

STATEMENTS OF POLICY

Title 25—ENVIRONMENTAL PROTECTION

DEPARTMENT OF ENVIRONMENTAL PROTECTION

[25 PA. CODE CH. 16]

Water Quality Toxics Management Strategy—Statement of Policy

The Department of Environmental Protection (Department) amends Chapter 16 (relating to water quality toxics management strategy—statement of policy). The final changes are described as follows.

A. Effective Date

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

B. Contact Persons

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C. Background and Summary

The Commonwealth's water quality standards in Chapter 16 and Chapters 92a and 93 (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance; and water quality standards) implement sections 5 and 402 of The Clean Streams Law (35 P.S. §§ 691.5 and 691.402) and section 303 of the Federal Clean Water Act (33 U.S.C.A. § 1313). Chapter 16 is a water quality toxics management strategy, establishing policy for regulating toxic pollutants in this Commonwealth's surface waters. It sets forth the guidelines for development and modification of water quality criteria for toxic substances. Chapter 16 is directly referenced as a supporting policy document in the Department's toxic substances regulations in §§ 93.8a and 93.8c (relating to toxic substances; and human health and aquatic life criteria for toxic substances).

The amendments update Chapter 16 to be consistent with the amendments to Chapter 93, as related to the Commonwealth's triennial review of water quality standards. This statement of policy may affect persons who discharge wastewater into surface waters of this Commonwealth or otherwise conduct activities which may impact these waters.

D. Summary of Amendments

In § 16.21 (relating to acute and chronic protection) amendments are made to the language to clarify endpoints, magnitude and duration.

Section 16.23 (relating to sources of information) is updated to include the ECOTOX web site as a source for aquatic life information. Reference to the Aquire database is removed because it is no longer available.

In § 16.24 (relating to metals criteria) the Department incorporates the use of the Biotic Ligand Model (BLM), to determine new and updated site-specific criteria, which is only available for copper in freshwater systems.

In § 16.32 (relating to threshold level toxic effects) the Department adds Benchmark Dose Modeling as an alternative way of calculating adverse effect levels for human health criteria development. Also, the reference to the United States Environmental Protection Agency (EPA) 2004 publication *National Recommended Water Quality Criteria* (EPA-822-H-04-001, 2004) and Exhibit 3-1 of the EPA's 1994 *Water Quality Standards Handbook, Second Edition* (EPA 823-0-94-005A), August, 1994, as sources of developing water quality criteria are removed. The Department uses the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, October 2000) as its source for method development.

The Department amends language in §§ 16.33, 16.51 and 16.61 (relating to nonthreshold effects (cancer); human health and aquatic life criteria; and special provisions for the Great Lakes System) to maintain the consistency of the ambient water quality criteria throughout the State. The changes make clear that Chapter 93, Table 5 may apply to the Great Lakes System. The criteria in these tables are as protective as the criteria created using the Great Lakes Initiative guidelines.

In § 16.102 (relating to approved EPA and DEP analytical methods and detection limits) the Department removes language that pertains to Tables 1A, 2B and 3. The site-specific criterion originally contained in Appendix A, Table 1A is deleted and the content is moved to an online resource that includes an online table on the Department's web site. The online resource for site-specific criteria was developed, containing the online table and further details to serve as site-specific criteria guidance and reference.

The EPA-approved analytical methods and guidelines are referenced in § 16.102 and are found in the following Federal regulations as amended and updated: 40 CFR Parts 122, 136, 141, 143, 430, 455 and 465, *Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; National Secondary Drinking Water Regulations; Analysis and Sampling Procedures* (Final Rule, April 11, 2007).

In Appendix A, Table 2A (relating to approved DEP analytical methods and detection limits) the title is amended and the table contains methods developed and approved by the Department. The other analytical methods in Tables 2A and 2B are removed and Table 2B is deleted. The information in Table 3 is redundant and is also found in 40 CFR Parts 122, 136, 141, 143, 430, 455 and 465. It is therefore no longer necessary to have Table 3 so it is deleted. Section 16.102 is updated to compliment the changes made to the tables.

E. Public Hearings and Comments

The Department presented the proposed statement of policy to the Environmental Quality Board (Board) at the Board's April 18, 2017, meeting as a companion to the proposed Triennial Review of Water Quality Standards rulemaking, amending Chapter 93. Public notice for the proposed statement of policy was published at 47 Pa.B. 6703 (October 21, 2017) with provisions for 70-day public comment period, which was set to end on December 29,

2017. The Department published a supplemental correction at 47 Pa.B. 6730 (October 28, 2017) to correct an error that was published at 47 Pa.B. 6703 for the date and location for the public hearing to be held at the Northeast Regional Office on December 6, 2017.

The Board and Department held back-to-back public hearings for the purpose of accepting comments on the proposed rulemaking and statement of policy on December 6, 8 and 14, at the Department's Northeast Regional Office in Wilkes-Barre, the Southcentral Regional Office in Harrisburg, and the Southwest Regional Office in Pittsburgh, respectively.

In response to requests for an extension of the public comment period and to add a public hearing in the southeast region of this Commonwealth, a public notice was also published at 47 Pa.B. 7861 (December 30, 2017). An additional public hearing was held on January 30, 2018, at the Department's Southeast Regional Office in Norristown, for both the proposed rulemaking and proposed statement of policy. The extended public comment periods for these concurrent proposals closed on February 16, 2018.

As a result of the public hearings and extended public comment period, the Department received comments on the proposed statement of policy from five commenters, including from the EPA.

PATRICK McDONNELL,
Secretary

(Editor's Note: For a final-form rulemaking relating to this statement of policy, see 50 Pa.B. 3426 (July 11, 2020).)

Fiscal Note: Fiscal Note 7-516 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart A. PRELIMINARY PROVISIONS

ARTICLE II. STATEMENTS OF POLICY

CHAPTER 16. WATER QUALITY TOXICS MANAGEMENT STRATEGY—STATEMENT OF POLICY

Subchapter A. GUIDELINES FOR DEVELOPMENT OF CRITERIA FOR TOXIC SUBSTANCES AND WATER QUALITY CRITERIA FOR TOXIC SUBSTANCES

INTRODUCTION

§ 16.1. General.

Water quality criteria are the numeric concentrations, levels or surface water conditions that need to be maintained or attained to protect existing and designated uses. They are designed to protect the water uses listed in Chapter 93 (relating to water quality standards). The most sensitive of these protected uses are generally water supply, recreation and fish consumption, and aquatic life related. Therefore, criteria designed to protect these uses will normally protect the other uses listed in Chapter 93. This chapter specifies guidelines and procedures for development of criteria for toxic substances.

GUIDELINES FOR DEVELOPMENT OF AQUATIC LIFE CRITERIA

§ 16.21. Acute and chronic protection.

To provide for protection of aquatic life, it is necessary to consider both chronic, that is, long-term (reproduction,

growth, survival) and acute or short-term (survival) endpoints. Aquatic life can generally survive excursions of elevated concentrations of a pollutant as long as the excursion is of relatively short duration and does not frequently recur. However, to provide protection over a lifetime, a lower concentration shall be maintained. Thus, each aquatic life criterion consists of two magnitudes. The EPA defines these as a criterion maximum concentration (CMC) for acute protection and a criterion continuous concentration (CCC) for chronic protection. Each criterion is defined in terms of magnitude (a scientifically derived number), duration (the period of time over which the number must be achieved), and the maximum desired frequency (the number of repetitions per unit time) of occurrence. Consistent with this approach, the Department whenever possible develops acute and chronic criteria and specifies the applicable magnitude and duration. The frequency of occurrence is accounted for through the specification of factors appropriate to the criteria and in Chapter 96 (relating to water quality standards implementation). Basis for the magnitude, duration and frequency is described in criteria development rationale or other appropriate supporting documentation.

§ 16.22. Criteria development.

The Department will establish criteria for toxic substances to provide for protection of aquatic life in accordance with the following guidelines:

(1) For those toxics for which the EPA has developed criteria in accordance with the National guidelines as set forth in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985), as amended and updated, the Department will review and evaluate the criteria. If the Department determines that the criteria are adequate to protect indigenous aquatic communities in the State's waters, these criteria will serve as the basis for establishing total maximum daily loads (TMDLs) under Chapter 96 (relating to water quality standards implementation) or NPDES effluent limitations under Chapter 92a (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance). If the Department determines that the EPA National criteria are inappropriate, the Department will adjust these criteria in accordance with National guidelines to reflect the levels required for protection of aquatic life in this Commonwealth's waters.

(2) For those toxics identified or expected in a discharge for which the EPA has not developed criteria, the Department will develop criteria using EPA-approved National guidelines.

§ 16.23. Sources of information.

The Department will use the following sources of information in establishing criteria for aquatic life protection:

(1) United States EPA 1986 Quality Criteria for Water (Goldbook).

(2) United States EPA Ambient Water Quality Criteria Development Documents and updates.

(3) Aquatic life toxicity data available in the published scientific literature.

(4) Aquatic life toxicity data available on EPA computerized databases (for example, ECOTOX, Great Lakes Initiative (GLI) Clearinghouse).

§ 16.24. Metals criteria.

(a) Metals criteria are established to control the toxic portion of a substance in the water column. Depending upon available data, aquatic life criteria for metals are

expressed as either dissolved or total recoverable. As information develops, the chemical identifiers for the toxic portion may be added, changed or refined. The criteria form one of the bases for water quality-based effluent limitations, which are expressed as total recoverable metal. When calculating equation-based metals criteria for determining effluent limitations, the criteria must be developed in accordance with § 93.8c (relating to human health and aquatic life criteria for toxic substances).

(b) Chemical translators are used to convert dissolved criteria into effluent limitations which are required by Federal regulations to be expressed as total recoverable metal. The default chemical translator used by the Department is the reciprocal of the conversion factor (listed in the Conversion Factors Table located in § 93.8b (relating to metals criteria)) that was used to determine the dissolved criterion. If an NPDES discharger performs a chemical translator study for a dissolved criterion, the study of this site-specific translator should be conducted in accordance with the EPA's "The Metals Translator: Guidance for Calculating a Total Recoverable Permit Limit from a Dissolved Criterion" (June 1996), as amended and updated.

(c) NPDES dischargers may request alternate effluent limitations by using site-specific water quality characteristics in a request to modify an existing water quality criterion, in accordance with § 93.8d (relating to development of site-specific water quality criteria). This may be accomplished through one or more of the following methods:

(1) Recalculating a water quality criterion in accordance with the EPA's "Interim Guidance on the Determination and Use of Water-Effect Ratios for Metals, Appendix B: The Recalculation Procedure" (February 1994), as amended and updated. The Recalculation Procedure accounts for corrections, update and additions to the original criterion dataset to create an appropriate dataset to calculate the site-specific criterion. If the optional deletion process is used to evaluate the taxonomic composition, this process should follow the EPA's "Revised Deletion Process for the Site-Specific Recalculation Procedure for Aquatic Life Criteria" (April 2013).

(2) Developing a water quality criterion by performing a Water Effect Ratio (WER) study, which is a factor that expresses the difference between the measures of the toxicity of a substance in laboratory water and the toxicity in site water. The WER provides a mechanism to account for that portion of a metal which is toxic under certain physical, chemical or biological conditions. WERs are applicable only to certain metals, which are listed by the EPA in "Interim Guidance on the Determination and Use of Water-Effect Ratios for Metals" (February 1994), as amended and updated. WERs should not be used for the development of site specific criteria for copper.

(3) Developing a water quality criterion by performing a Biotic Ligand Model (BLM) study for copper in freshwater systems. The BLM is a metal bioavailability model that uses receiving water body characteristics and monitoring data to develop site-specific water quality criteria. The BLM is used in evaluating the differences in the bioavailability and toxicity of metals. These differences occur as a result of variation in local water chemistry. The BLM may be used to derive site-specific criteria for copper in freshwater systems. The BLM incorporates the best available science for determining site-specific water quality criteria for copper and is therefore preferred by the Department. The Department will require use of BLM for copper in freshwater systems. Subject to Departmental approval of the testing and its results, the Department

will evaluate the use of the BLM to establish alternate site-specific criteria. In the absence of available site data to run the BLM, estimates for missing water quality parameters may be developed using EPA's guidance, "Draft Technical Support Document: Recommended Estimates for Missing Water Quality Parameters for Application in EPA's Biotic Ligand Model," (March 2016), as amended and updated.

(4) Developing a water quality criterion using other guidance approved by the Department, which is based on other EPA-approved or scientifically defensible methodologies.

(d) Either the WER or BLM may be combined with a chemical translator study. The WER may also be used in combination with the Recalculation Procedures. If the Recalculation Procedure is selected, the procedure requires the recalculation of the existing criterion before the WER is applied. The BLM cannot be used in combination with the recalculation procedures or the WER.

GUIDELINES FOR DEVELOPMENT OF HUMAN HEALTH-BASED CRITERIA

§ 16.32. Threshold level toxic effects.

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(b) Control of threshold toxics is based upon animal testing or epidemiological studies that report no- or lowest-observed adverse effect levels of the substance (NOAEL or LOAEL). In evaluating a particular toxic, toxicologists weigh the merits of all the tests, and choose, in their best professional judgment, the safe level. By applying standard margins of safety to the NOAEL, extrapolations from the laboratory animals to humans (factor of 10), for sensitive subpopulations (10), and from short-term to chronic studies (10) can be taken into account. An additional factor of 10 is used if only a LOAEL is available. Modifying factors (1–10), which account for deficiencies in the toxicity studies, are also considered in determining an acceptable exposure level. The current term for this acceptable level is reference dose (RfD); it was previously called the acceptable daily intake (ADI). Adverse effect levels may be calculated using Benchmark Dose (BMD) Modeling. The purpose of the BMD is to derive a point of departure for calculating a risk value, such as a reference dose or a reference concentration. In the customary approach, the point of departure is the NOAEL or the LOAEL. The BMD values are calculated by dividing a point of departure by the uncertainty factors. This most sensitive effect is also called the critical effect, and it is used as the point of departure in establishing a toxicity benchmark. The RfD, can be calculated using a LOAEL, a NOAEL or BMD. It is adjusted for protection of an average (80 Kg) person. It is then divided by expected exposure conditions to result in an applicable criterion. Exposure conditions by means of water include 2.4 liters per day of drinking water and consumption of 22.0 grams of fish per day. The bioaccumulation of toxics in edible portions of fish is accounted for by use of bioaccumulation factors (BAF). The BAF is the ratio in liters per kilogram that accounts for the chemical accumulation in aquatic organisms from all potential exposure routes, including water, food and sediment.

(c) The Department will establish criteria for threshold toxics in accordance with the following guidelines:

(1) If the EPA has developed criteria, the Department will evaluate and accept the criteria when it is determined that they are adequate to protect the designated water uses.

(2) If the EPA criteria have been evaluated, and have been determined to be inadequate to protect designated uses, or when no criteria have been developed for a substance identified or expected in a discharge, the Department will develop criteria following EPA's standard toxicological procedures outlined in the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA-822-B-00-004, October 2000), as amended and updated.

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§ 16.33. Nonthreshold effects (cancer).

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(e) The Department uses a 1×10^{-6} cancer risk level as specified in § 93.8a(d) (relating to toxic substances). Attainment of this risk level is predicated on exposure that includes drinking 2.4 liters of water and ingesting 22.0 grams of fish per day over a 70-year lifetime. Bioaccumulation of carcinogenic toxics in edible portions of fish are accounted for by use of bioaccumulation factors (BAFs).

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WATER QUALITY CRITERIA FOR TOXIC SUBSTANCES

§ 16.51. Human health and aquatic life criteria.

(a) Chapter 93, Table 5 lists the human health and aquatic life criteria for toxic substances which the Department uses in development of effluent limitations in NPDES Permits and for other purposes. The Department will maintain a table of site-specific human health and aquatic life criteria that have been developed or reviewed and approved by the Department. The approved analytical procedures and detection limits for these substances will be listed, as appropriate, in Table 2A. The human health criteria, which include exposures from drinking water and fish consumption, are further defined as to the specific effect (that is, cancer or threshold health effects). For those aquatic life criteria which are a function of local water quality conditions and are specified as a formula, such as several of the heavy metals, the hardness and pH values used to derive the appropriate water quality criteria will be determined by instream measurements or best estimates, representative of the median concentrations or conditions of the receiving stream for the applicable time period and design conditions on a case-by-case basis. Some of these criteria may be superseded for the Delaware Estuary, Ohio River Basin, Lake Erie Basin, and Genesee River Basin under interstate and international compact agreements with the Delaware River Basin Commission, Ohio River Valley Sanitation Commission and International Joint Commission respectively. The toxics substances in Chapter 93, Table 5 without a PP NO are State-derived criteria. Water quality criteria for the Great Lakes System are in § 93.8e, Tables 6 and 7. Criteria in § 93.8c, Table 5 may apply to the Great Lakes System for those substances not listed in Table 6. Criteria may be developed for the Great Lakes System for substances other than those listed in Table 5 or 6 under the methodologies in § 16.61 (relating to special provisions for the Great Lakes System).

(b) If the Department determines that the natural quality of a surface water segment is of lower quality than the applicable criteria listed in Chapter 93, Table 5, the natural quality shall constitute the aquatic life criterion for that segment. Notice of all draft natural quality determinations shall be published in the *Pennsylvania Bulletin* and be subject to a minimum 45-day comment period. The Department will maintain a publicly available list of surface waters and parameters where this

subsection applies, and will, from time to time, submit appropriate amendments to these chapters. Natural quality determinations are documented in stream investigation reports or water quality criteria rationale documents.

§ 16.52. Whole Effluent Toxicity Testing (WETT).

The Department may require WETT, under § 92a.21(d)(4) (relating to application for a permit), for any discharges covered by an NPDES permit or other activities where it is determined that the testing is necessary to assure the protection of aquatic life. Where WETT is required, the Department will use the criteria of 0.3 TUA (Toxic Units Acute) and 1 TUC (Toxic Units Chronic) design conditions and other applicable factors as a basis for evaluating test results. WETT shall be conducted in accordance with 40 CFR Part 136 (relating to guidelines establishing test procedures for the analysis of pollutants), Chapter 252 (relating to environmental laboratory accreditation), the NPDES permit, Quality Assurance Quality Control guidance issued by the Department or other protocols approved by the Department.

GREAT LAKES SYSTEM

§ 16.61. Special provisions for the Great Lakes System.

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(b) *Water quality criteria for the Great Lakes System.*

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(2) *Human health criteria.* Human health criteria for the Great Lakes System will be developed using the methods in §§ 16.32 and 16.33 (relating to threshold level toxic effects; and nonthreshold effects (cancer)). If criteria for a substance is not available in Chapter 93 Tables 5 or 6, and there are insufficient data to develop human health threshold criteria for a toxic substance identified in a discharge into these waters, the Department will develop, or require the discharger to develop, subject to Department approval, protective human health values using the methodologies in 40 CFR Part 132, Appendix C, Section III, as it relates to Tier II values, in accordance with exposure inputs at §§ 16.32 and 16.33, and guidance issued by the Department.

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Subchapter B. ANALYTICAL METHODS AND DETECTION LIMITS FOR TOXIC SUBSTANCES

GENERAL PROVISIONS

§ 16.102. Approved EPA and DEP analytical methods and detection limits.

Appendix A, Table 2A contains approved Department analytical methods and detection limits. The following data elements are to be used as follows:

(1) The Chemical Abstracts Service (CAS) number, a unique chemical identifier, is to be used for completeness of identification. The CAS number should always be verified to ensure proper identification, particularly with chemicals with ambiguous or unfamiliar names, or both.

(2) If the EPA has an approved test method for analysis of a specific pollutant, the NPDES permittee shall use the approved test method (or an approved alternate test method) for the specific pollutant under 40 CFR Part 136 (relating to guidelines establishing test procedures for the analysis of pollutants). Methods are detailed in one or more of the following sources:

(i) EPA-approved analytical methods and guidelines in 40 CFR Parts 122, 136, 141, 143, 430, 455 and 465. EPA-approved analytical methods must be sufficiently sensitive and capable of detecting and measuring the pollutants at or below the applicable water quality crite-

ria or permit limits consistent with the EPA's regulations in 40 CFR Part 122 (relating to EPA administered permit programs: the National Pollutant Discharge Elimination System) and 40 CFR Part 136.

(ii) If an EPA-approved analytical method is not available for a pollutant, an analytical method may be used that is capable of detecting and measuring the pollutant at or below the applicable water quality criterion or permit limit. The analytical method should be consistent with guidelines for developing analytical methods, as described in this Chapter.

(iii) *Standard Methods for the Examination of Water and Wastewater*, 20th Edition, APHA-AWWA-WEF, 1998.

(iv) *Hach Handbook of Wastewater Analysis*, Hach Chemical Company, 1979.

(v) *Direct Current Plasma (DCP) Optical Emission Spectrometric Method for Trace Elemental Analysis of Water and Wastes, Method AES0029*. Applied Research Laboratories, Inc., 1986-Revised 1991, Fison Instruments, Inc.

(vi) *ASTM Annual Book of Standards, Section 11, Water*. American Society for Testing and Materials, 1999.

(3) MDL is the method detection limit for each chemical for each method. The MDL is defined as the minimum concentration that can be measured and reported with 99% confidence that the value is above zero—that is, something is really there. The MDL achieved in a given analysis will vary depending on instrument sensitivity and matrix effects.

(i) When MDLs are not available, detection limits based on other criteria approved by the Department may be used.

(ii) For any pollutant with an effluent limitation below the method detection limit, the permittee is expected to generally achieve the detection limit of the most sensitive method that is below detection available.

(iii) If two approved analytical methods for the same parameter have detection limits that differ by less than 1 µg/l or a factor of 2 (whichever is greater), the permit may be written designating either method as acceptable. The permittee also has the option of using an alternate method approved by the Department and the EPA that the permittee selects as long as the level of detection of the cited method or the numerical water quality-based limit are achieved.

(iv) When the EPA has not performed an MDL study or reported the detection limit, other sources—particularly, Standard Methods—are consulted. When there is no literature on detection limit, the Department's Bureau of Laboratories may develop a detection limit or review and approve a Department-accredited lab's development of a detection limit using an MDL study.

(4) Permittees will be required to meet the detection limits listed in Appendix A, Table 2A.

(5) When permittees cannot meet a listed detection limit, they may be granted case-specific MDLs if they submit complete documentation demonstrating a matrix effect in their particular effluent. The permittees shall follow the procedure for determining MDLs published in Appendix B of 40 CFR Part 136. The Bureau of Laboratories will evaluate the data and advise the regional office of their decision.

APPENDIX A

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**TABLE 1A
(RESERVED)**

**TABLE 2A
APPROVED DEP ANALYTICAL METHODS AND DETECTION LIMITS**

	<i>Parameter (CAS)</i>	<i>Method Number (Description) Source</i>	<i>Detection Limit (µg/l)</i>
*	CYANIDE, FREE (00057125)	—(DEP Free CN method, Auto) Not EPA approved	1
—	BENZENE METADISULFONIC ACID (00098486)	OR 357A Test America, HPLC/UV or LC/MS/MS	50
—	BENZENE MONOSULFONIC ACID (00098113)	OR 357A Test America, HPLC/UV or LC/MS/MS	50
—	P-PHENOL SULFONIC ACID (00098679)	OR 357A Test America, HPLC/UV or LC/MS/MS	50

* EPA currently measures “total cyanide” to satisfy cyanide limits and has not yet approved analytical methods for “free cyanide.” Free cyanide is a DEP required analysis, and either of the three listed methods are acceptable for its determination.

**TABLE 2B
(RESERVED)**

**TABLE 3
(RESERVED)**

[Pa.B. Doc. No. 20-901. Filed for public inspection July 10, 2020, 9:00 a.m.]