or simulated matrix when a defined matrix is not commercially available] A laboratory control sample must consist of a matrix that is similar to the associated environmental samples and is free of the analytes of interest. When a matrix that is similar to the associated environmental samples that is free of the analytes of interest is not available, reagent water or an artificial or simulated matrix may be used.**

* * * * *

(i) Sample duplicate requirements are as follows:

(1) **A sample duplicate or matrix spike duplicate must be processed along with and under the same conditions as the associated environmental samples, including all steps of the preparation and analytical procedure.**

(2) A sample duplicate or matrix spike duplicate shall be analyzed at a minimum of one per preparation batch. When no separate preparation method is used, for example volatiles in water, the batch shall be defined as no more than 20 environmental samples that are analyzed together using the same method, personnel and lots of reagents.

[(2)] (3) An environmental laboratory shall document the calculations used for determining the relative percent difference or other statistical method for evaluation of the duplicate pairs.

[(3)] (4) Each duplicate relative percent difference shall be compared to the acceptance criteria in the method. When there are no established criteria in the method, an environmental laboratory shall determine internal criteria and document the procedure used to establish the acceptance limits.

[(4)] (5) For duplicate results outside established criteria, corrective action shall be documented and the data reported with appropriate data qualifiers.

* * * * *

(m) When manual integrations are performed for chromatography methods, the laboratory shall have written procedures for manual integrations and instrument manipulations.

(1) The manual integration procedures must detail the steps taken to perform the integrations and define proper and improper integrations.

(2) The laboratory shall document manual integrations with the reason for the integration and the initials of the individual performing the integration.

(3) The laboratory shall retain a copy of the data before and after manual integration.

(n) The laboratory shall employ confirmation techniques to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested

by the laboratory or for a sample location that has not previously yielded detectable results for a particular compound.

(1) The confirmations shall be performed when analysis involves the use of an organic chromatography method not utilizing a mass spectrometer.

(2) The confirmations shall be documented.

(o) Records of all equipment, reference materials, reagents, and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

§ 252.403. Essential quality control requirements—toxicity testing.

* * * * *

(q) Records of all equipment, reference materials, reagents and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

§ 252.404. Essential quality control requirement—microbiology.

* * * * *

(c) The following pieces of equipment shall be maintained according to this subsection:

(1) *Autoclave.*

(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. **[Pressure cookers may not be used.] Because of safety concerns and difficulties with operational control, pressure cookers should not be used. Pressure cookers may not be used for sterilization of media.**

(ii) **[Prior to first use, an environmental laboratory shall evaluate and document the performance of an autoclave by establishing its functional properties and performance (for example, heat distribution characteristics with respect to typical uses).**

(iii)] A continuous temperature-recording device or a maximum-temperature-registering thermometer shall be used during each autoclave cycle.

[(iv)] (iii) An environmental laboratory shall verify the sterilization capability of each autoclave by utilizing appropriate biological indicators (for example, spore strips or ampoules) once a month. Records of biological indicator tests shall be maintained **[in a laboratory notebook]** and include the autoclave identification, date, incubation time and temperature, results and initials of the responsible individual.

[(v)] (iv) An environmental laboratory shall verify the mechanical timing device, if used, for each autoclave every 3 months. Records of mechanical timer verification shall be maintained **[in a laboratory notebook]** and include the autoclave identification, date, mechanical timing device time, actual time and initials of the responsible individual. Correction factors shall be documented and used.

[(vi)] (v) Autoclaves shall be properly cleaned and maintained. **[A qualified person shall service autoclaves at least once per year. Servicing must include a pressure check and calibration of temperature devices. Records of annual service shall be maintained and the service date shall be recorded on the autoclave] Copies of service contracts or internal maintenance protocols and maintenance records shall be kept.**

[(vii)] (vi) Required times for autoclaving items at 121°C are set forth in this subparagraph. The following items must be at temperature for the required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times and may necessitate adjustment depending upon volumes, containers and loads. For autoclave runs that include membrane filters and pads and media, the total cycle time may not exceed 45 minutes. Autoclaved membrane filters and pads and media shall be removed immediately after completion of the autoclave cycle.

* * * * *

[(viii)] (vii) Records of each autoclave run shall be maintained **[in a laboratory notebook]** and include the date, contents, sterilization time and temperature, total cycle time (recorded as time in and time out) and initials of the responsible individual.

[(ix)] (viii) If an autoclave cycle fails to meet any requirement, corrective action shall be documented. Media may not be reautoclaved.

(2) *Hot air oven.*

(i) **[Prior to first use, an environmental laboratory shall evaluate the performance of each hot air oven by establishing its functional properties and performance (for example, heat distribution characteristics with respect to typical uses).**

(ii)] An environmental laboratory shall maintain a thermometer, graduated in 10°C increments or less with the bulb placed in sand, in each hot air oven.

[(iii)] (ii) An environmental laboratory shall verify the sterilization capability of each hot air oven by utilizing appropriate biological indicators (for example, spore strips) once a month. Records of biological indicator tests shall be maintained **[in a laboratory notebook]** and include the hot air oven identification, date, incubation time and temperature, results and initials of the responsible individual.

[(iv)] (iii) An environmental laboratory shall sterilize items in a hot air oven maintaining a temperature of 170°—180°C for a minimum of 2 hours. Only dry items may be sterilized in a hot air oven.

[(v)] (iv) Records of each hot air oven operation shall be maintained and include the date, contents, sterilization time and temperature, and initials of the responsible individual.

(3) **[*Optical counting equipment.***

(i) An environmental laboratory shall use appropriate optical counting equipment to view and enumerate colonies.

(ii) A dark field colony counter shall be used to count heterotrophic plate count colonies.

(iii) A 10X to 15X stereomicroscope with a fluorescent light source shall be used to count sheen colonies.

(4)] *Inoculating equipment.*

* * * * *

[(5)] (4) *Membrane filtration equipment.*

(i) Membrane filtration funnels must be stainless steel, glass**, porcelain** or autoclaveable **or presterilized** plastic. Membrane filtration funnels may not be scratched or corroded and may not leak.

(ii) Membrane filtration units shall be **[autoclaved] sterilized** before the beginning of a filtration series. A filtration series ends when 30 minutes or longer elapses after a sample is filtered.

* * * * *

(v) **[Records of membrane filters shall be maintained and include the type, lot number, date received and date opened. The manufacturer's specification/certification sheet shall be retained for each lot of membrane filters.**

(vi)] An environmental laboratory using an ultraviolet sanitation lamp to sanitize filtration funnels between successive filtrations shall test the ultraviolet sanitation lamp every 3 months for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Records of ultraviolet lamp tests shall be maintained and bulbs shall be replaced if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.

[(6)] (5) *Culture dishes.*

* * * * *

[(7)] (6) *Culture tubes and closures.* Culture tubes and containers must be of sufficient size to contain medium and sample without being more than three quarters full. Tube closures must be stainless steel, aluminum, plastic or a screw cap with a nontoxic liner.

[(8)] (7) *Pipettes.*

(i) Pipettes must have legible markings and may not be chipped or etched **and must be accurate to within 2.5% tolerance**.

* * * * *

[(9)] (8) *Sample containers.*

* * * * *

[(10)] (9) *Plastic and glassware washing procedure.*

* * * * *

[(11)] (10) *Ultraviolet lamp.* An environmental laboratory shall use a 365-nm, 6-watt ultraviolet lamp in a darkened room to view sample fluorescence.

[(12)] (11) *Quanti-Tray™ Sealer.*

* * * * *

(d) The requirements for reagent water are as follows:

* * * * *

(4) The **[monthly and annual reagent water] metals** analyses may only be performed by an environmental laboratory accredited under this chapter for **[the field] those fields** of accreditation **[that includes the analyte]**.

* * * * *

(6) The bacteriological water quality test need not be performed if the environmental laboratory can supply documentation to show that their laboratory pure water or reagent water meets the criteria, as specified in **section 1080 of** the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005), for Type I **(high-quality)** or Type II **(medium-quality)** reagent water.

(e) The requirements for dilution/rinse water are as follows:

* * * * *

(2) Stock buffers shall be autoclaved or filter-sterilized. **[Stock buffer containers shall be labeled and dated.]** Stock buffers shall be refrigerated**[.] and [Stored stock buffers]** must be free from turbidity.

* * * * *

[(4) Records of stock buffers and dilution/rinse water preparation shall be maintained and include the date prepared, lot number or laboratory identification of solutions used, amounts measured, final pH and initials of the responsible individual.]

(f) The requirements for media are as follows:

* * * * *

(2) **[An environmental laboratory that uses commercially prepared media shall maintain records on each lot received that includes the date received, type of media, lot number and pH verification. Media may not be used after the manufacturer's expiration date.**

(3)] An environmental laboratory that prepares media from dehydrated stock shall follow method specifications **[and maintain records of each batch that includes the date of preparation, type of media, lot number, amounts measured, sterilization time and temperature, final pH and initials of the responsible individual.**

(4)] (3) Media may not be reautoclaved.

[(5)] (4) After **[sterilization, prepared] preparation,** media shall be stored and maintained as follows:

* * * * *

(iv) **[Liquid] Fermentation** media stored in a refrigerator shall be incubated overnight at room temperature before use. Media that shows growth or bubbles may not be used.

* * * * *

(g) An environmental laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization or environmental exposure as follows:

* * * * *

(2) For each **reuseable** membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning, after every ten samples, and at the end of the series **[and record the results. If the membrane filtration unit sterility blank indicates contamination, the data from affected samples shall be invalidated and an immediate resampling requested. When a filtration series is interrupted for more than 30 minutes, the filtration funnels shall be resterilized]**. A series is consid-

ered ended when more than 30 minutes elapses between filtrations. The laboratory shall insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration in addition to the regular rinsing procedure. Records of sterility blank results must be maintained. If sterility blanks indicate contamination, the laboratory must treat affected sample according to program requirements.

(3) **[For pour plate technique, sterility blanks of the medium shall be made by pouring at least one uninoculated plate for each lot of preprepared, ready-to use media and for each batch of medium prepared in the laboratory. Results shall be recorded. If the sterility check indicates contamination, the data from affected samples shall be invalidated] For presterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot**.

* * * * *

(h) The requirements for positive and negative culture control checks are as follows:

(1) Each preprepared, ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one pure culture of a known positive reaction prior to first use of the medium **by the laboratory**. Records shall be maintained and include the date, media lot or batch number, type of media, positive culture control organism identification, results and initials of responsible individual. If positive culture control checks do not meet expected results, the affected media may not be used.

(2) Each preprepared, ready-to-use lot of selective medium and each batch of selective medium prepared in the laboratory shall be tested with at least one pure culture of a known negative reaction prior to first use of the medium **by the laboratory**. Records shall be maintained and include the date, media lot or batch number, type of media, negative culture control organism identification, results and initials of the responsible individual. If negative culture control checks do not meet expected results, the affected media may not be used.

* * * * *

(5) Culture controls may be single use or cultures maintained by the laboratory using a documented procedure that maintains the purity and viability of the organisms.

(6) For cultures maintained by the laboratory, the following criteria must be met:

(i) Reference control cultures may be revived and subcultured once to provide reference stocks.

(ii) Reference stocks shall be preserved using a method which maintains the characteristics of the organism strains. If reference stocks are thawed, they may not be refrozen and reused.

(iii) Working stocks shall be prepared from reference stocks for routine laboratory work.

(iv) If the laboratory sequentially cultures working stocks, the laboratory shall prepare a second working stock. Sequential culturing may not be performed from a working stock that has been used for routine laboratory work

(v) Working stocks may not be used for more than 30 days.

(vi) Working stocks may not be sequentially cultured more than five times and may not be subcultured to replace reference stocks.

(vii) Secondary working stocks shall be used to prepare sequential working stocks.

(i) **[The requirements for test variability/ reproducibility are as follows:**

(1)] For test methods that specify colony counts, duplicate counts shall be performed monthly on one positive sample for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more than 10%. In an environmental laboratory with only one analyst, the analyst shall count the same plate twice. Counts may not differ by more than 5%.

[(2) If the protocol for a method does not require a positive culture control during sample analysis, the environmental laboratory shall analyze a positive culture control organism through the entire method on a monthly basis.

(3) If the method determines organism density, a control sample shall be prepared from stock culture to contain 20 to 80 viable organisms per the usual volume analyzed. The positive control shall then be processed through all steps of the method and the density of the positive control determined and recorded.

(4) If the environmental laboratory is using a method for detecting as opposed to counting organisms, a control sample may be inoculated by transferring a portion of the sample from a positive stock culture to 100-mL of reagent or dilution water.]

(j) Records of all equipment, reference materials, reagents, media and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

§ 252.405. Essential quality control requirement—radiochemistry.

* * * * *

(m) Records of all equipment, reference materials, reagents, and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

* * * * *

(l) An environmental laboratory shall direct the proficiency test study provider to report the proficiency test study performance results directly to the **[Department] Department's Laboratory Accreditation Program** at the same time that the provider reports the results to the environmental laboratory.

* * * * *

Subchapter F. ONSITE ASSESSMENT REQUIREMENTS

§ 252.601. Onsite assessment requirements.

(a) Prior to **[accrediting] granting primary accreditation to** an environmental laboratory, the Department will perform an onsite assessment of the laboratory.

* * * * *

(f) **An environmental laboratory seeking NELAP accreditation shall submit a corrective action report to the Department within 30 calendar days from receipt of the onsite assessment report from the Department where the Department has found deficiencies. If TNI establishes a different time for submitting corrective action reports, the laboratory shall follow the time established by TNI. The corrective action report shall document the corrective action taken by the laboratory to correct each deficiency.**

(g) If any portion of the corrective action report is not acceptable, an environmental laboratory shall submit a revised written corrective action report within 30 calendar days from receipt of the Department's response. If the second corrective action report is not acceptable, the Department may revoke accreditation.

[(g)] (h) Unless otherwise approved by the Department, deficiencies shall be corrected within 120 calendar days of receipt of the onsite assessment report.

[(h)] (i) The Department may extend the period of implementing corrective actions, for specific deficiencies, for a maximum of 30 calendar days upon receipt of the laboratory's written petition and corrective action report, when the laboratory must take one or more of the following actions:

* * * * *

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.706. Recordkeeping.

(a) An environmental laboratory shall maintain records in **[a] an organized** manner accessible by the Department.

* * * * *

§ 252.707. Subcontracting.

* * * * *

(b) The **accreditation number of the** subcontracted environmental laboratory shall be indicated on the final report.

§ 252.708. Reporting and notification requirements.

(a) An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall **[meet the reporting and notification requirements of that chapter.]:**

(1) Meet the reporting and notification requirements of that chapter.

(2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbilogical, inorganic and wet chemistry analysis. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business.

(3) For organic analyses, review all sample analysis data within 7 days of acquisition of the initial sample results for organic anaylsis.

(b) An environmental laboratory shall notify the Department, in writing, within **[30] 20** calendar days of a change in laboratory supervisor.

* * * * *

(e) **An environmental laboratory shall notify the Department, in writing, if a change in the laboratory's capability to produce valid analytical results persists for more than 90 calendar days for any field of accreditation listed on the laboratory's scope of accreditation.**

(f) An out-of-State environmental laboratory with either primary or secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of any changes in the laboratory's accreditation status from any other primary accrediting authority.

[(f)] (g) The Department may require additional information or proof of continued capability to perform the testing or analysis for affected fields of accreditation upon receipt of notification under this subsection.

[(g)] (h) The Department may require an onsite assessment under § 252.601 (relating to onsite assessment requirements) upon receipt of notification under this subsection.

[Pa.B. Doc. No. 09-1103. Filed for public inspection June 19, 2009, 9:00 a.m.]