



COMMENT AND RESPONSE DOCUMENT

Water Quality Standard for Manganese and Implementation

25 Pa. Code Chapters 93 and 96

50 Pa.B. 3724 (July 25, 2020)

Environmental Quality Board Regulation #7-553
(Independent Regulatory Review Commission #3260)

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Abbreviations/Acronyms

AAB	Agricultural Advisory Board
AAP	American Academy of Pediatrics
ABS	Alternative Bond System
AMD	Acid Mine Drainage
AML	Abandoned Mine Land
ANPR	Advanced Notice of Proposed Rulemaking
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criterion
BAMR	Bureau of Abandoned Mine Reclamation (DEP)
BAT	Best Available Technology
BCW	Bureau of Clean Water (DEP)
BMP	Bureau of Mining Programs (DEP)
BPJ	Best Professional Judgement
CIM	Continuous Instream Monitoring
CSL	Pennsylvania Clean Streams Law
CWA	Federal Clean Water Act
DEP	Pennsylvania Department of Environmental Protection
ELG	Effluent Limitation Guideline
EPA	United States Environmental Protection Agency
EQB	Environmental Quality Board
FDA	United States Food and Drug Administration
g	Gram(s)
GDWQ	Guidelines for Drinking Water Quality
gpm	Gallons Per Minute
HAL	Health Advisory Level
HBGV	Health Based Guidance Value
IOM	National Academies of Science Institutes of Medicine (now the National Academy of Medicine)
IRIS	Integrated Risk Information System
IRRC	Independent Regulatory Review Commission
kg	Kilogram(s)

L	Liter(s)
lbs.	Pounds
LC ₅₀	Lethal Concentration resulting in a 50% mortality rate
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MDH	Minnesota Department of Health
MF	Modifying Factor
MGD	Million Gallons per Day
mg/kg-day	Milligrams per Kilogram per day
mg/L	Milligram(s) per Liter
Mn	Manganese
MRAB	Mining and Reclamation Advisory Board
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
OSMRE	U.S. Office of Surface Mining Reclamation and Enforcement
OW	Office of Water (EPA)
oz.	Fluid Ounces
PBPK	Physiologically-Based Pharmacokinetic
PennDOT	Pennsylvania Department of Transportation
ppm	Parts per Million
PSU	Pennsylvania State University
RAF	Regulatory Analysis Form
RRA	Regulatory Review Act
RfD	Reference Dose
RSC	Relative Source Contribution
SDW	Safe Drinking Water
SDWA	Safe Drinking Water Act
SMCL	Secondary Maximum Contaminant Level
SMCRA	Surface Mining Control and Reclamation Act of 1977
TAC	Public Water System Technical Assistance Center Board
TBEL	Technology-Based Effluent Limitation

TMDL	Total Maximum Daily Load
TPN	Total Parenteral Nutrition
TSS	Total Suspended Solids
UCMR4	Unregulated Contaminant Monitoring Rule – 4 th edition
UF	Uncertainty Factor
µg/L	micrograms per liter
UL	Tolerable Upper Intake Level
USDA	United States Department of Agriculture
USGS	United States Geological Survey
WHO	World Health Organization
WRAC	Water Resources Advisory Committee
WQ	Water Quality
WQBEL	Water Quality Based Effluent Limitation
WQI	Water Quality Index
WQN	Water Quality Network
WQS	Water Quality Standards

Introduction

The Environmental Quality Board (EQB) adopted the proposed rulemaking for the Water Quality Standard (WQS) for Manganese and Implementation at its December 17, 2019 meeting. On June 30, 2020, the Department of Environmental Protection (DEP) submitted a copy of the proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment in accordance with Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)). The proposed rulemaking was published in the *Pennsylvania Bulletin* on July 25, 2020 (50 Pa.B. 3724) with a 60-day public comment period that closed on September 25, 2020. The EQB held three virtual public hearings on September 8, 9, and 10, 2020. Comments were received from 957 commentators, including testimony from 13 witnesses at the public hearings. Support for the rulemaking was indicated by 924 of the commentators. Thirty commentators indicated opposition to the rulemaking. IRRC submitted comments regarding the reasonableness of the proposed manganese standard and requested the EQB seek additional input from DEP's Mining and Reclamation Advisory Board (MRAB) and Aggregate Advisory Board. IRRC further requested that the EQB explain why the rulemaking is consistent with the intent of Act 40 of 2017 (Act 40) and the General Assembly and how the inclusion of two alternative points of compliance in a single regulatory package is in compliance with the Regulatory Review Act (RRA) and the regulations of IRRC.

Copies of Comments

This document provides DEP's responses to comments on the proposed rulemaking. The full list of commentators is included as a separate attachment to this comment and response document. Copies of all comments received by the Board are posted on the Department's e-Comment website at <https://www.ahs.dep.pa.gov/eComment/>. Additionally, copies of all comments are available on IRRC's website at <http://www.irrc.state.pa.us> by searching for Regulation # 7-553 or IRRC # 3260.

General Comments Supportive of the Proposed Criterion

1. Comment: *Support for clean water and protection of water resources in the Commonwealth:*

- The commentator believes, consistent with the Pennsylvania Clean Streams Law (CSL), that instream and tap water should be protected and clean. Further, Pennsylvanians expect that public water suppliers are able to deliver clean water equitably and affordably to all citizens. To facilitate water suppliers' ability to meet expectations, discharges to waterways should be protective of the highest standard for human consumption at the point of discharge. (928)
- Human and environmental health is sacred; do no harm. Society, taxpayers and our government have been imposed upon to clean up the acid mine drainage damage (AMD) that began with coal mining in this country. Now that we know and understand that and can reason that an ounce of prevention is indeed worth a pound of cure, we cannot allow industry to pollute waterways and expect others to be responsible for clean up or dealing with damage to aquatic and or human life. The mercury in fish is already a threat to developing brains of fetuses. (699)
- The proposed rulemaking takes a positive step in meeting national and international health manganese guidelines. (500, 593-594, 596, 620-639, 641-686, 688-697, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)
- We are not islands removed from Nature. We use water to sustain our life and so we are the ones who need to make sure water is protected from those wishing to use it as a dumping ground instead for their industry waste. We need clean water, and so does everything else that is alive. Do the right thing here. (36)

Response: DEP appreciates the commentators' support for the proposed rulemaking.

2. Comment: This terrible project is going to happen no matter what's said in public comment and anyone reading this comment knows that. No matter how scientific and specific these comments are or what issue is brought forth. This public comment process is a hideous smokescreen so that PA residents can feel they have a say in what happens where they live. Further degrading PA's waterways through extra manganese dumping are just more of what the DEP was precisely designed to do: regulate the harm and poisoning on behalf of polluters thru the issuance of state-sanctioned permits. When the project inevitably goes sideways, the polluter will pay its fines, absorb its violations and apply for more permits, which will be granted by this agency. The polluter will always argue it was working within the confines of the issued permit. And best of all--the inevitable losses and contamination are socialized through PA's taxpayers. The mining industry has forced DEP to consider measuring manganese pollution NOT from the discharge point, but from the point where it enters public water supplies. This places the burden of the pollution on the public and not the polluter-- a system that works VERY well for industry and not at all for the population. No matter what

is said here, or how much outrage is typed out on this platform, this project will go through. Ditto what Mr Dudash said in his comment. “This stinks. To high heaven.” (611)

Response: DEP acknowledges the commentator’s concerns about moving the point of compliance from the point of discharge to the point of water supply withdrawal.

3. **Comment:** Manganese was evaluated as a toxic substance for human health that should be moved to Table 5. If the EQB recognizes it should be in Table 5, they should treat it as the other substances in Table 5 are treated. (76)

Response: DEP appreciates the commentator’s support for the proposed rulemaking.

4. **Comment:** The United States Environmental Protection Agency (EPA), Region III has reviewed the proposed amendments to Chapters 93 and 96 of the Commonwealth’s environmental regulation. The purpose of this [EPA’s] letter is to provide EPA’s comments on the proposed changes.

Under CWA Section 303(c), it is the responsibility of DEP to protect the existing and designated uses of the surface waters of the Commonwealth by establishing WQSs. In accordance with federal regulation at 40 CFR 131.11, states must adopt water quality (WQ) criteria based on a sound scientific rationale and these criteria must contain sufficient parameters or constituents to protect the designated use. States can adopt numerical criteria based on EPA’s national CWA 304(a) recommendations, EPA’s national recommendations modified to reflect site-specific conditions, or other scientifically defensible methods. EPA recognizes that Pennsylvania has developed a manganese WQS criterion for the protection of human health which follows EPA’s Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA-822-B-00-004, October 2000), and is supportive of this effort. In order to support a CWA 303(c) approval, EPA will need to document that Pennsylvania has met the requirements of 40 CFR 131. To that end, please consider the following questions and comments based on EPA’s review of the proposed amendments:

- EPA requests that Pennsylvania clarify why a bioaccumulation factor of 1 was used in the calculation of the ambient water quality criterion (AWQC) for manganese.
- If Pennsylvania establishes the point of compliance at the drinking water intake, EPA understands that Pennsylvania will ensure that the revised manganese criterion will be met at the point of all existing or planned surface potable water supply withdrawals to protect designated uses and ensure the protection of threatened and endangered species and their critical habitat.
- If the point of compliance is established at the drinking water intake, EPA notes that Pennsylvania’s narrative criteria at § 93.6, which applies to all waterbodies of the State, would apply where the numeric criteria for manganese do not and anticipates that the Commonwealth will rely on the narrative criteria where numeric criteria do not apply to ensure full protection of all designated uses. (61)

Response: DEP appreciates EPA’s support for the proposed rulemaking. DEP used a bioaccumulation factor of 1 based on the best scientific information that was available at the

time of criterion development. As detailed in DEP's criterion rationale document titled "Development of the Human Health Criterion for Manganese," DEP conducted a search of the available scientific literature to determine if manganese bioaccumulates in freshwater organisms and was unable to find any data to suggest that a factor other than 1 should be used.

The final-form regulation retains the point of compliance at the point of discharge.

5. **Comment:** The development and revision of safe levels for contaminants via exposure and hazard assessment decisions is influenced by multiple scientific, technical, and social factors, including managing scientific uncertainty, technical decisions and capacity, as well as social, political, and economic influences from involved stakeholders. Therefore, in addition to a thorough review of current information, the policies and procedures used to derive WQ criteria should be consistent and transparent. DEP has conducted a thorough review of current science, used recommended guidance to derive the standard, and followed established procedures in the proposed Rulemaking: Water Quality Standards for Manganese and Implementation. The proposed 0.3 mg/L manganese is equal to an EPA human health advisory level (HAL) for drinking water and comparable to manganese criteria adopted by other states with similar geology, resource extraction activities, or industries to Pennsylvania. (707)

Response: DEP appreciates this comment describing the many factors that should be considered in developing WQSs as well as the published policies and guidelines that are used to derive WQ criteria. DEP followed these guidelines and has made the rulemaking documents available to the public as required by law. No other states currently have manganese WQ criteria for the protection of human health from the neurotoxicological effects of manganese, but DEP agrees that the criterion is equivalent in magnitude to the current EPA HAL for drinking water.

Manganese in the Environment

6. **Comment:** Manganese is abundant in the environment and is naturally occurring in soils, sediments and water. Manganese is also found in over 300 different naturally occurring minerals. (7, 9, 10, 618, 905)

Response: DEP agrees that manganese is a common element and abundant in the environment. It is naturally occurring in soils, sediments, and many types of minerals. Manganese can be naturally occurring in surface waters as a result of the geology underlying the streambed and the land surrounding the stream. However, based on the available statewide data, manganese is generally not found to occur naturally in significant concentrations in Pennsylvania surface waters. Where a stream has been identified to have a manganese level exceeding 0.3 mg/L, it is usually due to anthropogenic activities.

7. **Comment:** Manganese does not degrade over time. Not removing manganese at the point of discharge allows manganese to deposit in surface water sediments, becoming a long-term

legacy pollutant in surface waters. Dilution is not the solution to pollution. (13, 14, 74, 595, 615, 917)

Manganese is a persistent contaminant that can be carried far downstream. (5, 16, 18-31, 33-59, 62-72, 75, 77, 79-88, 93, 103, 107, 276, 574, 589, 864, 882, 918, 931, 942)

Response: DEP agrees manganese is a conservative pollutant. Conservative pollutants are those that do not normally break down into non-toxic substances through physical, chemical or biological processes in the receiving water. These substances tend to be long-lived, stable compounds that can persist within the environment. Thus, manganese levels could increase in the waters and sediments of streams receiving National Pollutant Discharge Elimination System (NPDES) permitted discharges if the point of compliance were moved from the point of discharge to the point of water supply withdrawal. In this scenario, if a potable water supply withdrawal were not located near a discharge, many NPDES permittees would potentially be able to discharge significant quantities of manganese into the environment.

Many factors affect the behavior of manganese in the aquatic environment including, but not limited to, pH, ambient temperature, frequency of high-flow/scouring events, and the presence of other metals. Manganese is likely to remain dissolved and not settle out in low pH waters. Even when manganese is insoluble, settling times will vary. As has been noted in many comments by industry, manganese removal treatment that relies on chemical addition typically requires very high pH levels to precipitate the manganese out of solution. Many streams, particularly in coal-mining areas, tend to have lower pH levels (<6 and as low as 3 in some localized areas). Even if dischargers are releasing insoluble or “particulate” manganese into neutral pH (pH = 7) receiving waters at the point of discharge, downstream tributaries and other influences can change WQ, including pH, which could convert particulate manganese to dissolved and result in the transport of manganese farther downstream than has been suggested by the mining industry.

8. **Comment:** Manganese enters our waters primarily through discharges from mining and quarry operations as well as other earth disturbance activities. (32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 502-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 905, 914, 929)

Response: Since manganese is one of Earth's most abundant metals, it occurs naturally in the environment. The natural levels of manganese found in a particular region are largely dependent upon the underlying geology of that area, but other factors can influence the amount of manganese found, particularly at the surface in soil and rock. High levels of manganese at the earth's surface are typically a result of atmospheric deposition related to human activities or activities that disturb the Earth's crust, such as coal mining and quarry operations, which can also significantly increase the concentrations of manganese found at the surface in soil and rock. When this occurs, natural weathering processes and precipitation events can increase the amount of manganese found in surface waters. In Pennsylvania, historical mining operations represent one of the most significant contributors to elevated levels of manganese in surface waters.

9. Comment: According to DEP's 2020 Pennsylvania Integrated Water Quality Monitoring and Assessment Report, there are over 5,559 miles of stream miles impaired for aquatic life due to acid mine drainage (AMD) and another 12 miles are impaired for water supply due to AMD. Adopting the stricter effluent limit for manganese and maintaining the point of discharge compliance ensures that our waters are protected from future degradation and impairment whether or not a drinking water supply is downstream. (931)

Dr. Elizabeth Dakin from Duquesne University has been sampling in the southern half of the Allegheny (River) for the past 7 years as a partner in the Three Rivers QUEST program and has recorded 7 times where levels of manganese were above the EPA's lifetime health advisory of 0.3 mg/L and around 6% of her measurements over the years have exceeded 0.3 mg/L. With no limitations on manganese discharge into our streams, manganese concentration will continue to increase in our surface waters. With an enforced level of 0.3 mg/L at the site of discharge, we can afford some level of safety to both human health and aquatic health in surface waters of the Commonwealth. (702, 956)

Response: DEP agrees that maintaining the point of compliance at the point of discharge provides protection to all surface waters of the Commonwealth and that many surface waters are already impacted by elevated levels of manganese.

The final-form regulation retains the point of compliance at the point of discharge. In addition to reducing the amount of manganese entering streams from permitted dischargers, implementation of the 0.3 mg/L criterion at the point of discharge would allow DEP to assess the criterion in all surface waters.

10. Comment: *DEP did not examine background levels of manganese in PA streams:*

- The proposed rule fails to provide any information about current concentrations of manganese in surface waters of the Commonwealth. Without information on current conditions, it is not possible to determine whether a lower standard is needed. (497)
- Manganese is a very common element on earth. There are locations across PA, particularly in coalfield areas, where ambient background levels of manganese in the streams are greater than the proposed limit of 0.3 mg/L or even the current 1 mg/L manganese criterion, mainly due to pyrite oxidation. DEP acknowledges that groundwater in certain areas of the state is known to contain high levels of iron and manganese due to the underlying geology of the region. According to DEP, "An analysis of surface water samples collected in Pennsylvania between 2008 and 2018 revealed that 4% of 775 sample sites exceeded the current Potable Water Supply manganese criterion of 1.0 mg/L, and 48% of the sites exceeded the drinking water secondary maximum contaminant level (SMCL) of 0.05 mg/L." Natural sources of iron and manganese are more common in deeper groundwater wells where the water has been in contact with rock for a longer period of time. In coal mining regions of northern and western Pennsylvania, these metals may also occur from both deep and surface mining activities.

The Department has not considered in their analysis the background levels of manganese in streams that are upstream of noncoal facilities nor have they considered homogeneous manganese oxidation and precipitation reactions that naturally occur and can oxidize and remove soluble manganese from water. Testimony given by Tetra Tech at the September 9, 2020 Senate Environment, Resources and Energy Committee touched on this issue. It makes no sense to attempt to enforce a lower limit than what exists as background levels. (4, 8, 10, 12, 890, 922, 955)

- The proposed change to the manganese criterion is unnecessary on account of the minimal downstream impact from discharges containing manganese at the existing limits. The modeling done by Tetra Tech (2020) shows how unlikely it is that dissolved manganese from a treated discharge would reach a location more than a half mile from the discharge point and that under none of the modeled conditions would the concentration of manganese in the stream exceed the existing 1 mg/L criterion at any point further than one mile from the discharge point. This modeling is backed by real world data. The commentator examined the fate of manganese in discharges from six of its active operations for which there was extensive and consistent data.

At five of the six active operations, the concentration of manganese in the discharge was greater than the proposed 0.3 mg/L, yet the downstream monitoring point (typically located 100 feet downstream of the discharge) showed concentrations less than 0.3 mg/L at four of the five sites. The average decrease in concentration from the upstream point to the downstream point was 61% and the average decrease in concentration from the discharge to the downstream point was 51%. This significant reduction in the concentration, even over such small distances (approximately 150 feet), illustrates the point made in the Tetra Tech report that downstream impact from the manganese in a treated discharge is minimal. Both the modeling and the real-world monitoring show that the existing criterion is sufficient to limit the downstream impact of manganese in the discharge.

One additional observation that can be made from the commentator's data is that the proposed change to the manganese criterion is unwarranted as the manganese concentration in many of the streams that receive permitted discharges is already greater than the proposed 0.3 mg/L. Of the six active operations the commentator examined, four of them discharged treated water into streams with concentrations of manganese greater than 0.3 mg/L. This illustrates the point made in the Tetra Tech report that untreated legacy discharges contribute the majority of manganese in impaired waters. (951)

Response: During the development of the proposed rulemaking, DEP did consider and evaluate instream concentrations of manganese across the Commonwealth. DEP reviewed the available statewide data, including Water Quality Network (WQN) data, for manganese. This analysis is included in Appendix A. While DEP does not dispute that manganese is a common element in rock and soil, the data demonstrates that the natural background levels of manganese found in most surface waters of the Commonwealth are very low.

Analyses of manganese sampling data were conducted by DEP in 2019 and included an evaluation of over 21,000 surface water samples collected by DEP from the WQN stations, continuous instream monitoring (CIM) sites, and other monitoring sites, such as public water systems, throughout the Commonwealth between 2008 and 2018. The data collected at WQN stations span many years of sampling at each station location and provide valuable information on the long-term water quality trends in these waters. This statewide dataset was analyzed by DEP, and yearly mean total manganese concentrations for surface waters were calculated where sufficient data was available. While data from CIM and other monitoring sites was evaluated, sufficient manganese data generally was not available for the calculation of long-term average manganese concentrations, and therefore, data from these sites was not used in the analysis. Land disturbance and WQ scores were also determined for surface waters using DEP's Water Quality Index (WQI) tool. The development of this tool utilized 21 different WQ parameters to evaluate WQ data collected in Pennsylvania surface waters between 2007 and 2018. This tool generates an overall WQI score for surface waters, ranging from poor to good. The calculated yearly mean total manganese concentrations for surface waters were compared to the WQI scores for those same surface waters. Manganese concentrations in areas with poor WQI scores (that is, high land disturbance) were separated from those with good WQI scores to determine the average natural background concentration of manganese in surface waters across the Commonwealth. DEP's analysis of the WQN data revealed that 84% of the calculated yearly mean total manganese concentrations were less than 0.3 mg/L. When only yearly mean total manganese concentrations with a corresponding good WQI score were considered, the natural background level of manganese in surface waters across the Commonwealth was represented by a yearly mean total manganese concentration of 0.037 mg/L. These data suggest that for most sites across Pennsylvania, background concentrations of manganese are expected to be significantly less than 0.3 mg/L. See Figure 1 and Figure 3 in Appendix A. In addition to DEP's data, The Pennsylvania State University (PSU) provided an additional 600 sample results for manganese to DEP in 2021. While DEP did review and analyze this data, insufficient information was available to conduct a proper quality assurance/quality control check of the data. The mean value of this dataset (5 mg/L) was significantly higher than any of DEP's datasets. In sum, the available WQ data demonstrates that the proposed criterion of 0.3 mg/L is neither overly protective nor inconsistent with expected natural background conditions.

The elevated concentrations of manganese observed in coalfield regions are generally the result of human activities rather than natural conditions. In other words, the elevated concentrations observed in these regions are not representative of the natural levels that would otherwise exist in the absence of anthropogenic influences. In many cases, these elevated levels of manganese and other metals have led to impairment of the receiving streams. Permitted dischargers may not contribute to an impairment of a waterbody regardless of the cause of the impairment. Furthermore, the "natural conditions" provision provided in 25 Pa. Code Chapter 93 (relating to water quality standards) is only applicable to aquatic life criteria (§ 93.7(d)). Since the proposed manganese criterion is for the protection of human health, the Department would not consider relaxation of the criterion based on natural conditions for these waterbodies even if a natural condition were present.

DEP understands there are chemical reactions that will often occur in streams which will cause dissolved manganese to precipitate and deposit onto the streambed. Although it is recognized that dissolved metals are typically more toxic to aquatic life, the proposed criterion is for the protection of human health. Therefore, it is not relevant whether the instream manganese concentrations are in the form of particulate or dissolved manganese as all forms of manganese have the potential to be toxic to humans. Furthermore, the comment seems to suggest that natural streams will act as “treatment systems” to remove the manganese. Conservative pollutants, such as manganese, do not normally breakdown into non-toxic substances through physical, chemical or biological processes in the receiving water and, therefore, would have the potential to increase in streams as a result of moving the compliance point. Furthermore, these substances tend to be long-lived, stable compounds that can persist within the environment. Even if dischargers are releasing insoluble or “particulate” manganese into neutral pH receiving waters at the point of discharge, downstream tributaries and other influences can change WQ, including pH, which could convert particulate manganese to dissolved and result in the transport of manganese farther downstream than has been suggested.

- 11. Comment:** The commentator’s 2002 Schuylkill River Source Water Assessment identified abandoned mine drainage in Schuylkill County as the largest continuous source of metals such as manganese that negatively impact WQ throughout the Schuylkill River. Based on an analysis of metal loadings from 11 priority abandoned mine drainage sites and average annual mean flow, abandoned mines are shown to account for the majority of both iron and manganese concentrations observed throughout the Schuylkill River, even as far downstream from those sources as Philadelphia. In 2004, the Schuylkill Action Network (“SAN”) was formed to address priority sources of impairment in the watershed through a regional coordination framework. Since the inception of the SAN in 2004, a total of \$14.3 million has been invested by the network and its partners to support the implementation of abandoned mine drainage treatment systems. As a result of these remediation efforts, an estimated 6 tons of manganese is prevented from entering the Schuylkill River every year. Relaxing the manganese requirement for Pennsylvania dischargers would reverse the meaningful progress achieved over 15 years by a network of more than 150 partner organizations throughout the Schuylkill River Watershed. (890)

Response: DEP appreciates this comment and supports efforts to remediate impaired waters of the Commonwealth.

- 12. Comment:** The commentator has collected and evaluated the WQ and biologic condition of aquatic resources within the Susquehanna River watershed for decades. From 2000 through 2019, the commentator collected and analyzed more than 11,650 individual surface water samples for manganese. Data were obtained from approximately 1,500 unique locations throughout the Susquehanna River watershed. The commentator concludes that lowering the numeric manganese WQS will not necessarily improve source WQ in coalfield regions because manganese loads are dominated by unregulated, legacy discharges with no responsible party required to implement the proposed WQS. (925)

Response: DEP recognizes that historical mining operations, which resulted in abandoned mine lands (AMLs), are primarily responsible for many of the AMD/metals impairments documented in the Commonwealth. Section 303(d) of the CWA (33 U.S.C.A. § 1313(d)) requires states to create a list of waters impaired by pollutants that require the development of a total maximum daily load (TMDL) and Section 305(b) (33 U.S.C.A. § 1315(b)) requires states to report on the WQ status of all waters. The new manganese criterion will be incorporated into DEP's assessment program that supports Sections 303(d) and 305(b) of the CWA. DEP will assess surface waters for the new manganese criterion following implementation of the new criterion in DEP permit and approval actions. If waters fail to meet the new manganese criterion upon assessment under Section 303(d) and require the development of a TMDL, a TMDL will be developed to address this pollutant regardless of the source of the impairment. If nonpoint point source controls make more stringent load allocations practicable, then wasteload allocations for point sources may be made less stringent.

Any TMDL or other restoration plan must start with these stream assessments. Many restoration efforts rely on TMDLs and other restoration plans to secure critical funding to improve WQ. For example, Commentator 890 stated, "In 2004, the Schuylkill Action Network ("SAN") was formed to address priority sources of impairment in the watershed through a regional coordination framework. Since the inception of the SAN in 2004, a total of \$14.3 million has been invested by the network and its partners to support the implementation of abandoned mine drainage treatment systems. As a result of these remediation efforts, an estimated 6 tons of manganese is prevented from entering the Schuylkill River every year." Although waterbody improvements may not occur as quickly as in impacted waters with NPDES permitted discharges, WQ in these AML regions will improve over time as TMDLs are implemented and restoration projects are completed by both DEP and private organizations.

- 13. Comment:** In 1999, a surface mine permit was issued to a mining company in Somerset County, PA. The seams mined were the Upper, Middle and Lower Kittanning coal seams. The mine was very successful and today you could walk across the backfilled and reclaimed mine site and never know that mining ever took place. An erosion and sedimentation pond was left in as a post-mining structure at the request of the landowner. Above the pond, a pipe outlet from a DEP-approved pit floor drain flowed into the pond and provided a year-round source of cool water. Aquatic life that had been introduced into the pond were thriving. The permit was renewed in 2014 and imposed a manganese discharge limit to the pond. Chemicals were required to treat the manganese and now the pond is dead. Harmful chemicals replaced aquatic life, and treatment costs went from zero dollars to nearly \$20,000/year. There was no stream degradation and no drinking water standards were even remotely in jeopardy. In this instance, manganese restrictions on the pond are harming the environment not helping and ultimately created a solution without a problem.

In 1987, the commentator began monitoring the Stonycreek River located just upstream of the Hooversville Borough Water Supply Intake and currently have data that dates all the way back to 1982. This water sample collecting was done for various mining companies and continued almost uninterrupted until January 2020. The comparative data for manganese

above the Hooversville Water Supply Intake has actually improved and over the last few years, manganese levels have decreased. This has occurred even though many successful surface mines have operated within the watershed and within this same time period. Again, proving that manganese restrictions are a “solution without a problem.”

The commentator volunteers with the Stonycreek-Conemaugh River Improvement Project to conduct quarterly sampling and monitoring for the Oven Run treatment system, installed to passively treat pre-act AMD. Data shows this system has had a direct improvement on the Stonycreek River. If PA is to continue to be a leader and an example in WQ improvement, advancement and maintenance, then our focus should be on collaborative effort between the DEP, watershed groups and the industry, rather than spending time and resources on finding a solution to a nonexistent problem. (11)

Response: While DEP recognizes that the treatment pond described above may have provided some recreational benefit to the landowner, it was in fact a treatment pond and not a surface water of the Commonwealth. Without specific data, it is difficult for DEP to respond to the specific circumstances surrounding this situation. If manganese levels have the potential to violate WQSs, permit effluent limitations and treatment are needed to protect designated uses.

DEP supports collaborative efforts, such as the Stonycreek-Conemaugh River Improvement Project (SCRIP), to solve challenging environmental issues and is familiar with the extensive AML restoration work that has been completed in the Stonycreek River basin. Following installation of the Oven Run passive treatment system, it is not surprising that WQ has improved significantly in this basin. More recent mining operations in the basin would not be expected to negatively impact the success of such remediation projects as any discharges would be subject to current environmental laws and regulations, which were established to prevent the type of environmental degradation and pollution that occurred historically. Current regulations require the manganese criterion to be met in all surface waters (that is, at the point of discharge). If the point of compliance is moved, higher amounts of manganese in wastewater effluent would be permitted, and for industries that are without best available technology (BAT) limits, this increase could be significant. Thus, moving the point of compliance has the potential to undo the success of AML remediation projects like SCRIP.

- 14. Comment:** The presence of manganese in the commentator’s discharge is due entirely to the presence of manganese in the groundwater. Analytical results from incoming groundwater well water collected in 2018 show that manganese was present at concentrations ranging from 0.11 mg/L to 0.810 µg/L. The testing shows that manganese concentrations from the groundwater can exceed the proposed manganese limit of 0.3 mg/L in ambient groundwater. The attached excerpt from the Cheswick Borough Water Department Wellhead Protection Plan (PWSID: 5020008) references a 1995 study assessing groundwater quality in this area. The groundwater sampling performed in this study showed that the manganese “exceeded the secondary contaminant level in 6 of the 7 monitoring wells,” confirming that manganese “is consistently present in the sand and gravel alluvial deposits in the study area.” Therefore, for more than 20 years, and as confirmed by the current raw water data, it has been known that

high concentrations of manganese are present in the area groundwater used by local facilities, including [the commentator].

The second alternative, which could implement a manganese limit of 0.3 mg/L at the point of discharge, would require significant expensive facility upgrades to remove the manganese prior to discharge. Point source discharges from [the commentator] are not likely to cause a significant increase in manganese concentration at the Allegheny River, due to the insignificant flow rate compared to the river and the manganese concentration being at “background” levels as compared to groundwater. Commentator suggests that the second alternative unjustly imposes a conservative limit uniformly on all dischargers to all receiving streams in all areas, with no consideration to the fact that groundwater contributes an ambient source of manganese. (860)

Response: The presence of manganese in groundwater does not eliminate the need to protect the WQ of surface waters of the Commonwealth and the protected water uses. Regardless of the source of pollutants, NPDES discharges must protect WQS.

DEP intends to implement the final-form manganese criterion consistent with current implementation guidance and regulations for toxic pollutants. This will not result in a WQ-based effluent limitation (WQBEL) of 0.3 mg/L for all discharges, considering mixing and receiving water characteristics. NPDES permits may be subject to technology-based effluent limitations (TBELs). Coal mining industries must additionally meet the Federal ELGs of 2.0 mg/L (monthly average), 4.0 mg/L (daily maximum), and 5.0 mg/L (instantaneous maximum), where applicable. See 40 CFR § 434. These requirements will not change as a result of the final-form regulation. Permits may include TBELs as long as they are more stringent than WQBELs. While the final-form criterion will be implemented uniformly, it will not result in a uniform effluent limitation for all dischargers.

- 15. Comment:** Manganese is a transition metal that can be found in aqueous solution (dissolved) principally as manganous ion (Mn^{2+}), which is the reduced form of manganese, but other oxidation states of manganese found in aqueous environments under natural conditions, including Mn^{3+} and Mn^{4+} . Both of these oxidation states are more common in oxygenated environments, such as surface waters, and both have very low solubility at pH greater than 4. As a result, concentrations of soluble or dissolved manganese in natural surface waters are typically not found except in close proximity to the source of the dissolved manganese.

Dissolved manganese, the reduced form of manganese, in surface waters with circumneutral pH is highly unstable. This is because the reduced form is subject to natural oxidation process to insoluble oxidized forms, thereby forming insoluble oxyhydroxide precipitates. These precipitates become a relatively small component of the surface water sediment load, or bed load. Transport or suspension of this bed load occurs but only as part of the natural stream and river transport processes associated with high storm event flows.

These instream manganese removal processes are documented in the literature (Hem, J.D. 1981). “Rates of manganese oxidation in aqueous systems.” *Geochimica et Cosmochimica Acta* Vol. 45 pp. 1369-1374; and Scott, D.T., D.M. McKnight, B.M. Voekler, and D.C.

Hrncir. 2002. "Manganese Fate and Transport in a Mountain Stream." *Environ. Sci. Technol.*, Vol. 36, pp.453-459.), and are important natural processes that remove natural and anthropogenic dissolved manganese from surface waters. Based on these instream mechanisms, dissolved and suspended manganese in stream waters would be short-lived. Manganese would likely be lowered from the water a short distance from the discharge (typically less than 1 mile), as long as the stream meets all other surface WQSSs (specifically pH > 6).

It appears DEP has assumed manganese is conservative in the stream similar to parameters like sodium and chloride. DEP has not conducted any modeling to evaluate the fate and transport of manganese to determine the length of stream or surface water that is affected by the discharge of dissolved or total manganese at the mining BAT limits, TMDL limits, or the proposed rulemaking. Nor has DEP determined whether dissolved manganese (the form of concern to water purveyors) is currently or can potentially reach a potable water supply intake at various discharge effluent limits. The proposed rulemaking should be withdrawn until DEP uses known information to properly assess the potential impacts (lengths and conditions) of discharged manganese (total and dissolved) and determine the concentrations of dissolved manganese that may reach downstream potable intakes. (861)

Response: Manganese, like many metals, is considered by DEP to be a conservative pollutant. Conservative pollutants are substances that are not physically or chemically transformed to non-toxic substances in the receiving water and typically include salts and metals. Conversely, non-conservative substances will be transformed to non-toxic substances in the receiving water through physical, chemical or biological processes and include parameters like biochemical oxygen demand, ammonia and some organic compounds. While manganese may change between valence states in the receiving water, it is still manganese. As previously described, the valence state of the manganese does not matter with respect to this proposed rulemaking because the proposed criterion is for the protection of human health not aquatic life. Therefore, modeling to evaluate the fate and transport of manganese in surface waters as different valence states would not be utility to the development efforts and this evaluation was not pursued.

DEP acknowledges that manganese will oxidize and settle out of the water in some receiving streams. However, the behavior of manganese in natural aquatic systems is complex, and many factors will influence the fate and transport of manganese in each stream. While DEP does often allow a limited mixing zone for permitted discharges, also known as a compliance travel time, the CWA and CSL do not permit the use of surface waters of the United States or the Commonwealth as treatment systems to address pollutants from permitted discharges. Manganese is a conservative pollutant, so while it may change between dissolved and particulate forms as a result of stream chemistry and other factors, it is not actually removed from the water through these processes. Dischargers must comply with all applicable WQSSs and must protect water uses. In addition, human health protections apply to all waters in accordance with the narrative criteria found in 25 Pa. Code § 93.6, which states "water may not contain substances attributable to point or nonpoint source discharges in concentration or amounts sufficient to be inimical or harmful to the water uses to be protected or to human, animal, plant or aquatic life". The statewide protected water uses contained in § 93.4(a)

Table 2 include the Potable Water Supply use. These uses apply to all surface waters of the Commonwealth unless specifically removed in §§ 93.9a-93.9z.

16. Comment: Manganese is one of the most common elements in the earth's crust at an average concentration of about 0.1%. Manganese is ubiquitous in the environment and is found in soils, sediments, rocks and waters in various mineral forms including oxides, carbonates, silicates and sulfides. It is an important mineral that is used to produce various steel alloys and other metallic products (IMI 2020). In surface waters, manganese can be found in both dissolved (Mn^{2+}) and particulate (Mn^{3+} and Mn^{4+}) forms that when combined represent total manganese.

Of the three, Mn^{2+} (manganous) is the soluble form typically found in natural water. Mn^{3+} (manganic) typically has some limited solubility but may have some solubility at acidic pH, typically less than 3. Mn^{4+} is considered insoluble in natural waters. Dissolved Mn^{2+} is generally only found under reducing or low oxygen environments (e.g., groundwater, flooded soils and anoxic lake conditions). However, some mining conditions where pyritic oxidation and acidic conditions develop, dissolved Mn^{2+} may be released from chemical weathering (e.g., pyrite oxidation and acid leaching). This dissolved Mn^{2+} may remain in this soluble form for short periods or where the pH remains acidic but will be transformed to insoluble manganese where conditions support oxidation/precipitation, which are the typical conditions in most surface waters. The concentration of dissolved manganese in surface waters is low due to its low solubility under oxidative conditions.

Manganese is found in suspended solids in surface waters due to its common presence in soils, in oxidized and insoluble forms. In a United States Geological Survey (USGS) report by Shacklette and Boerngen (1984), soil and surficial material concentrations were evaluated in the conterminous United States that included Pennsylvania. Pennsylvania was found to have manganese (insoluble) ranging from 100 parts per million (ppm) to 5,000 ppm in soils and surficial materials depending on the location in Pennsylvania. This mineral manganese would mostly be in the Mn^{3+} and Mn^{4+} oxidation states and would be insoluble.

Soluble manganese is more commonly found in groundwaters where natural reducing conditions cause stable soluble forms to remain in solution. Soluble manganese can also be present in the deeper anoxic zone of surface water impoundments where reducing conditions from seasonal lake stratification can solubilize manganese from soil sediments deposited in the impoundment from erosion. It is noteworthy that neither of the above can be attributed to mining activities but are instead environmental processes occurring due to the common presence of manganese in the environment.

Various anthropogenic earth disturbance activities can release this insoluble manganese to surface waters in the form of suspended solids or particulate (total) manganese and not dissolved manganese. These earth disturbance activities that can release suspended solids and particulate manganese include non-coal mining, road construction, industrial/commercial/residential development, urban stormwater runoff, and agriculture. The manganese is released from erosion of soil and surficial material and from breaking rock that exposes minerals to increased weathering. The concentration of manganese released from

earth disturbance activities will depend on the concentrations found in the soils, surficial materials, and broken rock. Analysis indicates total suspended solids (TSS) produced from erosion can cause total manganese values that approach and exceed the proposed 0.30 mg/L manganese WQS. While regulations and erosion control may aid in lowering TSS, the analysis indicates the vast majority of earth disturbance activities have a “reasonable potential” to exceed the WQS.

The USGS report by Shacklette and Boerngen (1984), shows a high degree of variability and no consistency of manganese concentrations in Pennsylvania soils and surficial materials. It is likely the underlying geology and minerals in the rock formations also have this high degree of uncertainty with variability within a region and a locality. However, since this analysis shows a “reasonable potential” could occur anywhere in Pennsylvania, additional material testing would be needed for each and every site proposed for non-coal mining, public infrastructure construction (e.g., roads, schools, hospitals, treatment facilities), and private development projects. If soil, surficial, and rock testing for manganese concentration is required for earth disturbance permitting, there could be added overall project costs and construction delays. Where there is a high likelihood of elevated total manganese in runoff from earth disturbance activities that could cause exceedances of the WQS and where control or treatment is not possible, the earth disturbance activity could be prohibited.

The presence of manganese in mine waters is typically a result of secondary weathering of mine spoil and coal deposits following the initial iron sulfide (i.e., pyrite) oxidation and acidity release. The secondary manganese weathering reactions result from 1) dissolution of manganese carbonate minerals, 2) cation exchange of manganese from clays and other minerals, and 3) acidic leaching of minerals. Concentrations of manganese can vary depending on site specific conditions, but in mine waters manganese typically ranges from 0.5 to 100 mg/L. (618)

Response: DEP agrees that manganese is an abundant element that can be found in rocks and soils. However, natural background levels of manganese in Pennsylvania waters are rarely above 0.3 mg/L.

DEP reviewed the USGS report by Shacklette and Boerngen (1984). The commentator states that “Pennsylvania was found to have manganese (insoluble) ranging from 100 ppm to 5,000 ppm in soils and surficial materials depending on the location in Pennsylvania.” However, the study lacks any specific text or discussion on any of the sampling data collected in Pennsylvania. There is no description of where each sample was collected, how it was collected, who collected the samples (e.g., USGS, EPA, other), the valence state of the manganese, other soil parameters that could influence the availability of the manganese or how the samples were analyzed. The only information available is visual and is contained on a map of the United States. The map shows the very general geographic location for each sample along with a small bar graph in the corner of the map. The graph depicts groupings of samples according to the amount of manganese (in ppm) contained in the samples. Each grouping is represented by a different symbol, and those symbols are plotted on the map. Samples in the lowest group contained manganese that ranged from <2 to 150 mg/L. The upper most group ranged from 1,000 mg/L to 7,000 mg/L. It is assumed that each notation on

the map represents a single sample, so approximately 17 samples in total were collected in Pennsylvania. It is unclear how the commentator determined that the levels of soil manganese in Pennsylvania range from 100 ppm (mg/L) to 5,000 ppm based on the information provided in the study.

Upon reviewing the map in the Shacklette and Boerngen (1984) study, DEP noted that some of the highest soil manganese concentrations occurred in the southeast region of the Commonwealth. These results generally do not correlate with the WQ data available for this region. As described in the response to Comment 10, DEP analyzed over 35,000 WQ sample results across the Commonwealth. The analysis of the WQN data for the southeast region revealed that manganese concentrations at all of the sample sites were at or below 0.33 mg/L.

Shacklette and Boerngen (1984) noted that, to the greatest extent possible, specific sampling sites were selected that had surficial materials that were very little altered from their natural condition and supported native plants; however, they indicated that only cultivated fields and plants were available in some areas, and these sites would not necessarily reflect natural conditions or natural weathering of rock.. In addition, the authors stated they collected samples approximately 20 cm deep in an attempt to avoid surface contamination, when possible, but they had no way of measuring any contamination that may have occurred. Thus, outside of sampling depth, it does not appear that there was any quality assurance/quality control plan in place to prevent, minimize, or identify sample contamination, whether contamination occurred prior to collection or during the collection, transport or analysis of the samples.

With regard to anthropogenic earth disturbance activities, applicants seeking to disturb one or more acres of earth must, with certain exceptions, apply for and obtain NPDES permit coverage under 25 Pa. Code Chapter 102 (relating to erosion and sediment control) prior to commencing earth disturbance activities. When applying for permit coverage, applicants must conduct “environmental due diligence,” as that term is defined in DEP’s Management of Fill Policy (ID No. 258-2182-773). This is done, in part, to comply with 25 Pa. Code §§ 102.4(b) and 102.8(f), requiring an identification of naturally occurring geologic formations or soil conditions that may have the potential to cause pollution during or after earth disturbance activities, and implement best management practices to avoid such pollution. Unless environmental due diligence warrants it, soil sampling for manganese is not expected of Chapter 102 applicants. Where environmental due diligence has identified a concern, DEP’s Erosion and Sediment Pollution Control Program Manual (ID No. 363-2134-008) and Pennsylvania Stormwater Best Management Practices Manual (ID No. 363-0300-002) include recommendations for managing earth disturbance activities in areas of known soil contamination or hazardous geologic conditions, including but not limited to, mineral hazards.

- 17. Comment:** The following provides a discussion on the fate and transport of soluble manganese (Mn(II)) found in surface waters from the water discharged from coal mining sites. The low concentration of soluble manganese in surface waters is due to the relative instability of Mn(II) in circumneutral waters ($\text{pH} = 7 \pm 1$), typical of surface waters. This is because under these conditions Mn(II) is oxidized to its insoluble forms including Mn^{3+} and

Mn^{4+} . The oxidation (and precipitation) reactions are known as homogeneous manganese oxidation and precipitation reactions. However, there are additional manganese sorption and oxidation reactions occurring in the natural environment that can also oxidize and remove soluble manganese ($Mn(II)$) from water. These reactions have been described by Stumm & Morgan (1981), Hem (1981), and others. The actual rate of the reactions is more relevant to the removal of $Mn(II)$ from oxygenated surface waters, which is known as kinetic or rate reactions. The combined homogeneous and heterogeneous aqueous reaction rates that lead to the removal of $Mn(II)$ from waters are described by an equation from Cauglin and Matsui (1975).

The homogeneous oxidation reaction and rate (k_1) has been found to be highly sensitive to pH with the rate increasing a 100-fold for every pH unit change over the pH range from 6 to 9. At circumneutral pH it is a relatively slow reaction. The heterogeneous reaction is less sensitive to pH and more sensitive to the type and amount of manganese oxide solids involved in the sorption and subsequent oxidation. In other words, the rate is dependent on the concentration of insoluble manganese ($MnO_2(s)$) present. It is the later heterogeneous kinetic reaction that affects the $Mn(II)$ removal rate in streams and rivers where the solids ($MnO_2(s)$) are present and accumulate in the stream and river bottom or substrate. This accelerated removal has been documented in the mine drainage affected sections of the Susquehanna River (Lewis 1976) and was also supported by later research conducted by Hem (1981). Hem (1981) suggested the rate of oxidation would be pseudo-first order and likely occur over an extensive and elongated area in the direction of stream flow. More recently, Scott *et al* (2002) conducted instream studies investigating $Mn(II)$ removal in streams. This was a controlled study where the results demonstrated the importance of surface-catalyzed oxidation of manganese within the stream. The study provided a stream removal rate of 64 μmol of $Mn(II)$ per day per meter of stream length. This rate may be of value in assessing implications of an upstream treated mine drainage discharge containing manganese (total) on a downstream potable water intake.

Modeling results for low flow discharges in headwater locations, representative of discharges from surface and underground coal mines into small streams at common NPDES permit locations show how the instream concentration of manganese decreases rapidly from the discharge point, which is due to the combined effects of reaction (fate) and dilution (transport). This analysis uses an NPDES effluent concentration of 2.0 mg/L, which the treated effluent must be below (as a monthly average) in order to comply with the EPA technology-based effluent limitations in the permit. In addition, the discharge flow from sedimentation ponds is likely to be dependent on receiving stream flow condition, where lower than permitted discharge flow occurs at lower (baseflow) stream flow conditions. Overall it is evident in the modeling analysis that even in effluent-dominated headwater streams (i.e., where the discharge from the coal mine operation provides essentially all of the stream flow), the in-stream concentration of manganese decreases to approximately 1 mg/L (the current Chapter 93 criterion) within one-half mile downstream of the discharge point. When the discharge flow to streamflow ratio is 1:1, 1:3 and 1:10, the in-stream manganese concentration decreases to well below 1 mg/L within one-half mile of the discharge. This analysis indicates treated coal mine discharges located in headwater locations have minimal

effect on downstream manganese concentrations, typically less than one-half mile downstream of the discharge point.

Modeling results for high flow discharges that are more typically located in larger streams and rivers and representative of larger underground coal mines with discharges show the in-stream concentration of manganese decreases a short distance from the discharge point, which is due to the combined effects of reaction (fate) and dilution (transport). These are a small number of coal mine NPDES permit locations. This analysis uses an NPDES effluent concentration of 2.0 mg/L, which the treated effluent must be below (on average) in order to comply with the EPA technology based effluent limitations in the permit. Overall, it is evident in the modeling analysis that under none of the conditions modeled does the in-stream concentration of manganese exceed the current Chapter 93 criterion of 1 mg/L at any point beyond one mile of the discharge location. (618)

Response: While DEP does often allow a limited mixing zone for permitted discharges, also known as a compliance travel time, the CWA and CSL do not permit the use of surface waters of the United States or the Commonwealth as treatment systems to address pollutants from permitted discharges. Manganese is a conservative pollutant, so while it may change between dissolved and particulate forms as a result of stream chemistry and other factors, it is not actually removed from the water through these processes. The manganese continues to exist either as a dissolved metal that is carried downstream or as suspended solids that settle out and coat the stream bed as the flow travels downstream. In both cases, manganese has the potential to negatively impact the aquatic ecosystem and the protected water uses. Furthermore, the existing Potable Water Supply use criterion of 1.0 mg/L was not developed for the protection of human health and is being replaced with a criterion of 0.3 mg/L for the protection of human health based on the science and information available on the toxicological effects of manganese. The most appropriate application of human health toxics criteria is in all surface waters.

- 18. Comment:** Studies have not been conducted by DEP in Moshannon Creek or state-wide surface waters to determine the manganese concentrations (dissolved and total) found in surface waters, sources of this manganese, and the waters that will be affected by implementation of this statewide WQS for manganese. (861)

DEP has not determined the basic aqueous chemistry of manganese (dissolved versus total) nor manganese fate & transport in surface waters. (861)

Response: See the response to Comment 10. DEP did evaluate the available statewide data to determine the expected naturally occurring levels of manganese in surface waters. Additional information is also available in Appendix A.

Manganese in Humans

- 19. Comment:** Manganese deficiency is harmful to the human body and is associated with adverse health effects, such as effects on bone development. Throughout the world,

manganese deficiency and toxicity in human populations is considered rare, although “more than 35% of the world population is possibly deficient” (INstiks 2017). (**618, 728, 816, 901**)

Response: DEP agrees that manganese deficiency can lead to a number of health issues and negative health outcomes and that manganese deficiency and toxicity are not common in the general population. DEP describes the effects of manganese deficiency in greater detail in its criterion rationale document titled “Development of the Human Health Criterion for Manganese.”

One commentator cited that “more than 35% of the world population is possibly deficient.” The source cited (INstiks) appears to be an online health and wellness magazine/website with unknown sources of data. Furthermore, it is unclear how this information is relevant to this rulemaking and the establishment of protective WQSSs for Pennsylvania. DEP could not find any credible sources either to support this claim or if deficiencies do exist in world populations, to support that manganese deficiency is prevalent in the United States, or more specifically, Pennsylvania. Based upon DEP’s comprehensive scientific review of manganese, manganese deficiency is generally encountered only in situations involving the following: severe dietary restrictions, illness, or chronic disease. An average diet provides adequate daily amounts of manganese for most individuals.

20. Comment: The Senate Environmental Resources and Energy Committee and others comment that manganese is a common element found in the human body and is an essential nutrient that is critical for biological processes such as metabolism, bone development, reproductive health and good health in general. (**3, 9, 10, 497, 618, 728, 816, 922, 953, 954, 955**)

Response: DEP agrees that manganese is an essential micronutrient that is critical for good health.

21. Comment: Manganese is a component of the human diet and is the primary source of manganese intake in the general population, with adults typically consuming between 1 and 10 mg/day. Higher intakes are associated with diets high in whole grain cereals, nuts, leafy green vegetables and tea. Dining on 6 ounces of mussels results in the ingestion of 11.6 mg of manganese; add 100 g of whole wheat bread to the meal and another 2.174 mgs is ingested. The World Health Organization (WHO) has reviewed investigations of diets and has concluded that 2-3 mg/L of manganese is adequate for adults and 8-9 mg/L is perfectly safe, with the upper range intake value of 11.0 mg/day from dietary studies considered a no observed adverse effect level (NOAEL). Vegetarian diets containing up to 20 mg/day manganese have not been shown to be associated with adverse health effects (Schroeder *et al.*, 1966; Greger, 1999). Manganese is also added to infant baby formula, as recommended by the Food and Agriculture Organization of the United Nations and WHO.

Manganese intake from water consumption is often much lower than manganese intake from food (EPA, 2002; WHO, 2003). WHO’s Guidelines for Drinking-Water Quality lists manganese as a naturally occurring chemical that has no adverse health effects, but does provide acceptability aspects for taste, odor and appearance. EPA’s Integrated Risk

Information System (IRIS) summary indicates that while average levels of manganese in various diets have been determined, no quantitative information is available, and environmental, biological, and host factors such as alcohol consumption, anemia, liver function, and general nutritional status can significantly influence an individual's manganese status. Further, of the one study describing toxicologic responses in humans consuming large amounts of manganese, it was determined that the concentration of manganese exposure was as high as 28.0 mg/L, which is fourteen times the criterion in 25 Pa Code Chapters 86-90 and 40 CFR §434. Based on this, it is hard to understand why the current standard of 1.0 mg/L total manganese is not adequate for protecting human health. (**497, 618, 728, 905, 922, 954, 955**)

Response: DEP agrees that dietary sources of manganese provide an adequate daily intake for most individuals. DEP acknowledges that some dietary practices, such as vegetarianism, can result in higher dietary exposures to manganese and that such exposures are not known to lead to adverse health effects. DEP recognizes that manganese is added to infant formula. However, it is important to note that the Minnesota Department of Health (MDH) recently evaluated the manganese content of a variety of infant formulas and found that the measured amount of manganese was 1.3 to 5 times more than the labeled amount. While the United States Food and Drug Administration (FDA) has established a minimum level of manganese in infant formula (~34 µg/L), no maximum level has been established. Current research indicates newborns and infants that consume excessive amounts of manganese are at greater risk of suffering from impaired neurodevelopment leading to behavioral and cognitive deficiencies later in life. See the response to Comment 65.

While DEP does not disagree that manganese intake from water consumption is generally lower than intake from food, there are important differences between water and dietary sources that can affect bioavailability and absorption. See responses to Comments 65, 69, 73 and 91 for more discussion on bioavailability. In addition, many scientific studies have been published since the EPA IRIS evaluation was completed in 1995, subsequently updated by EPA through the Health Effects Support Document for Manganese in 2003 (EPA 822-R-03-003). Detailed discussion on the toxicological data is provided in the criterion rationale document and the responses to the numerous toxicological comments is this document. See subsection "Manganese Toxicity and Human Health; Comments on the Retention of the Current Manganese Criterion."

General Support for the Proposed Table 5 Manganese Criterion of 0.3 mg/L

22. Comment: The commentator supports the designation of manganese as a toxic substance. (**925**)

Response: DEP appreciates the commentator's support of the proposed regulation which identifies manganese as a toxic substance. The final-form regulation also identifies manganese as a toxic substance.

23. Comment: *Support for the deletion of the existing manganese criterion for the protection of the Potable Water Supply use and the addition of a manganese criterion to Chapter 93,*

Table 5 for the protection of human health from threshold level toxic effects, which will also provide adequate protection of aquatic life and other water uses:

- The commentator urges the EQB and DEP to change the WQS for manganese from 1 mg/L to a more stringent 0.3 mg/L. (13, 14, 60, 74, 78, 589, 595, 596, 615, 699, 700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 863, 865-866, 871, 873-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-917, 919, 921, 923-924, 926-927, 932, 934, 937, 939-940, 945, 947, 949-950)
- Commentator supports the proposed rulemaking to amend Chapters 93 (relating to water quality standards). (13, 14, 74, 595, 615, 917)
- The proposed standard of 0.3 mg/l is protective of human health (and other water uses), and so it should be adopted by the EQB. (32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 501-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)
- Commentator supports the proposed rulemaking amendments that add the manganese criterion of 0.3 mg/L to Table 5 at § 93.8c – Water Quality Criteria for toxic Substances (93, 95, 536, 597, 702, 864, 867, 918, 929, 930, 931, 938, 942) and remove the manganese criterion of 1.0 mg/L from the existing Potable Water Supply Table 3 at § 93.7. (597, 702) (867, 938)
- Commentator supports the proposal of a new numeric human health criterion for manganese of 0.3 mg/L in Table 5 in Pa. Code § 93.8 and the deletion of the existing 1 mg/L in Table 3 § 93.7 standard. The new numeric [criterion] for manganese of 0.3 mg/L is a step in the right direction in protecting human health and aquatic life. (500, 593-594, 620-639, 641-686, 688-697, 705, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)
- Please change the WQS for manganese from 1.0 mg/L to 0.3 mg/L...Changing the WQS to 0.3 mg/L is necessary to protect human health and the health of our waterways. (589, 700-701, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 873-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 934, 937, 939-940, 945, 947, 949-950) This is what my children would call a “no-brainer”. (872)
- EQB should adopt the 0.3 mg/L manganese standard. (701)
- Regulatory impacts of shifting the surface water manganese criterion from the Potable Water Supply use criterion in section 93.7 Table 3 to section 93.8c Table 5 Water Quality Criteria for Toxic Substances notwithstanding, the commentator generally supports the reduction of WQ criterion for manganese regulated in the Commonwealth’s surface water. To prevent a gap in public water protection, we support the adoption of the rule

change into section 93.8c prior to the elimination of regulatory oversite covered in section 93.7. **(907)**

- Public health science thus supports changing the current outdated 1.0 mg/l manganese criterion in 25 Pa. Code § 93.7 (relating to specific water quality criteria) and replacing it with the proposed 0.3 mg/L in Chapter 93.8 - Water Quality Criteria For Toxic Substances, because the existing 1 mg/L standard is not protective of human health. This change is fully supported and based upon sound science to protect the public health of the Commonwealth's citizens. **(936)**
- The commentator supports the adoption of a more stringent standard in order to protect aquatic life and human health if the applicability of the Pennsylvania manganese WQS is shifted to the point of public water intakes. Without a stronger standard, eliminating the requirement to minimize manganese in discharges leaves streams, and the people and aquatic organisms that use them, insufficiently protected from these potential impacts. **(928)**
- The commentator urges the EQB and DEP to protect human health and all uses of our streams by adopting the more stringent manganese WQS of 0.3 mg/l. **(90, 91, 92, 94, 96-102, 104-106, 108-275, 277-496, 498-500, 502-535, 537-573, 575-588, 590, 591, 598-610, 612-614, 616, 617, 619)**
- The commentator urges the EQB and DEP to protect aquatic life, stream health, and water supplies by adopting the most stringent WQS being proposed for manganese currently – 0.3 mg/l. This standard will offer much help in getting toxins out of our streams that often originate from mining and industry. **(16, 18-31, 33-59, 62-72, 75, 77, 79-88, 107, 276, 574, 589, 882)**
- The commentator is deeply concerned about our WQ from all sources, both now and into the future. Consequently, commentator encourages the EQB and DEP to protect human health and all uses of Pennsylvania streams by adopting the more stringent manganese WQS of 0.3 mg/l and by requiring that the discharge point remains the point of compliance for this standard. **(501)**
- The commentator supports the EQB's proposed amendment deleting the outdated manganese WQ criterion of 1.0 mg/L and adopting the new water criterion of 0.3 mg/L to protect human health, aquatic life, and other water uses from the toxic effects of manganese. **(870)**

Response: DEP appreciates the commentators' support for the proposed criterion. The final-form regulation updates the manganese criterion to 0.3 mg/L to protect human health, but to also ensure the protection of aquatic life and other water uses.

24. Comment: *The current criterion of 1.0 mg/L was not developed for the protection of human health:*

- The current manganese effluent limit in Pennsylvania of 1.0 mg/l was not designed to be protective of human health, aquatic life, or water supply use. (93, 864, 918, 930, 931, 942)
- The current manganese standard of 1.0 mg/L is not sufficiently protective of human health. (13, 14, 74, 595, 615, 917)
- Current scientific knowledge and recommendations make clear that the existing 1 mg/L criterion in Table 3 § 93.7 is not protective enough. (929)
- The current manganese standard of 1.0 mg/l is inadequate to protect human health from the neurotoxicological effect of manganese. (32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 501-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)
- The commentator supports DEP's proposal to change the manganese criterion to 0.3 mg/L. This standard is long overdue after years of analysis, but the mining industry is pressuring officials to ignore science at the expense of public health. The existing Potable Water Supply use criterion of 1.0 mg/L is based on taste, odor, and to prevent laundry staining. It does not take human health, aquatic life, or water supply use into consideration and is therefore inadequate to protect these uses. It is also higher than the EPA HAL and other national and international standards set by governmental bodies. The EPA's lifetime HAL for adults and children is 0.3 mg/L and was calculated using the reference dose (RfD) in the IRIS. Adopting a manganese criterion of 0.3 mg/L in Pennsylvania would match the EPA's HAL and be more protective to human health, aquatic life, and water supply use. (5, 103)
- It is clear that the current manganese WQ criterion of 1.0 mg/L is not protective. (870)

Response: DEP agrees that the current manganese criterion of 1.0 mg/L was not developed for the protection of human health; rather, it was intended to protect the Potable Water Supply use and represented a technology-based value. Following a review of the available, peer-reviewed literature, DEP determined that the current WQ criterion of 1.0 mg/L is not recommended for the protection of public health.

25. Comment: The commentator appreciates the time and attention that DEP put into reviewing and updating the criterion for manganese to ensure adequate criteria for manganese exist to protect all of Pennsylvania's waters and the people that use them. (929)

Response: DEP appreciates the commentator's recognition and support.

26. Comment: This is important to Pennsylvania's waters because manganese is discharged by a number of industries, including coal mining. (863)

Response: DEP agrees with the comment.

27. Comment: Both the Water Resources Advisory Committee (WRAC) and the Public Water System Technical Assistance Center (TAC) Board voted to support the 0.3 mg/L standard proposed by DEP. (14, 595, 615, 917)

Response: The commentators are correct in stating that both the WRAC and Public Water System TAC Board voted to support the proposed rulemaking.

Manganese Toxicity and Human Health; Support for the Proposed Manganese Criterion of 0.3 mg/L

28. Comment: *Support for the proposed criterion based on scientific review:*

- The commentator supports the proposed 0.3 mg/L criterion for manganese based, in part, upon the proposed rulemaking's discussion of both the health effects from manganese exposure and DEP's review of critical peer-reviewed scientific literature and health based information and documents, including numerous human health studies related to the toxic effects of manganese. (938)
- The commentator supports the more stringent criteria because it is based on the most recent scientific toxicity studies and is the first revision since 1967. (863)
- DEP reviewed the effects of manganese on human health and determined that current science shows manganese is harmful to human health as a possible nervous system toxin with implications to early childhood development at levels that are less than the threshold levels that impact aquatic life. DEP believes the new proposed 0.3 mg/L toxic health standard will protect human health from the neurotoxicological effects of manganese, as well as ensure adequate protection of all water uses. (13, 14, 74, 595)
- The informational and health study analyses performed by DEP represents the first comprehensive review in decades. Current public health science supports changing the 1.0 mg/L manganese criterion in 25 Pa. Code § 93.7 and replacing it with the proposed 0.3 mg/L in Chapter § 93.8. This change is supported and based upon sound science to protect the public health of the Commonwealth citizens. (536, 929)
- The informational and health study analyses performed by DEP represents the first comprehensive review in decades. DEP solicited information for the development of this proposed rulemaking through an ANPR published at 48 Pa.B. 605 (January 27, 2018). DEP sought scientific and current toxicological information to comprehensively review the manganese standard as it relates to the water uses identified in §93.3 (relating to protected water uses) and, in particular, to determine the need to develop manganese toxics criteria related to human health and aquatic life exposure.

DEP also conducted an independent search of the scientific literature available on the toxic effects of manganese to aquatic life and humans. With respect to impacts on humans, DEP reviewed over 60 human health studies relevant to the toxic effects of manganese and included areas of epidemiology, epigenetics, and animal toxicity studies. DEP also reviewed information available through the EPA's IRIS database. At levels beyond those necessary to maintain adequate health, manganese has been identified as a nervous system toxin and has been specifically linked to negative impacts on fetal and childhood neurodevelopment.

Current public health science supports changing the 1.0 mg/l manganese criterion in 25 Pa. Code §93.7 and replacing it with the proposed 0.3 mg/L in Chapter §93.8 (Water Quality Criteria for Toxic Substances). This change is supported and based upon sound science to protect the public health of the Commonwealth citizens. (536)

Response: The commentators are correct in stating that DEP had not conducted a comprehensive evaluation of the manganese criterion since 1979. Since that time, a number of toxicological studies and literature have been published, which have continued to identify that manganese is a neurotoxin. Based on the current science and data, the final-form regulation updates the manganese criterion to 0.3 mg/L to protect human health, aquatic life and other water uses.

29. Comment: *Comments relating to excessive exposure to manganese:*

- Although manganese is naturally occurring, in excess it has been shown to be harmful to brain health and the nervous systems of children and exposed workers, potentially impact fetus development, the placenta and fertility. (928)
- Manganese is an essential nutrient required as a cofactor for a variety of enzymes; however, high oral levels of exposure can also result in adverse neurological effects. (907)
- While manganese is an essential micronutrient for plants and animals, only small quantities of manganese are necessary to achieve adequate health. Exposure to levels of manganese beyond those necessary to maintain health may lead to a variety of adverse health effects. For example, it can lead to irreversible neurological problems, brain damage, and development issues with children. According to the more than 60 human health studies reviewed by DEP and EPA, the toxic effects of manganese are many and most of them are neurological in nature and irreversible. EPA has issued a manganese health advisory level of 0.3 mg/L, and WHO has set a manganese health guideline level of 0.4 mg/L. These numbers further show that the current 1.0 mg/L is outdated and insufficient to protect public health and the environment. (929)
- Research has proven that exposure to manganese is harmful to human health and, depending upon the degree of exposure, can cause lasting neurological damage. (589, 699, 700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 872-879, 881, 883-884, 886-889, 891-896,

899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 934, 937, 939-940, 945, 947, 949-950)

- The commentator is well aware that the human body needs some manganese, but waterborne manganese has a greater bioavailability than dietary manganese. Overdosing of manganese can lead to intellectual impairment and reduced intelligence quotients in school-age children. (Per Wikipedia) **(60)**
- The science has shown that human exposure to levels of manganese beyond those necessary for maintaining adequate health can lead to excess manganese in brain tissue resulting in symptoms that mimic Parkinson's disease. Depending upon the length and severity of the exposure, these neurological effects may result in permanent, irreversible damage to the brain. **(5, 103)**
- Manganese is a naturally occurring element and an important micronutrient necessary for good health, but as true with other naturally occurring elements, the dose makes the poison. High or long-term exposures can lead to serious human health impacts including neurological impacts. **(501)**
- Research has proven that exposure to manganese is harmful to human health **(699, 872, 942)** ...and, depending on the degree of exposure, can cause lasting neurological damage. **(699, 872)**
- While manganese is a naturally-occurring element, with high or long-term exposure, it can lead to serious human health impacts including neurological impacts. **(32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 502-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)**
- Manganese is a neurotoxin. **(76, 536, 925)**
- With documented studies on the negative impacts on cognitive development in adolescents (Sanders, 2015) (Haynes, 2015), the commentator feels that it is the EQB's duty to do everything possible to protect residents within the region. **(702, 956)**

Response: DEP agrees that manganese is an essential micronutrient and important to maintaining good health. However, when levels exceed those necessary for good health, the science and data continue to demonstrate that manganese can negatively impact neurodevelopment in infants and children and that many of these negative effects are likely permanent. The final-form regulation updates the manganese criterion to 0.3 mg/L for the protection of human health including infants and children.

30. Comment: The Agency for Toxic Substances and Disease Registry's (ATSDR) chronic reference dose media evaluation guide (RMEG) represents concentrations of substances in water, soil, and air that humans may be exposed to daily for a lifetime without experiencing adverse health effects. The RMEG for manganese is 0.350 mg/L for children, and the

commentator supports that the proposed rule change is lower than the ATSDR RMEG for manganese. Although it is highly unlikely that the primary source of water consumption for a child would come from a waterbody such as a stream, river, or lake, the overall reduction of contaminants in surface water attenuates the risk of non-regulated exposures to manganese due to incidental or intentional ingestion of surface waters. (907)

Response: DEP appreciates the commentator's support for the rulemaking.

Manganese Toxicity and Effects on Aquatic Life, Agriculture and Other Water Uses; Support for the Proposed Manganese Criterion of 0.3 mg/L

31. Comment: *Manganese is toxic to aquatic life and harmful to water uses:*

- Studies have shown that manganese harms aquatic life, such as fish, by impairing gill functions and causing hormonal interference. (5, 103, 589, 699-700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 872-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 929, 931, 934, 937, 939-940, 945, 947, 949-950)
- Manganese would harm water ecosystems and all critters that live in the streams, creeks & rivers or feed on those critters. (60)
- Manganese in high enough concentrations can be toxic to aquatic life. (73)
- Manganese is harmful to aquatic life as it can be significantly bio-concentrated by aquatic biota at lower trophic levels (cited Howe et al. 2005; see WHO 2004). (5, 103, 931)
- Excessive manganese is harmful to aquatic life and can impact other water uses including agriculture and recreation. (32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 501-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914, 918, 930, 931)
- Manganese is toxic to aquatic ecosystems. (76)
- Although manganese is naturally occurring, in excess it has been shown to...also settle in sediment where it can be accessible to aquatic life. (928)

Response: DEP agrees that manganese can be harmful to aquatic life and detrimental to other protected water uses.

32. Comment: The surface water in Pennsylvania needs to be valued holistically, not just for its Potable Water Supply use. A study done in 2019 found that a general trend for aquatic ecosystems, specifically lakes and rivers, is that the parts of these ecosystems we use most for goods/services, are the most at risk for being negatively impacted by human activities

[Culhane et al., 2019]. The same study also concluded that protecting these areas alone was not enough to protect all the areas at high risk. The only way to use natural resources sustainably is by protecting the whole resource. (76)

Response: DEP agrees that all surface water uses require protection, which necessitates taking a holistic approach to the evaluation and development of WQ criteria. For existing pollutants, changing the WQ criteria protections for a single protected water use without an evaluation of potential impacts to other water uses could result in inadequate protection for one or more of those other water uses. Under the CWA and CSL, DEP has the responsibility to establish protected water uses and the criteria necessary to protect those uses.

33. Comment: Manganese is harmful to aquatic life at high concentrations. Like other metals, the temperature, pH and other properties of receiving water influence uptake and toxicity to aquatic life. DEP conducted a thorough review of available information on manganese effects on human health and a preliminary evaluation of the available toxicity data indicated that the manganese level required to protect human health would be more stringent than the level needed to protect aquatic life. (707)

Response: At the present time, DEP's review of the available science indicates that the levels necessary to protect human health from the toxic effects of manganese are more stringent than those necessary to protect aquatic life. However, DEP recognizes the effects of manganese on aquatic organisms is an area of evolving science and will evaluate additional data in future updates to WQSSs as needed. Some of the more recent studies have examined the impacts of manganese on different types of organisms not previously studied (such as, freshwater mussels) as well as examined the effects of "chemical cocktails" and the effects associated with increasing salinity of freshwaters.

Several studies conducted in the Clinch River, which begins in Virginia and ends in Tennessee, found that freshwater mussels are sensitive to manganese (Archambault et al., 2017; Zipper et al., 2014). Sections of the Clinch River are impacted by coal mining.

Other researchers are examining the effects of chemical mixtures and salinization. They have found that combinations of chemicals and changes in salinity can alter the expected behavior and toxicity of specific pollutants (Kaushal et al., 2018, 2019 and 2021). As the commentator above describes, there are factors, such as temperature, pH, specific conductance and organic matter, that influence how metals and other pollutants behave, which cause the toxicity of those pollutants to increase or decrease. One current trend, known as freshwater salinization, has been shown to cause mobilization of the manganese and other metals contained in sediments leading to increases in the instream concentrations of these substances. This trend is very noticeable after precipitation events in regions that rely heavily on road salt in the winter, which includes Pennsylvania.

34. Comment: The commentator is pleased to see that DEP did a comprehensive review of scientific and toxicological information for manganese to determine the appropriate WQ criteria to protect all existing and designated water uses and to evaluate the impact of the proposed alternative to move the point of compliance to the potable water supply withdrawal.

Studies indicate that elevated manganese has negative impacts on aquatic life, including freshwater mussels which are among the most imperiled aquatic animal groups in the United States (Stein & Flack 1997). As evidenced in several recent studies in the Clinch River in Virginia (Johnson et al., 2014; Archambault et al., 2017; Rogers et al., 2018), mussel abundance, growth, and survival are adversely affected by exposure to manganese at high concentrations in water and sediments. (597)

Response: DEP agrees and appreciates that the commentator provided the full literature citations for those studies referenced in the comment.

35. Comment: Excess manganese can potentially degrade Exceptional Value and High Quality streams by impairing aquatic life and accumulating on the very substrates where benthic life resides – causing cascading impacts throughout the ecosystem. Oxidized manganese forms tightly bound, dark precipitates on exposed rock surfaces of rivers, impacting aquatic life. Since DEP often uses benthic macroinvertebrate diversity scores and metrics for redesignation petition qualifications, it is absolutely critical manganese never enters the stream in the first place to avoid these harms. (931)

Response: The final-form manganese criterion will not change the existing protections for Exceptional Value Waters (EV) and High Quality Waters (HQ). EV and HQ streams are protected at their existing quality or, in the absence of appropriate stream data to characterize the natural condition, the existing quality of a suitable reference stream. The protections for HQ and EV waters are not based on the numeric criteria in Chapter 93. However, non-special protection streams would still have protections against the scenario described in the comment. Non-special protection waters are protected through the narrative general WQ criteria in addition to the numeric criteria in Chapter 93. The Department generally agrees that if manganese is present in sufficient amounts, it can negatively affect aquatic life. Soluble manganese can be directly toxic and will gradually oxidize into a particulate form which settles out of the water column onto streambeds thereby affecting benthic habitats. Applying the proposed criterion in all surface waters would provide protection to all water uses, including aquatic life uses.

36. Comment: References to manganese studies and aquatic toxicity:

- The commentator referenced manganese toxicity studies on *Ceriodaphnia dubia* and *Hyalella azteca*, noting these organisms may serve as model organisms for the wider variety of crustaceans in our waterways. In a study by Lasier et al., *H. azteca* was found to have an acute LC50 (concentration of a substance that is lethal to 50% of test organisms) of 4.0 mg/L of manganese and *C. dubia* was found to have a chronic IC50 (concentration of a substance that inhibits a biological process or component by 50%) value of 3.9 mg/L of manganese in relation to reproductive inhibition (Lasier et al. 2000). If there is a lack of regulation on manganese levels at discharge sites, they could damage populations of zooplanktonic crustaceans like these which form the base of freshwater food webs. Even with concentrations at half or a quarter of the LC50 and IC50 values, zooplankton are known to be efficient at biomagnification of dilute pollutants and could likely affect the health of aquatic ecosystems.

The commentator reviewed Peter Samuel Reimer's thesis statement for the University of British Columbia, in which he compiles the lowest acute manganese concentrations for different freshwater species after an in-depth literature review (Reimer, 1999). The crustacean, *daphnia magna*, is of concern with the lowest acute value of 0.8 mg/L manganese. Beyond this, many trout can be predicted to have acute ranges between 2 and 5 mg/L manganese considering our local stream hardness values. There is also prior research indicating that manganese has deleterious effects on gas exchange at the gills in freshwater fish and mussels (Aliakbar, 2014) (de Oliveira, 2019). The commentator is concerned that if point of compliance is lifted from the discharge sites, levels of manganese will far exceed toxic levels in some Pennsylvania's streams. (702, 956)

- While space does not permit an extensive literature review, the conclusions presented from the following scientific studies provide the necessary facts to either reject the alternative compliance point or at a minimum, require further analysis of its impact to other critical uses:
 - Reimer (1999) found acute manganese concentrations [that impact freshwater aquatic life] ranged from 0.6 to 3.8 mg/L and are proposed as guidelines for exposure of <96 hours. The resulting chronic manganese concentrations ranged from 0.6 to 1.9 mg/L and are proposed as guidelines for exposure exceeding 96 hours.
 - Lasier, P., Winger, P. & Bogenrieder, K (2000) found in acute tests LC50s determined for *H. azteca* progressively increased from 3.0 to 8.6 to 13.7 mg Mn/L in soft, moderately hard, and hard waters, respectively. Acute LC50 values for *C. dubia* averaged 6.2, 14.5 and 15.2 mg Mn/L and chronic IC50 values averaged 3.9, 8.5 and 11.5 mg Mn/L for soft, moderately-hard and hard waters, respectively. Manganese toxicity should be considered when assessing solutions with concentrations approaching these levels. (936)

Response: DEP agrees that manganese has the potential to be toxic to aquatic life and more recent studies on previously untested organisms have suggested that animals such as freshwater mussels, particularly juveniles, are very sensitive to metals, including manganese. DEP is aware of the referenced aquatic life studies. The final regulation will protect surface waters between the point of discharge and downstream potable water supply withdrawal.

- 37. Comment:** The commentator partially concurs with [DEP's] conclusions about the lack of protection for critical uses between the point of discharge and the point of potable water supply intake. However, the science supports the fact that there will be impacts to fish, aquatic life, and recreational uses if manganese is allowed to be unregulated in waters between the point of discharge and potable water supply intake. Should EQB change the point of compliance, DEP staff should conduct a comprehensive risk assessment (similar to the public health risk assessment that was done to change the protection criterion DEP 2019 <http://files.dep.state.pa.us/PublicParticipation/Advisory%20Committees/AdvCommPortalFile s/WRAC/2019/072519/Managanese07.25.19.pdf>) based upon the most current literature available on the toxicity of manganese to fish and aquatic life and the nuisance impacts of manganese precipitates to recreational activities downstream of these unregulated discharges.

This is extremely important since this regulatory change would place thousands of miles of headwater streams and the aquatic life they support at risk. (936)

Response: Regardless of the point of compliance for the manganese criterion, the general WQ criteria in § 93.6 will continue to apply to all surface waters of the Commonwealth. The final-form regulation will maintain the point of compliance at the point of discharge and protect surface waters between the point of discharge and downstream potable water supply withdrawal.

38. Comment: As a conservation organization made up of trout anglers, we are most concerned that the streams and rivers where our membership recreate are as clean as can be. Trout are a very sensitive species and cannot tolerate pollution – much as we are not tolerant of pollution. (93)

Response: DEP agrees that trout are sensitive to many environmental pollutants, including metals, and appreciates the commentator's concern for clean water.

39. Comment: Excess manganese has negative implications for water uses such as agriculture. The EPA found that irrigation water containing manganese at concentrations of slightly less than 1.0 mg/L to a few milligrams per liter may be toxic to plants when applied to soils with pH values lower than 6.0. (5, 103)

Response: DEP is familiar with this language on the impacts to agriculture, which is contained in EPA's manganese criterion rationale document ("Gold Book," 1986). Pennsylvania is an agricultural state with soils that are naturally acidic due to the amount of annual rainfall that occurs in this region. Other factors, such as geology and mining activity, can also influence soil conditions. If surface waters used for irrigation contain elevated levels of manganese, agricultural operations could be negatively affected in areas where soil pH is 5.5 or less. Irrigation (IRS) is a statewide protected water use.

40. Comment: The commentator reminds us that all ecosystems are closed systems: what one does at point A affects all other points. One cannot do something to harm one part of this continuum without it harming everything else. (36)

Response: DEP agrees that ecosystems are complex and connected.

General Comments Opposing the Proposed Criterion of 0.3 mg/L

41. Comment: The commentator opposes changing the current limit. (7, 8, 10, 11, 12, 89, 922, 935, 955)

Response: DEP acknowledges the commentators' opposition to the proposed criterion of 0.3 mg/L.

42. Comment: The commentator requests that the EQB retain its current manganese human health criterion of 1 mg/L, as it is fully protective of human health and the environment. (89, 859, 905, 935)

Response: DEP disagrees that a human health criterion of 1.0 mg/L is protective as the current manganese criterion of 1.0 mg/L was adopted to protect the Potable Water Supply use and represents a technology-based value. See also responses to Comments 24 and 58.

43. Comment: The House and Senate Environmental Resources and Energy Committees and other commentators urge EQB to withdraw the proposed rulemaking. (861, 901, 922, 935, 952, 953)

Response: DEP acknowledges the commentators' request to withdraw the regulation.

44. Comment: The commentator notes that the background manganese levels are typically higher than the current discharge manganese levels contained in its discharges. It is also common to find upstream manganese levels that are higher than our discharge, while our discharge is higher than the downstream manganese levels. This data supports the idea that the manganese may be dropping out naturally. None of our sites have a public drinking water supply that is sourced within five miles of our discharge points. If it is dropping out naturally long before reaching a public water supply, we don't believe that there is any point to consuming resources to remove manganese when those same resources could otherwise be used for projects with more return on investment for the general public. (7)

Response: Natural background of levels of manganese in surface waters across Pennsylvania are generally low, less than 0.3 mg/L. In areas that have been altered by anthropogenic activities, levels of manganese tend to be higher, and in some cases, they are significantly elevated. See response to Comment 10 for more detail on the levels of manganese contained in surface waters across Pennsylvania. While DEP agrees the natural chemistry of streams will typically cause manganese to oxidize over time and deposit on the stream bed, it is inappropriate to use the waters of the Commonwealth as treatment systems to remove pollutants. In addition to the Potable Water Supply use, DEP must protect all other statewide designated uses including aquatic life, recreation, other water supply uses and esthetics.

45. Comment: DEP already has the tools to manage site specific challenges. There is no need to spend taxpayer dollars on an issue with no proven risk or benefit to the public. (12)

Response: As described in DEP's criterion rationale document and the responses to Comments 54-91, current toxicological data and studies support a link between manganese in water and developmental neurotoxicity. The federal Clean Water Act requires states to adopt WQSs to protect public health or welfare and enhance the quality of waters. DEP disagrees that the rulemaking results in spending taxpayer dollars for no proven risk or benefit to the public. The final-form manganese criterion will be applied at the point of discharge and may increase treatment costs for some permitted dischargers, such as those in the coal mining industry. Furthermore, as described in DEP's criterion rationale document and the responses

to Comments 54-91, current toxicological data and studies support a link between manganese in water and developmental neurotoxicity.

46. Comment: The proposed rule does not indicate whether the standard is for total manganese (i.e., soluble and insoluble fractions) or dissolved manganese. Insoluble manganese presents fewer issues concerning toxicity and treatability than the soluble fraction. Moreover, the pH required to dissolve particulate manganese is very low ($\text{pH} < 3$) and would not be an issue in rivers and streams used as a source for a public water system. Insoluble manganese comprises much of the manganese in many NPDES discharges. These discharges should not be regulated as if all the manganese is as dissolved manganese. The proposed rule should include provisions for industrial wastewater discharges to develop a total-to-dissolved manganese translator on a case-by-case basis. (497)

Response: DEP disagrees with the statement that manganese will only dissolve in streams at $\text{pH} < 3$. The behavior of manganese in streams and rivers is very complex, and many factors can affect the solubility and valence-state of manganese in natural systems. The commentator has provided no data to support the claim that nearly all of the manganese from NPDES discharges is particulate or that manganese will not dissolve once in the receiving waterbody. Discharges from coal mining operations tend to be located in areas with streams impacted by AMLs, so even if the direct receiving waters are pH neutral, downstream tributaries can cause localized drops in stream pH.

The final-form WQ criterion for manganese of 0.3 mg/L is for total manganese. While DEP generally agrees that dissolved metals tend to exhibit more toxicity to aquatic life than total metals, the criterion was not developed for the protection of aquatic life. The criterion is for the protection of human health. Manganese does not need to be present in a dissolved state to be toxic to humans. Once ingested, any manganese consumed will enter the extremely acidic environment of the stomach. The pH of stomach acid typically ranges between 1 and 3, so any non-dissolved manganese will dissolve and become bioavailable. Metals translators are generally only applicable to aquatic life criteria.

47. Comment: This regulatory overreach comes at a time when the Federal government is working to substantially reduce the regulatory workload on businesses around the country so that people can make a living and provide for their families. Nationwide and here in PA, many small businesses are struggling to just to stay alive. Adding a new regulatory burden to PA businesses in the midst of a job eating pandemic is not a wise move. Instead, it would be more sensible for the Commonwealth and DEP to look for ways to help businesses by eliminat[ing] overburdensome regulations. It is unreasonable for the Commonwealth to take such an unprecedented action at this time. (15)

Response: DEP developed the manganese rulemaking in response to the mandate of Act 40 of 2017, which required the development of proposed regulations concerning manganese. It is in the public interest that DEP keep pace with science and revise the manganese criterion to reflect that science and protect public health. Throughout the rulemaking process, DEP has been working closely with many individuals, organizations and programs to evaluate the

potential impacts of the proposed regulation and is working to address those concerns to the greatest extent practicable.

48. Comment: The EQB is setting Pennsylvania policy regarding the point of compliance for all human health criteria, not just manganese. Hiding this important policy decision in the context of a pollutant known to affect a limited subset of NPDES permittees is disingenuous and dangerous. The same logic would apply for all human health criteria – any discharge has the potential to increase treatment costs for a public water supply intake. This should be handled through a separate rulemaking process and not be hidden in a proposed revision to the manganese human health criterion. It is a major policy decision that affects all Pennsylvanians. (905)

Response: DEP is not setting a new policy regarding the point of compliance for human health criteria as part of this rulemaking. Human health toxics criteria have always been applied at the point of discharge in accordance with 25 Pa. Code § 96.3(c), which requires water quality criteria for toxic substances to be achieved in all surface waters at least 99% of the time. All 122 of the human health toxics criteria contained in Table 5 must be met in all surface waters (that is, at the point of discharge).

49. Comment: The commentator is an active environmental professional that designs, constructs, and maintains water treatment systems, including systems that effectively remove manganese from mine drainage, with first-hand knowledge of the excessive costs associated with manganese treatment. The commentator is concerned this action will end up increasing the cost to our government as more mining companies will be forced to walk away from their responsibilities, and there will be less organizations available to help manage Pennsylvania's common mining legacy. Tremendous progress has been made to address the impacts of mine drainage over the past several decades through partnership efforts, please do not hamper this good work by creating hurdles too high to overcome. (89)

Response: DEP agrees that much progress has been made to address the legacy of AMD over the years and continues to support that effort through partnerships with the mining community, conservation groups, river basin commissions and other organizations. DEP is working closely with those potentially impacted by the regulation to understand and address concerns to the extent practicable.

50. Comment: The Pennsylvania Mines, LLC, Rushton AMD Treatment Plant (Plant) is located Centre County, PA and discharges into the Moshannon Creek between Osceola Mills and Phillipsburg. This Plant treats pumped water from a flooded underground deep mine complex to maintain groundwater levels and prevent breakout of mine water at multiple locations throughout the watershed. The underground coal mine is closed and ceased producing coal in 1992. Despite being an inactive facility, owned by a company with no coal mining interests, Rushton continuously treats of up to 5,000 gallons per minute (gpm) of mine pool water under permits with DEP. If the Department were to establish the more stringent manganese limit of 0.3 mg/l at the discharge point, that limit would be 10 times lower than the manganese concentration which is typically found in the receiving stream (Moshannon Creek) resulting from upstream, untreated abandoned mine sources. So, such a requirement would cause Rushton to incur extremely higher costs to implement new treatment systems

(\$10s million) and to operat[e] the systems with no measurable improvement to the WQ in the receiving stream, let alone improvement to quality of any downstream surface water intakes. **(861)**

Response: DEP is aware that many waters with designated use impairments and elevated levels of manganese are related to the AMLs in the watershed. However, DEP disagrees that there is no benefit to be gained by implementing the criterion at the point of discharge in impaired waters. Although resources necessary to restore AML-impaired waters are limited, the lack of remediation of AML-impaired waters does not justify the discharging of more manganese by other entities, such as NPDES-permitted industries which would add additional manganese to an already impaired waterbody.

51. Comment: The Senate Environmental Resources and Energy Committee and others comment that this proposed rulemaking will not solely, or even primarily, affect the coal industry. It will also significantly and unnecessarily increase treatment costs for other industry sectors and could impact other state agencies. For example, as of February 2020, the DEP issued NPDES permits containing manganese limits or monitoring requirements to at least 99 non-coal mines, 174 industrial facilities, 196 public water suppliers, and 243 publicly-owned or other sewage treatment works in Pennsylvania. Adopting a more stringent manganese criterion and imposing it at the discharge point contrary to Act 40 will increase costs on private and public permittees, including individual homeowner customers of public water and public sewage facilities.

The proposed rulemaking could also result in significant negative unintended consequences. It will discourage coal operators, from re-mining and reclaiming abandoned mines if operators must incur significant additional treatment costs to treat non-Subchapter F and non-Subchapter G discharges. Watershed organizations do not have the money to treat to the new criterion, which means they likely will stop their good samaritan work. A final rule could result in more abandoned mine sites if operators forfeit bonds for post-mining discharges they cannot afford to treat. In many cases, post-mining discharge treatment trust funds are already underfunded and the responsible companies no longer exist. Significant costs would be imposed on the Bureau of Abandoned Mine Reclamation (BAMR) program to fund treatment of AMD or to treat sites permitted under the Commonwealth's now defunct Alternative Bond System, pursuant to the *Pennsylvania Federation of Sportsmen's Clubs, Inc. v. Quigley*, Civil No. 1:99-CV-1791 (M.D. Pa.) (Settlement Agreement, 11/2/2016). A final rule could also lead to the recalculation of post-mining discharge treatment trust funds to address increased manganese treatment costs.

Other activities could be newly subject to the proposed stringent manganese limits, including MS4 permits, construction stormwater permits, and industrial stormwater permits. Thus, the building and transportation industries may be discouraged from projects requiring a stormwater construction permit. It is very likely to dramatically reduce the use of general permits for stormwater, such as MS4 or industrial stormwater permits, because regulating manganese as a toxic substance will likely disqualify the use of general permits where manganese is present in the discharge. Most facilities that currently use general stormwater permits do not treat for manganese. They now would need to obtain an individual NPDES

permit, which will increase cost and delay projects, some undoubtedly to the point of not proceeding at all. (15, 618, 728, 897, 901, 929, 935, 953, 954)

Response: DEP agrees that the manganese rulemaking would apply to more than just the mining industry. WQSSs, when applied in an NPDES permit, affect any persons proposing to discharge to surface waters of the Commonwealth. As noted by the commentator, DEP evaluated potential impacts of the regulation on NPDES permittees as part of the rulemaking development process and identified hundreds of non-mining permits that contained either manganese effluent limitations or requirements to monitor and report manganese levels in the discharge. The impacts of the rulemaking will likely vary significantly from industry-to-industry and permittee-to-permittee. See the response to Comment 215 for additional discussion about anticipated costs associated with the rulemaking.

DEP is working with the mining industry and the Office of Active and Abandoned Mine Operations to identify the impacts of the regulation on remining and AML cleanup projects. The commentators have claimed that the costs associated with manganese treatment will increase the number of bond forfeitures. DEP does not expect the rulemaking to lead to an increase in AML sites as a result of bond forfeiture. DEP reviewed a 2006 request to EPA by the Interstate Mining Compact Commission, which represents mining regulatory agencies in 28 states, 2 additional state permitting agencies and several mining companies, to remove the current manganese effluent limitations of 2.0 mg/L as a 30-day average, 4.0 mg/L as a daily maximum and 5.0 mg/L as an instantaneous maximum. At that time, the petitioners asserted that “manganese treatment doubles or triples overall treatment costs resulting in the forfeiture of Surface Mining Control and Reclamation Act (SMCRA) bonds.”

In turn, EPA conducted a detailed study (EPA-821-R-08-012) in 2007 to address the question of whether bonds are being forfeited because of the cost of manganese treatment. The study focuses on examining bonding and trust fund requirements, past bond forfeiture rates, and the issues related to the assumption of long-term water treatment responsibilities for mines where the bonds have been forfeited. In EPA’s Notice of Final 2008 Effluent Guidelines Program Plan (73 FR 53219), EPA discussed the results of the study and determined that the ELG for manganese was appropriate. “In conducting its study, EPA also reviewed the costs of manganese treatment, which coal mining companies use to comply with manganese effluent limits derived from State manganese water-quality standards or site-specific BPJ technology-based effluent limits. Based on information received from the Commonwealth of Pennsylvania and the state of West Virginia, EPA concluded that only a small percentage of coal mine bond forfeitures are due to the cost of manganese treatment. Overall, EPA found that there is little potential for future forfeiture of bonds on SMCRA permits that have been granted during the past five years or will be granted in the future. EPA’s analysis indicates that “forfeitures are largely a legacy of the first decade of SMCRA implementation during the 1980s and early 1990s... Science supporting the Probable Hydrologic Consequence (PHC) analysis has subsequently improved to the point where the Pennsylvania Department of Environmental Protection anticipates that less than 1 percent of recently SMCRA permitted mines will develop AMD after reclamation and bond release.” Regarding this proposed regulation to update the manganese WQ criterion, the commentators have provided

no data or information to DEP to support the claims that bond forfeiture rates will increase as a result of the regulation.

Regarding existing AMLs, DEP would like to note that BAMR has no legal obligation to remediate AMLs. Under this regulation, BAMR would continue in its effort to restore the designated water uses to as many impacted streams as possible given the limited amount of public funding that is available to do so. In addition to BAMR sites, the Bureau of Mining Programs (BMP) is responsible for managing the treatment sites that were permitted under the Alternative Bond System (ABS). The Bureau of Clean Water (BCW) is working with BMP to address any concerns regarding potential impacts to ABS discharges as a result of the changes in regulation. DEP agrees that the final-form regulation could lead to the recalculation of post-mining discharge treatment trust funds to address increased manganese treatment costs.

Regarding stormwater-related permits, BCW has met internally with the NPDES Division and externally with the Pennsylvania Department of Transportation (PennDOT). The final-form rulemaking is not expected to impact DEP's current implementation practices for stormwater permitting or otherwise affect DEP's existing stormwater management programs. When applying for permit coverage, applicants must conduct "environmental due diligence," as that term is defined in DEP's *Management of Fill Policy* (ID No. 258-2182-773). This is done, in part, to comply with 25 Pa. Code §§ 102.4(b) and 102.8(f), requiring an identification of naturally occurring geologic formations or soil conditions that may have the potential to cause pollution during or after earth disturbance activities, and implement best management practices to avoid such pollution. Unless environmental due diligence warrants it, soil sampling for manganese is not expected of Chapter 102 applicants. Where environmental due diligence has identified a concern, DEP's Erosion and Sediment Pollution Control Program Manual (ID No. 363-2134-008) and Pennsylvania Stormwater Best Management Practices Manual (ID No. 363-0300-002) include recommendations for managing earth disturbance activities in areas of known soil contamination or hazardous geologic conditions, including but not limited to, mineral hazards.

- 52. Comment:** DEP's primary motivation for considering maintaining the current point of compliance in all surface waters (i.e., at the point of discharge) is that the lower criterion of 0.3 mg/L is needed to protect aquatic life and other surface water uses. Lowering the criterion is not needed to protect these uses, and so moving the compliance point to the point of potable water intake makes the most sense, is protective of the aquatic environment, and does not unnecessarily place the economic burden of excessive treatment to dischargers. (880)

Response: DEP's goal is to protect all water uses and to protect humans, animals, plants and aquatic life from toxic substances in concentrations or amounts that are harmful. The federal Clean Water Act requires states to adopt WQSs to protect public health or welfare and enhance the quality of waters. To that end, DEP has the duty to adopt protected water uses, WQ criteria and an antidegradation program. DEP was prompted by the passing of Act 40 to evaluate the WQ criterion for manganese, which has not been comprehensively evaluated and updated since 1979.

While DEP asserts that the application of the new criterion at the point of discharge provides protection to other designated uses beyond human health, it is not DEP's primary motivation for maintaining the point of compliance in all surface waters. The application of the new criterion at the point of discharge is in accordance with DEP's long-standing policy on the implementation of human health toxics criteria. As stated in the response to Comment 48, human health toxics criteria have always been applied at the point of discharge as stated in 25 Pa. Code Chapter 96. At the present time, all 122 of the human health criteria contained in Table 5 are applied at the point of discharge and must be met in all surface waters at least 99% of the time.

DEP disagrees that moving the point of compliance would have been protective of the aquatic environment. One of the mining industries' primary positions for this assertion is that the Federal ELGs provide for control of manganese at the point of discharge, and therefore, manganese would not be discharged in large or uncontrolled amounts. The mining industry is the only permitted sector that has additional Federal regulations in place to limit the amount of manganese released at the point of discharge as an end-of-pipe limit. And in Pennsylvania, drinking water treatment plants are the only facilities that have a state-developed BAT limit in their NPDES permits that applies at the point of discharge as an end-of-pipe limit. As also noted, while the mining industry does hold many of the NPDES permits with manganese effluent limitations, there are still hundreds of non-mining and non-drinking water permits that contain WQ-based effluent limits or "monitor and report" requirements for manganese. For these other permits, it is important to have a point of compliance at the point of discharge if there is no downstream potable water supply withdrawal within a reasonable distance from the discharge; otherwise, a manganese effluent limitation will not be calculated during DEP's reasonable potential analysis and thus, no manganese limit will be included in the permit. Without a limit, there will be no protection for the water uses, such as aquatic life. Furthermore, while it is recognized that mining activities are regulated by Federal ELGs which limit the discharge of manganese to a 30-day average of 2.0 mg/L, the mining industry may also discharge up to 4.0 mg/L as a daily maximum and 5.0 mg/L as an instantaneous maximum. These levels are not protective of aquatic life or the aquatic environment.

Manganese Toxicity and Human Health; Comments on the Retention of the Current Manganese Criterion

53. Comment: Commentator does not agree with the statements made by the EQB in the proposed rule which assert that current data and science support the need for a lower WQS to protect human health. **(698, 862)**

Response: DEP acknowledges the commentators' disagreement regarding the science to support the final-form criterion of 0.3 mg/L.

54. Comment: There is no conclusive evidence to suggest that exposure to manganese in drinking water at concentrations at or less than 2 mg/L is associated with health effects (Gradient, 2020). **(4, 618, 890, 951)**

Response: As evidenced by the numerous published studies referenced in this rulemaking and as described in more detail in the responses to Comments 65, 70, 75 and 79-91, DEP disagrees with the statement that there is no evidence to suggest that exposure to manganese in drinking water at the concentrations stated above is associated with negative health effects. Additional information on DEP's manganese criterion is available in the rationale document developed for this final-form rulemaking. See DEP's "Development of the Human Health Criterion for Manganese" (July 2021).

55. Comment: Manganese toxicity is associated with chronic exposure and high dosages. (4, 9, 859, 890)

Response: DEP disagrees that manganese toxicity only occurs with chronic exposure to high doses. As current scientific studies show and as described in DEP's responses contained herein, negative health effects can result at lower doses, particularly when exposures occur during early childhood development.

It is common for substances to initially be identified as toxic based on high exposure scenarios. Prior to the studies conducted over the past 10 to 15 years, much of the toxicological information available on manganese was from individuals that had experienced exposures to high levels of manganese resulting from industrial work settings or environmental contamination. This is a common first step in identifying the human health effects associated with a toxic substance. In many cases, scientists will identify that a substance is toxic to humans based on effects that occur when individuals are exposed to very high (acute) doses in the exposure scenarios described above. As scientists continue to examine the effects of chronic and lower dose exposures to toxic substances as well as examine additional exposure pathways or specific subpopulations, other negative health effects are often identified. It is not uncommon for different doses and exposure periods to result in different health effects, and it is typically only after additional study has been completed, which evaluates the potential health effects at lower doses over extended periods of time, that scientists begin to understand whether or not safe levels of exposure exist for a particular substance. Lead is an example of this situation. It took decades of study for scientists to understand that there is no safe level of lead exposure for children. While manganese is recognized as an essential nutrient, unlike lead, emerging studies and information have shown that negative health effects are associated with exposures beyond those necessary to maintain adequate health, and those exposures do not only include high doses of manganese via inhalation.

56. Comment: Manganese has not been widely categorized as a toxic substance by EPA or other states. (9, 15, 859, 862, 897, 935)

Response: While manganese has not been widely categorized as a toxic substance to date, EPA, States, and other health-focused groups, such as WHO and Health Canada, are currently reevaluating the science and data on manganese due to the number of studies that have emerged which support a link between manganese in drinking water and neurotoxicity.

Several states have reviewed the more recent toxicological data available on manganese and have adopted health-based guidance values for drinking water. These values specify the maximum allowable amount of manganese in finished drinking water. In 2012, MDH adopted a health-based guidance value (HBGV) of 0.1 mg/L to protect bottle-fed infants from neurological impacts. MDH relied on the Kern et al. (2010) study to develop the reference dose used in establishing the HBGV. MDH reevaluated the 2012 HBGV, and it was readopted in 2018. The agency recently published a paper in Environmental Health Perspectives (EHP, April 2021), which is available online. In addition to MDH, the Kern et al. (2010) study has also been used by WHO and Health Canada to develop their recommendations. New Hampshire is also currently evaluating the need for manganese drinking water standards to protect infants and developed an updated RfD based on the current oral RfD published in EPA's IRIS database. The updated RfD uses an adjusted point of departure based on the 2015 EPA updates to exposure factors including body weight assumptions. Other assessment inputs include the application of the EPA-recommended modifying factor (MF) of 3, a relative source contribution (RSC) of 0.5 and body-weight adjusted water intake rates for infants. The New Hampshire recommendation for manganese is also 0.1 mg/L.

WHO withdrew its recommendation of 0.4 mg/L for manganese from the WHO Guidelines for Drinking Water Quality (GDWQ) in 2011 on the presumption that “this health based value is well above concentrations of manganese normally found in drinking water.” However, drinking water levels above this value can be found in many countries including in the U.S. Following a more recent review of the published scientific literature, a draft document, titled “Manganese in Drinking Water,” was published for public review and comment in December 2020. Comments were due to WHO by February 8, 2021. The draft document recommended a maximum value of 0.08 mg/L to protect bottle-fed infants, which is significantly lower than the organization’s previous recommendation of 0.4 mg/L. On December 22, 2021, WHO published an update to its 4th edition of the GDWQ containing the recommendation that manganese in drinking water not exceed 0.08 mg/L to protect bottle-fed infants.

Health Canada also recently evaluated manganese in its “*Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Manganese*” (Health Canada, 2019) and determined that a maximum value of 0.12 mg/L for drinking water was warranted to protect infants based on the emerging science and data. Additional discussion on the Health Canada evaluation can be found in the responses to Comments 69, 83, 86, 87 and 91.

57. Comment: The House and Senate Environmental Resources and Energy Committees and other commentators state the manganese value is overly-conservative. (3, 89, 618, 862, 880, 932, 935, 952, 953, 954)

Response: DEP developed the manganese criterion recommendation following published EPA guidelines and methodologies for the development of ambient WQ criteria for the protection of human health as well as DEP’s regulations established in Chapter 93 and guidance in 25 Pa. Code Chapter 16 (relating to water quality toxics management strategy – statement of policy). In general, WQ criteria are not overly conservative when developed in

accordance with these established regulations and guidelines. EPA's "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000) makes the following statement:

"Although AWQC are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures. That is, through the use of conservative assumptions with respect to both toxicity and exposure parameters, the resulting AWQC should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water- or fish intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects. The Agency recognizes that there may be some cases where the AWQC based on chronic toxicity may not provide adequate protection for a subpopulation at special risk from shorter-term exposures. The Agency encourages States, Tribes, and others employing the 2000 Human Health Methodology to give consideration to such circumstances in deriving criteria to ensure that adequate protection is afforded to all identifiable subpopulations."

Most, if not all, of Pennsylvania's current human health criteria were developed using EPA's 2000 recommendations for default exposure inputs, which included an adult body weight of 70 kilograms (kg), or 154 pounds (lbs.) and average daily water intake and fish consumption values of 2 liters (L) and 17.5 grams (g), respectively. EPA updated these default exposure values in 2015, and the Department developed the proposed manganese criterion recommendation using the 2015 exposure inputs. The average body weight, drinking water intake and fish consumption values were updated to 80 kg (176 lbs.), 2.4 L and 22 g, respectively.

In developing WQ criteria, States must also consider the RSC for the pollutant, which accounts for the amount of pollutant in water vs. the total amount of a pollutant that a person is exposed to including from water, air, food, personal care products, and other pathways. A conservative RSC value is used when comprehensive data identifying the possible sources of the pollutant is not robust or when it is known that water contributes little to an individual's daily exposure. EPA has set the conservative, low-end RSC value at 20% of an individual's total exposure. The upper RSC for water contribution is set at a maximum of 80% since it is generally not possible to exclude the possibility of an unknown source of a pollutant. DEP used an RSC value of 20% in the development of the manganese criterion since manganese in water represents only a small portion of an individual's total daily exposure.

WQ criteria are intended to be moderately conservative in nature. Establishing some measure of conservatism provides for protection of the greater population, which includes more sensitive subpopulations such as children, adults weighing less than 176 lbs., pregnant and breastfeeding women, subsistence fisherman and other populations that fall outside of the average assumptions for body weight, fish consumption and water intake used in the development of a criterion.

58. Comment: The House and Senate Environmental Resources and Energy Committees and other commentators state EPA's MF of 3 is outdated and unnecessary, and it is not consistent with current science on manganese. The calculations and methodology used to arrive at the proposed surface WQ criteria limit of 0.3 mg/L is based on this outdated science and minimal data. If DEP had considered the most up-to-date science, it would have arrived at a different conclusion. Since the modifying factor is unnecessary, the current criterion of 1.0 mg/L is protective. (3, 9, 10, 618, 725, 728, 832, 859, 862, 880, 901, 905, 922, 935, 951, 952, 953, 954, 955)

Response: DEP disagrees with the statement that EPA's MF is outdated, unnecessary and inconsistent with current science. A number of studies have been published evaluating the effects of manganese on the central nervous system over the last 10 to 15 years. While further study is still needed to identify the dose-response relationship that establishes the safe concentrations in drinking water for various age groups, the current data and studies collectively support the concern that exposure to elevated manganese levels during early fetal development through childhood can impact neurodevelopment. DEP did review and consider the research published on physiologically-based pharmacokinetic (PBPK) models in its evaluation of manganese. Additional responses to PBPK models are discussed in Comments 65 and 77.

DEP is not aware of any studies or work relating to manganese in drinking water that supports 1.0 mg/L as protective of human health. The commentators' premise for the statement that 1.0 mg/L is protective is related to the application of the MF to EPA's IRIS reference dose and is not based on scientific study.

The IRIS reference dose is based on known dietary levels of manganese that have not resulted in adverse effects in humans. None of the commentators provided any scientific studies or data on manganese in drinking water to support 1.0 mg/L as a safe value. As DEP noted in its 1979 rationale document, the existing Potable Water Supply use criterion of 1.0 mg/L was not established to protect human health when it was adopted on a site-specific basis in 1967 or on a statewide basis in 1979. Rather, it is a technology-based limit that was established to protect the Potable Water Supply use. Based upon the definition of Potable Water Supply use in Chapter 93 (§ 93.3, Table 1), surface waters should be suitable after conventional treatment, without going beyond conventional filtration, for drinking water, culinary and other domestic purposes, such as inclusion into foods, either directly or indirectly. Potable Water Supply use is a statewide protected use, which means it applies in all surface waters of the Commonwealth except where specifically excluded in Chapter 93, Sections 93.9a-93.9z.

59. Comment: In 2004, EPA recommended discontinuing the use of MFs, based on a comprehensive review of the processes used to derive reference dose concentrations (EPA/630/P-02/002F). EPA has discontinued use of the MF for the manganese RfD in its own calculations. For example, the EPA Regional Screening Level (RSL) for Resident Tapwater (May 2020) uses an RfD of 0.14 mg/kg-day for manganese from the IRIS 1995 publication without the use of the MF. (859, 905)

Response: In EPA's "A Review of the Reference Dose and Reference Concentration Processes" (December 2002), the technical panel does recommend that going forward EPA discontinue the use of MFs, not because they are unnecessary, but because they are very similar to the uncertainty factors (UFs). UFs are applied to toxicology studies to account for uncertainties and variability associated with the data. As described in EPA's "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000), UFs may be applied to data to account for (1) the variation in sensitivity among the members of the human population (i.e., interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) the uncertainty in extrapolating from a lowest-observed-adverse-effect-level (LOAEL) rather than from a NOAEL; and (5) the uncertainty associated with extrapolation from animal data when the database is incomplete.

The technical panel indicated that any potential concerns with the toxicological data used to inform a reference dose should be sufficiently accounted for in the application of UFs particularly the database UF. As stated in the report, "the Panel considers the purpose of the MF to be sufficiently subsumed in the general database UF, and recommends that use of the MF be discontinued." The technical panel does not state that the existing MFs are based on bad science or are no longer applicable. The panel also does not recommend that EPA immediately discontinue the use of the existing MFs in the IRIS database.

Thus, the technical panel's conclusion was not that MFs should be removed but that MFs should be replaced with existing UFs in future assessments of toxic substances. EPA does not endorse altering previously published IRIS values without an in-depth evaluation and evidence-based rationale through re-assessment and review. The RfD (and attendant UF) in the 1995 assessment is based on dietary exposure data, and the MF was applied to address concerns for potentially more sensitive effects by non-dietary exposures. As such, the continued use of the MF-adjusted IRIS value for manganese with respect to non-dietary exposures is still appropriate. The concerns addressed by this MF (relating to toxicokinetic issues and differential life stage susceptibility) would be addressed through a UF in a modern day assessment.

Regarding EPA's use of the IRIS RfD and MF to calculate RSLs for manganese, DEP could not locate any information that indicates a reference dose of 0.14 mg/kg-day was used by EPA to establish an RSL for resident tap water. DEP reviewed EPA's online RSL – Generic Tables (current as of November 2020), and it is clearly stated that the RfD used to calculate the RSL for non-dietary manganese is 0.024 mg/kg-day. An explanation of this value is provided in the RSL users guide, which states the following:

"The IRIS RfD (0.14 mg/kg-day) includes manganese from all sources, including diet. The author of the IRIS assessment for manganese recommended that the dietary contribution from the normal U.S. diet (an upper limit of 5 mg/day) be subtracted when evaluating non-food (e.g., drinking water or soil) exposures to manganese, leading to a RfD of 0.071 mg/kg-day for non-food items. The explanatory text in IRIS further

recommends using a modifying factor of 3 when calculating risks associated with non-food sources due to a number of uncertainties that are discussed in the IRIS file for manganese, leading to a RfD of 0.024 mg/kg-day. This modified RfD has been used in the derivation of some manganese screening levels for soil and water. For more information regarding the Manganese RfD, users are advised to contact the author of the IRIS assessment on Manganese.”

The generic tables also include a category for dietary manganese, which is based on the IRIS RfD of 0.14 mg/kg-day. It is possible that the commentator is referring to this value in the table. However, it should be noted that while dietary manganese is included in the table, there is no corresponding RSL value for that category.

60. Comment: The House Environmental Resources and Energy Committee and other commentators state EPA chose not to regulate manganese with a national primary drinking water regulation to protect human health in 2003 because it “would not present meaningful opportunity for health risk reductions for persons served by public water systems” since the EPA health reference level of 0.3 mg/L is well below the tolerable level and public drinking water accounts for only a small proportion of a person’s daily manganese intake. Instead, EPA regulates manganese as an SMCL because manganese is not generally thought to be toxic. The SMCL is intended to minimize aesthetic and taste considerations. (9, 69, 89, 618, 698, 859, 860, 862, 897, 935, 952, 954)

Response: DEP agrees that the current EPA SMCL was established to minimize aesthetic and taste issues associated with manganese in potable water. While EPA may not have chosen to regulate manganese in drinking water with a primary maximum contaminant level (MCL) in 2003, it is important to note that EPA Office of Water (EPA OW) published a Drinking Water Health Advisory for Manganese with a Lifetime Health Advisory value of 0.3 mg/L and a footnote that states “The lifetime health advisory includes a 3-fold modifying factor to account for increased bioavailability from drinking water.” It is also important to note that EPA’s Safe Drinking Water program identified manganese as a pollutant of potential concern and recently collected data on manganese in drinking water as part of the fourth unregulated contaminant monitoring rule (UCMR4), which was published in the *Federal Register* on December 20, 2016 (81 FR 92666). The 1996 Federal Safe Drinking Water Act (SDWA) amendments require that once every five years EPA issues a new list of no more than 30 unregulated contaminants to be monitored by public water systems. Contaminants may be candidates for consideration if they are not regulated by national primary drinking water regulations, are known, or anticipated to occur at public water systems and may warrant regulation under the SDWA. The UCMR4 required monitoring of manganese at certain drinking water facilities between 2018 and 2020 using a reference concentration of 0.3 mg/L. The UCMR4 data is currently available to the public for review at the following link: <https://www.epa.gov/dwucmr/data-summary-fourth-unregulated-contaminant-monitoring-rule>. EPA’s evaluation of this manganese data is ongoing. It is not presently known when, or if, the EPA Safe Drinking Water program will publish a primary MCL for manganese. However, even in the absence of a primary MCL, Pennsylvania’s Safe Drinking Water regulations require public water systems to achieve an SMCL of 0.05 mg/L for manganese in potable water, which is more stringent than the manganese WQ criterion

and EPA HAL of 0.3 mg/L. The current drinking water SMCL for manganese, established to address esthetics, is protective of human health.

61. Comment: DEP has not completed or relied upon any in-house studies, but rather relies on outside studies from third world countries like Bangladesh, rural Canada and far east countries like Japan and South Korea. Have studies been done among children in first world nation's like the U.S., Great Britain, or Canada? What other factors could have impacted children in third world nations besides manganese exposure? The studies and information used by DEP show an extreme confirmation bias by referencing studies from countries like WWII Japan, South Korea and Bangladesh and other less developed nations. These studies do not discuss the other social and physical factors beyond manganese that also contribute to negative health effects. (15, 922)

Response: EPA and State WQSs programs across the country typically rely on peer-reviewed, published literature and studies conducted by individuals and organizations outside of their respective governmental agencies, particularly when developing human health criteria. The gold standard for any evaluation involves laboratory-controlled studies of the chemical and the target organism. However, unlike for aquatic life evaluations, it would be generally unethical to conduct toxicological studies on humans, particularly children. As such, human health studies will always be limited to certain types of study. The data and information required to develop ambient WQ criteria for the protection of human health often includes data from a variety of sources such as animal toxicity studies, epidemiological studies, genetic or cell line studies and other types of studies that are beyond most states' abilities to conduct in-house, including Pennsylvania. Most human epidemiological studies will inherently have some limitations and may not be able to control or evaluate all potential confounding factors. DEP is not aware of any state government environmental protection agency that conducts its own toxicology studies with respect to human health criteria development.

DEP did not reference studies from World War II Japan. DEP did review and reference studies that took place in South Korea and Bangladesh. South Korea is not a third world country and has been considered a developed country since at least the time of the earliest study referenced. Studies examining the effects of manganese on adults, infants and children have been conducted in many countries, and DEP would disagree that only studies conducted on humans in certain countries are relevant. In addition to India and South Korea, DEP evaluated data and information collected in the U.S., Canada, Mexico, Brazil, and Costa Rica. As mentioned above, studies designed to evaluate human populations will often have some limitations. In many of the studies reviewed by DEP, potential confounding factors were identified by the authors, and they noted where potential factors were not addressed. No specific individual study among those evaluated by DEP was directly used to develop the criterion recommendation of 0.3 mg/L. Rather, the evaluation of recent epidemiological data was considered by DEP, and DEP determined that current science continues to support EPA's IRIS database information, the Health Effects Support Document and the HAL from the EPA Office of Groundwater and Drinking Water (OGWDW). Chapter 16 in Title 25 of the *Pennsylvania Code* outlines the Commonwealth's guidelines for water quality criteria development and identifies the sources used to obtain risk assessment information. First and

foremost, DEP uses verified references doses listed in EPA's IRIS database. These EPA recommended values for toxic substances have been developed by toxicologists specifically for oral or inhalation exposure routes and have been both thoroughly vetted and publicly participated. Although more recent studies have been published since the 1995 manganese oral reference dose was established in IRIS and the 2003 OGWDW HAL published for drinking water utilities, the current information continues to support manganese as a neurotoxin, and the public continue to raise concerns about the negative health effects of manganese and highlight the need for additional research.

62. Comment: The House Environmental Resources and Energy Committee and a commentator state if manganese is a parameter that merits protection against drinking water ingestion, establishment of an MCL under either or both the federal and state SDWAs would appear to be a necessary step. An in-stream WQ standard would not apply to water withdrawals from groundwater sources, such as springs or subsurface aquifers accessed by a well. These, not streams, are the sources most likely to provide water for seasonal homes or water systems with 15 or fewer taps, and a primary MCL for manganese would protect drinking water for the public served by such systems in a way that an in-stream WQ standard would not. Where the Department has not chosen to protect the public generally from ingestion of manganese via water supply systems, it seems arbitrary and inappropriate for the Department to promulgate a rulemaking on the grounds of protecting public health that would leave some portion of the public unprotected from manganese. But it also bears emphasizing that manganese is an element that EPA has not found to be dangerous to human health such that a nationwide primary MCL would be necessary. (897, 952)

Response: At the federal level, EPA OW includes both the safe drinking water and WQSs programs. Thus, toxicological evaluations of pollutants conducted under EPA OW may be used by both programs to develop regulatory recommendations, such as MCLs or WQSs. In Pennsylvania, the Safe Drinking Water (SDW) and WQSs programs are governed by separate statutes and acts. As such, these programs operate under separate regulations, and the programs generally only intersect in so much as they both apply to surface waters.

The commentator is correct in stating that Chapter 93 WQSs do not apply to groundwater. While the WQS program does not disagree that drinking water regulations would also be beneficial in protecting residents and visitors of Pennsylvania, the lack of regulation for a specific parameter by the SDW program does not imply that it is inappropriate for the same parameter to be regulated under the WQSs program. As stated earlier, the Commonwealth's SDW program operates under different statutory and regulatory authority and guidelines than the WQSs program. The SDW program uses different protection thresholds, including selection of less stringent cancer risk levels within the allowable range, and may consider other factors, such as taking cost into consideration to develop a feasible MCL. The WQS program follows the CWA and EPA WQSs guidelines for criteria development and may not consider economics and related factors when establishing protective WQSs.

Furthermore, as noted in the response to Comment 60, EPA's SDW program is currently reviewing the science on manganese and may reconsider its earlier decision for manganese with an MCL once an evaluation of the UCMR4 monitoring is complete. Even in the absence

of a primary MCL, Pennsylvania's Safe Drinking Water regulations require public water systems to achieve an SMCL of 0.05 mg/L for manganese in potable water, which is more stringent than the manganese WQ criterion and EPA HAL of 0.3 mg/L. The current drinking water SMCL for manganese, established to address esthetics, is protective of human health.

63. Comment: Research indicates there is a paucity of data indicating human manganese toxicity from drinking water. (10)

Response: DEP disagrees with this statement. While it is recognized that there are data gaps in the current knowledge on manganese toxicity, there are a number of peer-reviewed, published studies that link manganese to negative neurological and developmental health effects including the literature cited by DEP, WHO, Health Canada, EPA and others.

64. Comment: DEP should review or conduct additional studies to make certain the current or proposed limit is protective and makes sense, and the analysis should be made public with a public review and comment period. (10, 15, 862)

Response: DEP does not agree that additional studies are necessary before establishing a protective limit for manganese. Overall, the emerging data and science continues to support EPA's IRIS recommendation, and ongoing evaluations suggest that any future recommended values are likely to become more stringent as new data becomes available to fill any existing gaps and strengthen the existing data. Under the CWA, DEP is required to periodically review WQSs as part of the process known as the triennial review of WQSs and will adjust the WQ criterion going forward, if needed, to reflect the most recent science.

DEP's recommendations for WQSs, including rationale documents, are made available to the public for review and comment during the rulemaking process. These documents are also submitted to EPA for their review of WQSs as required by law.

65. Comment: DEP has neglected to update its analysis – or, more specifically, the almost 20-year old analysis DEP relies on that was conducted by EPA in establishing the IRIS RfD for manganese. Notably, since that analysis was performed, studies, including existing and validated human PBPK models for adults, pregnant and lactating women, neonates and infants, have now demonstrated that manganese taken into the body via ingestion of drinking water does not lead to greater tissue concentrations of manganese in critical tissues, such as the brain, than manganese ingested in food. The results showing adverse impacts are not biologically plausible based on the best available current science, including validated human PBPK models for manganese inhalation and ingestion. DEP did not evaluate and consider recent human PBPK model studies published between 2011-2019 by Song et al. (2018), Yoon et al. (2011, 2019), Schroeter et al., (2011), Ramoju et al. (2017) which refutes the need for the application of the MF and results in an overly-conservative criterion.

Recently, Song et al. (2018) developed a human PBPK model to evaluate manganese bioavailability from drinking water and validated the model through simulating published datasets of human consumption of drinking water containing manganese, showing that modeled bioavailability of manganese from food and drinking water in humans is similar.

Importantly, the Song et al. (2018) PBPK model assumed normal daily manganese intake of up to 10 mg/d manganese (i.e., the NOAEL identified by DEP, 2019). For the average adult, this suggests that manganese up to 0.14 mg/kg-d is absorbed into the blood stream similarly, regardless of whether manganese exposure occurred from a food or water source.

DEP (2019b) discussed increased manganese absorption in infants (relative to adults) as a point of susceptibility to manganese. Specifically, DEP (2019b) discussed immature liver manganese excretion, increased manganese absorption in the digestive system due to increased expression of DMT-1 proteins, increased water intake (per unit of body weight), increased permeability of the blood-brain barrier to manganese, and increased retention of manganese relative to adults as points of concern for infants. However, as discussed by Yoon et al. (2011, and as cited by DEP, 2019b), enhanced uptake of manganese likely reflects developmental requirements for manganese. For example, Yoon et al. (2011) discussed that manganese present in bone and muscle is redistributed into other tissues during early postnatal development. Mechanisms unique to infants and that subside during later development, including enhanced expression of receptors that selectively bind lactoferrin-bound manganese (i.e., manganese in breastmilk) and increased active transport of manganese across the blood-brain barrier, may explain observed findings that are interpreted as increased manganese absorption in infants (Yoon et al., 2011). Importantly, these mechanisms related to manganese absorption and distribution are specialized processes for normal brain development during infancy (Yoon et al., 2011). Under conditions in which high manganese content from food or formula milk are ingested, Yoon et al. (2011) noted that human infants have a fully developed biliary excretory pathway.

The updated science on manganese suggests that infants, whether breastfed or formula fed, are at no greater risk compared to adults in their capacity to absorb manganese. Using PBPK modeling and the observed results discussed above related to infant manganese absorption, distribution, and excretion, Yoon et al. (2011) estimated similar and lower internal manganese levels in the infant brain compared to the adult brain for various air and diet manganese exposure scenarios in humans. As discussed in Section 3.1, Yoon et al. (2019) also used an updated model for different age groups and showed that the impact of manganese in drinking water on manganese brain concentrations was similar for both children and adults at 1 mg/L when simultaneously simulating manganese exposure from food, water, and ambient air. Further, modeled manganese brain concentrations for formula-fed infants (prepared with manganese in drinking water up to 1 mg/L) were similar to that of breastfed children across the range of manganese water concentrations measured and were within the range of normal manganese brain concentrations. Results from these PBPK modeling studies, which incorporated observed differences in manganese exposure and absorption parameters from infants to adults, suggest infants are not more susceptible than adults to health effects following oral manganese exposure from drinking water. (3, 618, 725, 728, 951, 954)

Response: DEP did review and consider several PBPK model studies in its evaluation of and recommendation for the manganese criterion of 0.3 mg/L (Schroeter et al., 2011; Schroeter et al., 2012; Yoon et al., 2011), and DEP also reviewed the more recent studies conducted by

Song et al. (2019) and Yoon et al. (2019) following the December 2019 EQB meeting and in response to comments received on the proposed rulemaking.

PBPK models were primarily developed to reduce the amount of experimental pharmaceutical data that would be required to evaluate the fate and transport of therapeutic drugs over a wide range of variables. Models can be used to predict the results of either future experiments or studies that would be too costly and time-consuming to complete. PBPK models are mathematical models that predict the absorption, distribution, metabolism, and elimination of synthetic or natural chemical substances (Wagner, 1981).

DEP generally agrees that PBPK models add information to the toxicokinetic database for a chemical substance, but as with all types of studies and models, PBPK models also have limitations. As noted by WHO (2010) and other researchers (Chiu et al., 2007; Khalil et al., 2011), PBPK modeling requires extensive and comprehensive datasets that characterize the physiological, biochemical, and physiochemical processes that occur in different age groups and under varying physiological and pathological conditions. Since models are based on the scientific information available at the time, some processes may be well understood while others may contain significant data gaps. In other words, models are only as good as the data which inform them. As with any other type of study design, PBPK models have limitations and shortcomings. They can be poorly designed, biased or overestimate predictability of outcomes. Models should be thoroughly vetted, and model simulation results should be well-supported through comparison to actual experimental data (Khalil et al., 2011). Models are not intended to replace data collected from well-conducted studies. Rather, they can be very useful in extrapolating the available data to better understand and predict health outcomes over a greater range of scenarios. Health Canada and WHO both recognized that the human PBPK models developed by Schroeter et al., Song et al. and Yoon et al. have not been validated against actual measurements of manganese in brain tissue and stated that simulation results should be treated with caution. DEP agrees with this statement. In reviewing the Schroeter et al. and Song et al. studies, DEP identified a number of questions and concerns, which ultimately resulted in DEP not using these studies in the development of the manganese criterion recommendation.

Studies completed by Schroeter et al. (2011 and 2012) described PBPK models for humans that were developed from existing PBPK models for rats and monkeys. The 2011 study only examined the inhalation exposure pathway for manganese and did not evaluate oral exposures. In Schroeter et al. 2012, the authors updated their 2011 model to include parenteral and oral exposure pathways. As noted by the authors in the 2012 publication, “studies performed prior to the 1990s had limited histological, neurochemical, or neuropathological assessments...With the exception of the inhalation exposures, most studies either used one monkey in each dose group or reported effects for individual monkeys.” Most of the oral studies cited were published prior to 1990 (Chandra et al., 1979; Gupta et al., 1980; Van Bogaert and Dallemande, 1946; Mella, 1924; Eriksson et al., 1987; Pentschew et al., 1963; Suzuki et al., 1975) with only 2 references to studies conducted in or after 1990 (Olanow et al., 1990 and Eriksson et al., 1992a,b). The authors’ own statements on the completeness of the data raises concerns about potentially important data gaps that might exist in the model.

In addition, the 2012 model does not describe or discuss how the model was verified using actual human tissue data. As stated above, model simulation results should be well-supported through comparison to actual measured concentrations of manganese in tissue samples. Regarding the data used to inform the 2011 and 2012 models, the tissue data used by the authors appears to come primarily from two sources published in 1967 and 1975 (Schroeter et al., 2011). Little to no information is provided on the source of the tissue data and how the data is appropriate for use in the model. The authors indicated the human model was verified using human tracer kinetic studies. However, the number of subjects participating in all three tracer studies was extremely small and included only adults (3 subjects for Mahoney and Small (1968), 8 subjects for Mena et al. (1967), and 6 women for Davidsson et al. (1988)). In addition, the authors stated that no information was given in the Mahoney study regarding the subjects' body weight, gender, or diet. The authors also did not provide any such information for Mena et al. and, other than gender, for Davidsson et al. No human tissue data was used to verify the model.

Yoon et al. (2011) also raises a number of questions about the sufficiency and quality of the data used to inform the model. Much of the model data and assumptions used in Yoon et al. (2011) came from autopsies and other studies conducted in the 1970s and 1980s with some studies being referenced from as early as 1920. While the date of publication for a study does not necessarily preclude it from use today, the authors did not provide much, if any, discussion about the source of the adult or fetal/infant tissue data and how it was acceptable for use in the current model. There was no discussion of potential confounding factors that might have influenced the levels of manganese found in the tissue samples such as disease, cause of death, age of death, were the infants breastfed or formula fed, smoking habits (adults), drug or alcohol abuse (adults), maternal smoking/drug use during pregnancy (infants), secondhand smoke exposure before or after birth (infants/children), or other related considerations. Therefore, it is unknown whether the observed levels of manganese in the adult or fetal autopsy bodies represent "normal" or expected tissue levels. It is possible the observed levels of manganese were outside of a "normal" range and may have been associated with disease or any of the other factors mentioned above.

In addition to the lack of background information on the tissue samples, the authors noted that manganese concentration data was only available for bone and skeletal muscle tissue. It was stated that skeletal muscle tissue concentrations were used as a surrogate for the rest of the body manganese content. DEP questions whether that is appropriate since manganese does not preferentially deposit in skeletal muscle. Based on how the information is presented in the Yoon et al. (2011) study, it appears that no actual tissue data was used to describe or verify manganese levels in the body organs that are known to accumulate manganese such as the brain, liver, kidney, and pancreas.

Other assumptions were also made in the modeling that may affect the simulation results. For example, the authors assumed that manganese content in bone reached adult levels after 1 year of age and cited four studies that were conducted between 1920 and 1982. One of the studies, Lehmann et al. (1971) evaluated concentrations of manganese in various body tissues of children with protein-calorie malnutrition. The 1920 Reiman and Minot study examined

several manganese quantitation methods. This study included neither children as subjects nor information on the manganese content of bone in adults or children. Bonilla et al. (1982) and Tingey (1937) were studies on manganese content in the human brain. These two studies were not readily available, and therefore, DEP is uncertain whether or not the studies included an evaluation of children or the manganese content of bone. It is unclear why these four studies are referenced to support the assumption that the manganese content of bone in the fetus/child reaches adult levels by 1 year of age.

Yoon et al. (2011) recognized “the immaturity of biliary function during early neonatal period.” At the same time, the authors stated that the biliary excretion pathway appears to be fully developed in human infants, and the pathway was inducible when challenged with excess manganese by different exposure routes including food (formula milk). The authors cited five studies from the mid-1980’s. DEP was unable to obtain any of these studies but reviewed the literature abstracts if they were available online. Hambridge (1989) studied manganese plasma levels in infants and children receiving total parenteral nutrition (TPN) who developed cholestatic liver disease. Hatano (1985) studied erythrocyte manganese concentration in different age groups and in cord blood. Sampson (1983) conducted manganese balance studies in 16 infants (ages 3 days to 8 months) following surgery to correct congenital heart failure. Stastny (1984) evaluated manganese intake and manganese blood serum concentrations in breastfed and formula-fed infants. Zlotkin and Buchanan (1986) evaluated manganese intakes in full-term and pre-term infants receiving TPN. They stated, “biochemical evidence of manganese toxicity was not apparent”, but it is unclear what that means based on the abstract. None of the studies cited appear to be an evaluation of the ability of the neonatal liver to excrete manganese, and it is unclear how they support the author’s statement about the ability to induce biliary excretion in infants upon challenge with excess manganese. The authors generally made conflicting statements regarding biliary function in infants.

The authors increased biliary function to adult levels at 6 months of age stating that the neonate diet at this time changes from milk to adult foods and neonates were considered “weaned” abruptly at 6 months of age. While adults may begin introducing solid foods to infants by 6 months of age, the introduction of solid foods is a gradual process. Foods are generally introduced one at a time to an infant to identify potential food sensitivities or allergies and in a specific order starting around six-months of age. In addition, an infant will typically progress from a limited, pureed diet to a more balanced, child-like diet on a recommended schedule. Thus, there is no immediate transition from an infant diet to an adult-like diet. Breastfeeding/formula is still an important source of nutrition for infants through the first year of life in accordance with the recommendations from the American Academy of Pediatrics (AAP).

In the discussion, the authors note that “even with 100% bioavailability assumed for breastmilk, the simulations could not reach tissue manganese levels observed in human neonates and children. The model could not reach the levels of manganese in tissue as described by the four previously referenced studies (Bonilla et al., 1982; Lehmann et al., 1971; Reiman and Minot, 1920; Tingey, 1937). The authors cite an animal study conducted in 1974 (Widdowson) and suggest that bone and muscle tissue manganese were being stored

prenatally and redistributed postnatally to tissues, such as the brain, to explain the tissue levels observed. As stated, little to no data was provided on the tissue concentration data that was used to develop and subsequently evaluate the model to show that the tissue concentrations were representative of normal, expected tissue values for the various assumptions made in the model with respect to oral exposure (infant formula vs. breastmilk, age of the fetus at the time of death'autopsy, external and maternal factors, such as smoking, drugs, diet, occupation, etc. that could have affected manganese tissue concentrations).

Generally speaking, breastmilk composition changes substantially over time. It is unclear whether this was considered when determining the expected or average manganese content of breastmilk. Breastmilk produced during the first few days after birth is different than breastmilk produced during the first few weeks which is subsequently different than breastmilk produced after the first month. Unlike formula content, which doesn't vary in nutritional content over time, breastmilk is highly variable in its macro- and micronutrient content both during individual feedings and across at least the initial first 6 months of breastfeeding (Ballard & Morrow, 2013). Depending on when breastmilk was evaluated to establish the breastmilk manganese content for the model, the model may or may not contain sufficient or accurate data.

The authors stated "because manganese sources other than breastmilk were not included, simulated brain manganese during lactation could be considered to represent the lower end of normal variation in neonatal brain. They go on to state that "although it is difficult to define what brain concentration would be 'normal' for nursing infants, a level close to that of adults is likely an appropriate assumption because the fetal brain concentration was already similar to the adult level and there is no evidence in terms of either data or in the biology of brain development which indicates significant changes in brain manganese during the early postnatal period." No literature was cited here, and it is unclear if the statement refers to the concentrations of manganese in the brain being similar between infants and adults based on the model simulations or comparison to the historical tissue data, which as already described, seems to have a number of limitations. The appropriateness of the assumption that the brain concentration of manganese for nursing infants is similar to that of adults is not clearly presented. In contrast to the statement made in the comment above, the authors had previously noted in their publication that in many cases manganese tissue concentrations in infants and children exceeded adult tissue concentrations for manganese. However, as previously mentioned, skeletal muscle was used as a surrogate for other tissues.

In the discussion, the authors note that "homeostatic control of manganese gut uptake during lactation is different in nature from that of the adult. The neonatal gut regulates manganese absorption by expressing receptors for proteins that bind manganese in human milk, rather than sensing manganese concentration/amount in food by way of DMT-1 as occurs in the adult (Chan et al., 1982; Lonnerdal et al., 1985)." It is important to recognize that the valence form of manganese in human breastmilk is different than that in infant formula. This is important because the transferrin receptor system specifically binds trivalent manganese (Mn^{3+}), which is the form of manganese in breastmilk. Alternatively, manganese in infant formula is in the form of divalent manganese (Mn^{2+}). The divalent form of manganese enters cells primarily using the DMT-1 transport system, but it will also enter using a variety of

other transport systems including the zinc transporters (ZIP8 and ZIP14), the citrate transporter, the choline transporter, the dopamine transporter (DAT), and calcium (Ca) channels (Chen 2015). In addition, ATSDR (2012) noted that more manganese was absorbed by infants consuming formula even though the manganese absorption rates between cow- and soy-based milk sources were slightly less, 80-90% and 70%, respectively. This is likely due to the fact that cow- and soy-based formulas contain much higher amounts of manganese when compared to breastmilk. The manganese content of breastmilk averages around 15 µg/L. In contrast, formula can contain anywhere from 35 µg/L to over 700 µg/L.

Furthermore, MDH (Scher, 2021) recently evaluated the manganese content of a variety of infant formulas and found that the measured amount of manganese was 1.3 to 5 times more than the labeled amount. The Food and Drug Administration (FDA) has established a minimum level of manganese in infant formula (~34 µg/L), but no maximum level has been established. ATSDR (2012) also referenced animal studies that showed increased absorption of manganese in young. As a result, manganese gut uptake amounts may be significantly different in formula-fed infants versus breastfed infants, and this was not considered in the model.

For the model simulation, various seemingly important components do not appear to have been considered. In developing the maternal body burden prior to conception, only inhalation exposure to manganese was considered. Exposure through diet, water or other sources were not included in the preconception baseline. Otherwise, normal dietary levels of manganese for adults were assumed to be 3 mg/day, and for nursing infants, manganese intake was assumed to be solely from breastmilk during the first 6 months after birth. The model did not consider infant formula, which is known to contain much higher amounts of manganese. The manganese in formula is also in a different valence state than manganese in breastmilk (Mn^{2+} vs. Mn^{3+}), which has been linked to differences in availability and absorption.

The authors also assumed that the daily dietary intake of manganese for postweaning infants and children was 2 mg/day, which is the tolerable upper intake level (UL) for children ages 1-3 years as published by the National Academies of Science Institute of Medicine (IOM, 2000). The IOM adequate intake (AI) levels for infants are 0.003 mg/day of manganese for ages 0-6 months and 0.6 mg/day for ages 7-12 months. IOM noted that it was not possible to establish a UL for infants (1-12 months) and that the source of manganese intake for this age group should only be from food and formula. The ULs for children 4-8 years, 9-13 years and 14-18 years are 3 mg/day, 6 mg/day and 9 mg/day, respectively. It is unclear why Yoon et al. (2011) set the daily dietary intake level based on the UL for children ages 1-3, which is very high for infants 0-12 months of age, while the adult daily dietary intake level used in the model was set closer to the AI levels for men and non-pregnant/non-lactating women ages 19 years and older (which are 2.3 mg/day and 1.8 mg/day for men and non-pregnant/non-lactating women, respectively). These AI values are significantly lower than the adult UL of 11 mg/day.

The authors stated they conducted some evaluations of the model. However, model simulations were only evaluated using available data on human blood concentrations of manganese. Blood concentrations of manganese have not been found to be a good predictor

of toxicity or biomarker for overall body burden. The authors did not evaluate actual tissue sample data to confirm that the model's predicted manganese tissue concentrations were comparable to actual manganese concentrations physically measured in various human body tissues for the various exposure scenarios and assumptions made.

Yoon et al. (2019) updated the existing PBPK models to assess children's exposure to manganese in drinking water. The updated model is primarily based on a 2015 study by Foster et al. According to Yoon et al. (2019), the Foster et al. study in rats demonstrated that there was no significant difference in bioavailability between drinking water and diet. However, DEP identified several potentially important concerns with the Foster et al. study. First, the study was conducted on 7-week-old male rats. Rats of this age have entered puberty and are sexually mature. As such, the study did not evaluate exposure during a developmental period that would be equivalent to human infancy and early childhood. Second, the study did not address the effect that a fasted vs. non-fasted state has on the absorption of manganese. Third, authors stated that no clinical signs were seen in any exposure group, but they did not clearly define "clinical signs". The only "clinical sign" that appears to have been measured was weight. The authors noted no significant difference in overall body weight or organ weights between treatment groups. However, body and organ weights are not important clinical effects. It is unclear whether any neurological tests were completed to assess the effects of exposure on the central nervous system, which has been identified as the critical endpoint. The information provided suggests that such tests were not conducted.

For the drinking water ingestion model inputs, Yoon et al. (2019) used the mean drinking water ingestion rates from EPA's "Exposure Factors Handbook" (2011) for adults, pregnant women, lactating women, infants, and children. The authors generally used the reported mean ingestion rates for each subpopulation. However, the mean ingestion rate for adults \geq 21 years old (1.227 L/day) was used to represent lactating women even though a specific value for lactating women (1.665 L/day) was available. It is unclear why the authors did not use that value. From a WQS perspective, EPA and the States generally do not use mean values for exposure assumptions. When developing WQ criteria, DEP follows EPA's recommendation to use the 90th percentile for drinking water intake and fish consumption. The EPA "Exposure Factors Handbook" (2011) does not directly provide 90th percentile values, but it does provide the 95th percentile values for each category including pregnant women, adults \geq 21 years old and lactating women. These values are significantly higher than the mean values. For adults, pregnant women, and lactating women, the 95th percentile values were approximately 3 L/day, 2.5 L/day and 3.5 L/day, respectively. As stated in Comment 68 below, the IOM identifies a daily adequate intake of water to be 3.7 L/day and 2.7 L/day for young men and women, respectively. This value was based on U.S. survey data and represents a person's total daily water intake (food and drink). The same survey data indicated that drinking water and beverages accounted for approximately 3.0 L and 2.2 L of the total daily water intake for young men and women. These values increase to 3.0 L/day for women during pregnancy and 3.8 L/day during lactation/breastfeeding of which 2.3 L and 3.1 L is drinking water or beverages.

Thus, the values used in the model may underestimate water exposure. Furthermore, DEP would also like to emphasize the fact that EPA described confidence in the single study data used to establish the values in their 2011 handbook for pregnant and lactating women was low. Sample size was small (99 individuals) and no actual measurements of the amount of water ingested were taken. The IOM recommendations are better supported by data and information. In addition, neither Schroeter et al. nor Yoon et al. addressed the concerns regarding increased manganese absorption in fasted vs. non-fasted individuals.

Song et al. (2019) evaluated the bioavailability of manganese from diet and drinking water. While this study does provide some data on manganese, the study has important limitations. The PBPK model parameters for drinking water were estimated from tissue kinetic data obtained from the Foster et al. (2015) study. As previously described, that study was conducted using adult male rats and did not address the concerns associated with absorption when an individual is in a fasted state. Furthermore, 200 ppm manganese in diet is not considered to be “high” for a rat diet. In rats, dietary manganese generally doesn’t begin to cause problems until doses exceed 1,000 mg. See the response to Comment 87 for additional discussion on the dietary requirements of rodents. It is questionable as to whether the manganese doses evaluated in the Foster et al. study represent equivalent human doses. In addition, the study did not evaluate exposure during the critical time period of infancy/early development. Song et al. also states “for infants and children, potential differences in the bioavailability of drinking water manganese could be of a greater concern. This is due to potentially higher exposure resulting from higher water consumption rates than adults, and age-specific diet sources which may contain or be fortified with minerals including manganese.”

The use of data collected from human populations around the world is a common practice in the scientific community. DEP would like to note that a number of studies referenced by the authors of the PBPK model studies, which DEP was specifically directed to review, were also conducted outside of the U.S. DEP would further like to note that all of the currently available PBPK model studies for manganese (a total of five studies) and the Foster et al. (2015) publication were funded by the same company, Afton Chemical. Afton Chemical company produces methylcyclopentadienyl manganese tricarbonyl (mmt®), a commonly-used, manganese-based fuel/petroleum additive. DEP believes additional studies by independent research groups should be conducted to validate these models and any associated animal studies. Additional study and validation help to ensure that the reported results are credible and reproducible. Both the World Health Organization (WHO) and Health Canada noted that independent replication or validation studies have not been completed for these human PBPK models.

In a recent study (Scher et al. 2021), MDH evaluated Yoon et al. (2019) and had the following comment: “Modeling results indicated that manganese brain concentrations in formula-fed infants are actually lower than those of breastfeeding infants, up to water concentrations of 500 µg/L. However, it should be noted that the PBPK model utilized an extremely low manganese absorption rate of only 0.06% for reconstituted formula (1/1000th of that used for breastmilk), which is not consistent with limited available literature on

absorption in human infants or adults (Davidsson et al., 1989; Dorner et al., 1989) or neonatal rats (Keen et al., 1986)."

In addition, DEP consulted and collaborated with Drexel University to review and evaluate the available published toxicology data for manganese. In a report to DEP (Hamilton et al., 2022), Drexel noted that the figures in the Yoon et al. (2019) study "clearly demonstrate manganese concentrations in the globus pallidus of bottle-fed infants exceed that of breast-fed infants as the water level [of manganese] increases from the EPA Lifetime Health Advisory of 0.300 mg/L to 0.580 mg/L (95th percentile of the drinking water in Iowa according to the National Inorganics and Radionucleotide Study)."

DEP's review of these PBPK studies does not change its criterion recommendation.

66. Comment: DEP had no toxicologists on staff when developing this proposed rulemaking. The commentator thinks this is vitally important when evaluating any viable health concerns of a proposed rulemaking of this magnitude and refers to the testimony given by a toxicologist from Gradient Corporation. (922)

Response: DEP does not employ toxicologists at this time. A degree in toxicology is not required to work in the WQSs program, or to complete WQS-related tasks such as the review of toxicology studies or the development of WQ criteria. DEP's WQ Division is primarily composed of biologists, ecologists, environmental chemists and other scientists with appropriate degrees and professional experience. In addition, it is common for States to consult with the toxicologists and related experts at EPA and to utilize their knowledge and experience in developing criteria recommendations. EPA's review of the scientific literature and research on a pollutant often informs the criteria recommendations that are developed by the States. DEP does not typically develop its own reference doses to be used in statewide criteria development, and in the rare case that a reference dose would need to be calculated by DEP, the development of that value would be conducted in consultation with EPA. In addition, as previously mentioned, state WQS programs do not typically perform work requiring a toxicology degree, such as conducting their own, in-house toxicology studies when developing human health criteria.

Although not required by law, DEP agrees that involvement of professionals with knowledge and experience in toxicology can be beneficial to the development of human health criteria. DEP often consults with the Pennsylvania Department of Health (DOH) on human health criteria recommendations that are developed by the state. DEP consulted with the DOH toxicologist on the manganese recommendation for the proposed rulemaking. DEP also consulted with toxicologists and experts at EPA on the proposed and final-form rulemaking recommendations. Furthermore, DEP consulted with toxicologists and medical doctors at Drexel University regarding the final-form rulemaking and manganese water quality criterion recommendation of 0.3 mg/L. All of these organizations and individuals supported DEP's water quality criterion recommendation.

67. Comment: Gradient Corporation conducted an independent evaluation of protective manganese concentrations for possible exposure pathways associated with recreational and

fish-ingestion designated uses (Gradient 2020). Using an updated oral RfD, Gradient derived conservative swimming and fish-ingestion concentrations of 92 mg Mn/L for an adult and 41 mg Mn/L for a child. These recreational and fish-ingestion values are more than 2 orders of magnitude greater than the 0.3 mg Mn/L human health value proposed by DEP. The commentator agrees with the scientific basis behind the Gradient analysis. (880)

Response: The relevance of these calculated values is unclear since they do not follow the EPA's "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000, EPA-822-B-00-004). Information was not provided on the methodology or other guidelines that were followed in developing the values provided by Gradient Corp. and how they are relevant to WQ criteria development and WQSSs.

68. Comment: DEP made erroneous assumptions on drinking water intake per day and fish intake per person per day. The proposed criterion was calculated using assumed drinking water intake (DWI) of 2.4 liters per person per day and an assumed fish intake (FI) intake of 0.022 kg/day. According to data from the National Health and Nutrition Examination Surveys (c-NHANES, 2005-2006), the average American drinks approximately 1057 grams, or 1.057 liters, of plain water per day, obtaining the balance of their water intake from other beverages and foods. The U.S. EPA relies upon a more conservative estimate of 2 liters per day for their calculations (U.S. EPA, 2004). The inflated DWI used in the proposed rulemaking artificially lowers the calculated criterion. Regarding daily fish intake, the 2018 Fisheries of the United States report from the National Oceanic and Atmospheric Administration (NOAA, 2020) shows that per capita consumption of fish in the US was 16.1 pounds, of which 85-95% was imported. If only 85% was imported, then the per capita consumption of domestic fish would be 13.7 pounds, or 6.214 kg. This is equivalent to a daily FI of 0.017 kg/day from domestic fish sources, 23% lower than the rulemaking assumes. As with the inflated DWI, this inflated FI value artificially lowers the calculated criterion in the proposed rulemaking. (951)

Response: DEP used EPA's recommended values for drinking water intake and fish consumption in the calculation of the criterion. These exposure values were updated by EPA in 2015 (EPA 820-F-15-001) and adopted by DEP into regulation during the most recent triennial review of WQSSs, which was published in the *Pennsylvania Bulletin* in 2020 (50 Pa.B. 3426). These exposure inputs are not overly conservative since they are based on general population averages, and WQ criteria are intended to provide protection to all persons including children, pregnant and breastfeeding women, subsistence fishermen and other subpopulations that may fall outside of the average exposure assumptions.

The IOM (2000) identifies a daily adequate intake of water to be 3.7 L/day and 2.7 L/day for young men and women, respectively. This value was based on U.S. survey data and represents the total daily water intake (food and drink). The same survey data indicated that drinking water and beverages accounted for approximately 3.0 L and 2.2 L of the total daily water intake for young men and women. These values increase to 3.0 L/day for women during pregnancy and 3.8 L/day during lactation/breastfeeding of which 2.3 L and 3.1 L is drinking water or beverages. As such, a daily water intake of 2.4 L/day is not overly conservative.

EPA updated the fish consumption rate (FCR) to 22 grams per day (g/day) based on National Health and Nutrition Examination Survey (NHANES) data collected from 2003 to 2010 and a modification of the National Cancer Institute (NCI) model. The previous FCR of 17.5 g/day was based on Continuing Survey of Food Intakes by Individuals (CSFII) data collected from 1994 to 1996 and was calculated using ratio estimation methods. Development of both FCRs (17.5 g/day and 22 g/day) followed EPA's 2000 methodology, which recommends using a 90th percentile FCR to derive ambient WQ criteria. The FCR of 22 g/day is the 90th percentile estimate for freshwater and estuarine fish consumed by adults, 21 years and older. The 90th percentile value for total fish (including marine) is significantly higher at 52.8 g/day. Fish consumption data by region further indicates that a value of 22 g/day is slightly below the 90th percentile of 23.1 g/day for the Northeast region, which includes Pennsylvania. As with the daily water intake, a fish consumption value of 22 g/day is not overly conservative and is intended to provide adequate protection to sensitive subpopulations including children, pregnant and breastfeeding women, and subsistence fishermen.

69. Comment: The Senate Environmental Resources and Energy Committee and others comment that the studies cited by DEP have many limitations that make it impossible to attribute the reported effects to manganese, including: a cross-sectional study design that only evaluates one point in time and not exposure over a period of time; studies included limited (or sometimes no) individual exposure evaluations; and potential in all of the studies for other unmeasured factors to influence the study outcome (such as exposure to other possible contaminants in the drinking water, caregiver IQ, and quality of the home environment). The cross-sectional design is problematic in attempting to establish a causal relationship. All of the studies openly acknowledge confounding variables that limit the strength of any causal inferences that might be made concerning the effects of manganese exposure. Accordingly, it is impossible for these studies to establish a causal link between manganese exposure and developmental effects. The most recent assessments of the scientific literature by other highly respected regulatory agencies, such as the ATSDR (2012), Health Canada (2019)/the Ontario Ministry of Environment (MOE), reached similar conclusions regarding the scientific weaknesses inherent to the studies that foreclose causal inferences that would support the need to amend the manganese WQS. **(618, 725, 953)**

Response: DEP reviewed various types of toxicological studies in its review of the current peer-reviewed scientific data and information on manganese toxicity. The documents evaluated ranged from animal studies to epidemiological studies to epigenetics and literature reviews. Thus, not all of the studies cited by DEP utilized a cross-sectional design. When combined with animal toxicity and/or in vitro (cell line) studies, the real-life population studies on manganese in humans corroborate many of the findings in the studies DEP reviewed. These population level studies also support the need for additional research on the toxicological effects of manganese.

Generally speaking, it would be illegal and unethical to experiment on humans in the same way that other animal studies are conducted in a controlled laboratory setting. Thus, it is difficult to control for all possible confounding factors when evaluating human subjects.

Authors of cited studies generally noted any possible confounding factors and often recognized that the results warranted additional research. The possibility of confounding factors does not automatically invalidate a scientific study. The epidemiological studies conducted to date generally support findings reported in related animal studies on rats and mice as well as in vitro cell line studies involving mice, rats, and humans. It is important to note that DEP is not using any single study to establish causality. Rather, when taken collectively, these studies support a connection between oral manganese exposure and negative health effects, and they lend support to the EPA's Office of Water recommendation for an MF of 3 until additional scientific studies are able to clearly identify the exact levels of manganese in water that are safe for specific age groups.

As previously mentioned, WHO published draft guidelines for manganese in drinking water in December 2020 and final guidelines on December 22, 2021. WHO recommends a value of 0.08 mg/L, which is significantly more stringent than its previous recommendation of 0.4 mg/L and EPA's HAL of 0.3 mg/L. This new value is being recommended for the protection of bottle-fed infants. WHO reviewed much of the same literature as DEP and concluded that, although no single study clearly established dose-response relationships, collectively the studies supported the oral route as a potentially important route of exposure for manganese toxicity. As such, WHO stated that a health-based guidance value is warranted.

In addition to WHO's recent evaluation of manganese, Health Canada also recently completed an evaluation of manganese in drinking water (2019) and established a maximum limit of 0.12 mg/L to protect infants. Health Canada is the federal agency in Canada tasked with the responsibility to help citizens maintain and improve their health. Like WHO, Health Canada reviewed and cited much of the same literature used by DEP and determined that protection was warranted despite any limitations associated with individual studies. Health Canada noted in its guidelines that "the bioavailability of manganese from drinking water (in a fasted state) has been acknowledged to be greater than from food in both published literature and other risk assessments (Ruoff, 1995; U.S. EPA, 2002, 2004; Bouchard et al., 2011)".

These evaluations by Health Canada and WHO are more recent than ATSDR (2012).

70. Comment: The calculation of the manganese human health criterion contains a substantial measure of conservatism regarding the portion of human exposure attributable to drinking water source (that is, RSC = 20%). Even without this conservatism, the amount of manganese attributable to drinking water is small. The levels of manganese in drinking water are unlikely to add meaningfully to the normal daily ingestion of manganese from diet. (725, 905)

Response: In general, the quantity of manganese ingested through drinking water and beverages versus dietary sources is significantly less. Most adults and children receive the majority of their daily intake of manganese from dietary sources and many of those dietary sources are processed or cooked in water adding to the dietary component of the RSC. While exposure to manganese through drinking water may represent a substantially smaller proportion of daily exposure, studies and data suggest the amount of manganese absorbed by

the body, particularly in fasted individuals, may be greater for drinking water sources than for dietary sources (Ruoff, 1995; Health Canada, 2019). Furthermore, newborns and infants that are bottle-fed receive all of their daily nutrition through reconstituted infant formula, which itself can contain significant levels of manganese. Dependent upon the water quality characteristics of the drinking water used to prepare the infant formula, the levels of manganese present in the water may provide another significant contribution to an infant's daily exposure.

71. Comment: The studies do not indicate consistent dose-response relationship, and there is no clear pattern of association between adverse effects and within study populations or in comparison to the general population. There are no studies currently available that provide reliable evidence of an oral manganese dose in humans that leads to adverse effects. (3, 725)

Response: DEP disagrees that there is no association between adverse effects and within study populations. As previously stated in the responses to Comments 65, 69, and 70, the current epidemiological data in combination with other study data and available information does raise and support concerns about adverse health effects in humans, particularly children, resulting from oral exposures to manganese.

Regarding the dose-response relationship, DEP recognizes that the available literature is currently limited in its ability to establish a clear dose-response relationship for use in benchmark dose modeling as has been previously discussed. As research is still ongoing, DEP did not use any of the published studies to calculate a new RfD for manganese in developing the criterion recommendation. However, available animal toxicity studies (Kern et al., 2010; Beaudin et al., 2013) have identified LOAELs and were recently used by Health Canada and WHO to establish their drinking water manganese recommendations.

72. Comment: The studies do not use consistent biomarkers for manganese and apply different sets of tests to evaluate intellectual development. Unfortunately, there is not yet a validated biomarker for manganese exposure (similar to blood as a biomarker for lead exposure). (725)

Response: DEP recognizes that a validated biomarker for evaluating the body's levels of manganese has not yet been established. At this time, blood serum does not appear to be a reliable biomarker for manganese exposure. However, red blood cells (that is, whole blood) may be useful. Since manganese is an essential mineral, it is possible that cells quickly remove manganese from the blood serum and transport it, via red blood cells, to various organs and cells throughout the body. More research is needed to identify the most appropriate exposure biomarker(s) for manganese. Teeth, hair and nail tissue will accumulate metals in the body, and since these tissues grow slowly, they can reveal information about metals concentrations in the body over an extended period of time. Hair has shown promise as a biomarker of long-term manganese exposure and body burden (Eastman et al., 2013; Liang et al., 2016; Liu et al., 2020; Reiss et al., 2016). The fact that individual studies did not use the same biomarker does not mean the biomarkers used are not valid measures of manganese in the body.

Tests used to evaluate intellectual development included the following: Wechsler Abbreviated Intelligence Scale for Children (WASI), the Wechsler Intelligence Scale for Children, 4th edition (WISC-IV), the Bayley Scales of Infant Development, 2nd version (BSID-II), Revised Conner's Teachers Rating Scale (CTRS-R), Revised Conner's Parents Rating Scale (CPRS-R), Teacher's Report Form (TRF, 2010), and Child Behavior Check List (CBCL, related to TRF).

There is no standard intelligence test that is appropriate for all age groups and across all cultures and languages, especially if one is evaluating intellectual development from different countries (Gregoire et al., 2008). Thus, there are multiple approved and appropriate tests available to account for these differences. For instance, WASI/WISC is only suitable for children over the age of 6 years, and many adapted versions of the same test (for example, WISC-IV) exist to address language and cultural differences. Likewise, BSID tests are designed for children between the ages of 1 month and 42 months.

73. Comment: At the December 17, 2019 EQB meeting regarding this proposed rulemaking, an EQB member visually illustrated the levels of manganese in every-day items, showing that a bottle of grape juice, which can be purchased at any grocery store, contains levels of manganese above 10 mg/l. Manganese supplements can also be purchased at the local pharmacy. DEP claims that drinking water above 0.3 mg/l is toxic; and the proposed regulation is necessary to protect children. Yet there are many beverages that have much higher concentrations of manganese that are consumed regularly by children. For example, pineapple juice has a manganese concentration of 11.8 mg/l, 39 times more than the proposed limit of 0.3 mg/l. Based on this claim that manganese is toxic in concentrations above 0.3 mg/l, other beverages like cranberry juice, tea, grape juice would be more toxic than drinking water.

If the 95th percentile water consumption rate of 2.4 L/day is used, a person would obtain only 2.4 mg/day manganese exposure from drinking water at the current manganese criterion of 1 mg/l. This is a small fraction of the NOAEL for manganese of 10-11 mg/day. It is roughly equivalent to the manganese concentration in a One A Day multivitamin for men of 2 mg. The EQB is attempting to limit the manganese provided by drinking water to a level substantially lower than a common nutritional supplement. Commentators fail to understand how juice with this level of manganese, generally imbibed on a daily basis, can be sold to the general public in Pennsylvania and across the nation (as well as nutritional supplements), but industries across the Commonwealth may potentially need to treat to 0.3 mg/l in their discharges to protect human health. (728, 905, 922)

Response: As has been described in the rationale document, the bioavailability of ingested manganese from food sources, including juices, can vary significantly when there is binding to other substances within the food matrix or when combined with other foods during a meal. Dietary fiber, tannins, phytate, oxalic acid and other related components are known to bind with mineral ions and reduce their bioavailability. Grapes and grape juice naturally contain tannins and may also contain added fiber.

Food products sold in stores are regulated by the FDA and are not subject to the same regulation as surface waters. It is also important to note that vitamin and mineral supplements sold to the public are not regulated by the FDA or any other government agency and are ingested at the consumer's own risk.

Furthermore, DEP does not agree that most individuals, particularly infants and young children, consume fruit juices and teas on a daily basis in amounts comparable to daily water consumption. The AAP provides fruit juice consumption recommendations for children from birth through 18 years of age. The recommendations state that children less than 12 months of age should not be given fruit juice. The recommended daily serving size for children ages 1-3 years is limited to 4 oz. per day. The recommendations for children ages 4-6 and ages 7-18 years are limited to 4 to 6 oz. per day and 8 oz. per day, respectively. This amount of juice is significantly less than the daily recommended intake amounts for water, which for ages 1-8 years ranges between 44 oz. and 57 oz. per day. Beyond 8 years of age, the daily recommended amount of water is the same as adults (that is, 64 oz. per day).

It should also be noted that since manganese is found in foods and beverages other than the juices identified in the comment, DEP must consider these sources in establishing the RSC value, which is an important component of the criteria development equation.

- 74. Comment:** In 2004, EPA recommended a non-enforceable lifetime HAL of 0.3 mg/L for chronic exposure to manganese and a 1-day and 10-day HA of 1 mg/L for acute exposure. Option two seeks to tighten manganese treatment standards based on a "recommendation" by EPA and is not a Federal requirement. (15)

Response: DEP agrees that EPA's HAL is a recommendation and not an enforceable federal drinking water standard. However, if a public water system distributes water containing manganese that exceeds an acute exposure HAL value, Tier 1 publication notification requirements are triggered under the Commonwealth's safe drinking water regulations and policies. DEP's WQ criterion recommendation of 0.3 mg/L was developed in accordance with the water quality regulations and EPA's "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000). Although DEP's WQ criterion recommendation might appear to be based on the HAL since the recommendations are equivalent, it is not. The values are alike because EPA's drinking water HAL was developed using the same RfD information in EPA's IRIS database. However, the HAL and DEP's recommendation were developed for different purposes and followed different methodologies.

- 75. Comment:** EPA's IRIS assessment is based in part on findings from a study by Kondakis et al. (1989). Specifically, Kondakis et al. (1989) observed that neurological effects were associated with exposure to approximately ≥ 2 mg/L manganese from well water in people over 50 years old; however, it should be noted that EPA (2002) concluded it was "impossible to estimate the total oral intake of manganese in this study" due to "uncertainty in the amount of manganese in the diet and the amount of water consumed." Kondakis et al. (1989) is also limited by its study design. Specifically, Kondakis et al. (1989) measured manganese drinking water exposure concentrations and neurological effects only once rather than

collecting regular measurements over months or years, resulting in considerable uncertainty in using the data to establish a causal relationship between manganese exposure and neurological effects in the study population. In addition, Kondakis et al. (1989) considered few confounding variables; thus, it is unclear whether neurological effects were due to manganese exposure or another variable, such as a pre-existing condition. Although EPA (2002) concluded that it would be inappropriate to use the Kondakis et al. (1989) to derive a manganese oral RfD, EPA chose to use Kondakis et al.'s (1989) findings as reason for concern. The EPA's (2002) IRIS profile for manganese only describes three additional human manganese oral studies where toxic effects were observed. One study evaluated very high exposures to manganese in drinking water (14-28 mg/L Mn) in several individuals following contamination of the drinking water source from drycell batteries. Two case reports were described that resulted in high levels of manganese exposure via parenteral exposure in a 62-year-old male and another involving an individual with end-stage liver disease. Given the limitations in these studies, the data cannot be used to inform quantitative manganese risk assessment. Commentator 728 questions why DEP or EPA would then utilize the report to derive a quantitative dose and MF. (618, 728, 905)

Response: EPA recognized the limitations of the Kondakis et al. study and did not use it to derive a reference dose for manganese. However, EPA also recognized this study, when combined with the other available toxicological data and information, raised significant concerns related to non-dietary exposures to manganese. EPA makes the following statement in the 1995 IRIS chemical assessment summary for manganese:

“...This study, nevertheless, raises significant concerns about possible adverse neurological effects at doses not far from the range of [those essential for good health]. Because of this concern, it is recommended that a modifying factor of 3 be applied when assessing risk from manganese in drinking water or soil...”

In addition to human exposure data, EPA reviewed oral toxicity and bioavailability studies involving rodents and monkeys for the 1995 IRIS assessment and 2003 Health Effects Support Document for Manganese. In the IRIS assessment, EPA identified possible associations between manganese and learning disabilities based on research conducted in the 1970s and 1980s and stated that additional research in that area was warranted. The updated Heath Effects Support Document for Manganese also recognized these possible associations and continued to emphasize the need for additional research.

As required under the CWA, DEP reviewed the available, peer-reviewed scientific literature on the toxicological effects in its reevaluation of the WQ criterion for manganese. While newer science has yet to clearly identify a dose-response relationship for use in benchmark dose modeling and an appropriate threshold level for manganese in drinking water, the current data and information generally continue to support the need for EPA's recommendation that an MF be applied to the dietary NOAEL.

76. Comment: The considerations in manganese absorption, distribution, and elimination are important in interpreting studies cited by DEP (2019b), including Chen et al. (2015), Crossgrove and Zheng (2004), Brown and Foos (2009), and O'Neal and Zheng (2015). In

general, Chen et al. (2015), Crossgrove and Zheng (2004), and O'Neal and Zheng (2015) are reviews that primarily discussed studies of the characteristics of manganese absorption, distribution, and elimination, particularly when manganese exposure occurs via inhalation and in occupational settings, and generally did not focus on manganese exposure via ingestion. Characteristics of infant manganese absorption are rarely (if at all) discussed, with the exception of O'Neal and Zheng (2015), who cited three studies reporting higher intestinal manganese absorption, higher central nervous system levels of manganese, and higher serum levels of manganese in infants relative to adults. As discussed above, these reported findings very likely reflect a normal part of infant development and increased physiological requirement for manganese. (618)

Response: DEP disagrees with the commentator's assessment of the studies referenced above and the suggestion that the findings likely reflect a normal part of infant development.

Chen et al. (2015) examined major manganese uptake mechanisms and newly discovered efflux mechanisms that apply regardless of how manganese enters the body. This study was not focused on inhalation or occupational exposures and discussed nutritional toxicity as it relates to diet, vitamins, TPN and individuals with liver disease.

Crossgrove and Zheng (2004) discussed numerous aspects of manganese absorption, distribution, and elimination. This study also did not focus on the inhalation pathway or occupational exposure settings. In fact, the study states "...most of the reported toxicities have occurred through the inhalation exposure. This review, however, will focus on the vascular routes since contrast agents are routinely injected into the bloodstream." In addition to occupational exposures, the authors considered and discussed environmental exposures including drinking water contamination as well as medical exposure to manganese.

Likewise, while O'Neal and Zheng (2015) included inhalation and occupational exposures, their evaluation provided a similar level of discussion on the absorption, distribution and elimination of manganese following oral exposure and specifically referenced exposure from milk- or soy-based infant formula.

Brown and Foos (2009) specifically evaluated and discussed infant and childhood exposure to manganese through drinking water and infant formula.

Furthermore, ATSDR (2012) stated "There are inadequate data to determine whether metabolism of manganese is different in children versus adults. Manganese is necessary for normal functioning of certain enzymes. However, there are no definitive data to indicate that children might need more manganese than adults for normal body processes."

- 77. Comment:** It is important to note that the factors that affect manganese absorption via inhalation are different from the factors that affect manganese absorption via oral drinking water. Therefore, manganese inhalation studies are not directly relevant to the manganese oral drinking water pathway. However, since DEP (2019b) discussed the manganese inhalation pathway in its Rationale, we have critiqued that discussion here. DEP stated that "most manganese intoxication cases have been associated with occupational exposure" and

then stated that "[t]he increased level of toxicity associated with this exposure pathway is not unexpected since inhaled manganese has a direct pathway to the brain via the olfactory nerve (O'Neal 2015)" (DEP, 2019b, p. 7). It is very important to point out that studies have suggested that only very small manganese particles (ultrafine, 0.2 microns or smaller) can be transported from the nasal cavity across the olfactory tract to the brain (Elder et al., 2006), and these studies have all been conducted in nonhuman mammals. Further, DEP stated that "[t]he human body tightly regulates the amount of *ingested* manganese that enters the circulatory system via intestinal absorption" (DEP, 2019b, p. 7), suggesting the inhaled manganese is not regulated via homeostatic mechanisms. DEP further stated that "the body will typically absorb 100% of the inhaled manganese" (DEP, 2019b, p. 7). This statement is incorrect and not consistent with what is known about particle transport and deposition within the respiratory tract (including for manganese). Only respirable particles (2.5 microns or smaller) can reach the deep parts of the lung where they can be potentially absorbed into the bloodstream. Larger particles (>10 microns in diameter) become trapped in the upper respiratory tract where they are then typically removed via mucociliary escalation through coughing and sneezing and sometimes swallowed. Therefore, the statement that 100% of inhaled manganese is absorbed is not consistent with the current science regarding particle transport for manganese across the olfactory tract or within the respiratory tract. Further, as has been described through development of several manganese PBPK models (Schroeter, 2011; Yoon et al., 2011, 2019), inhaled manganese (at typical human exposure concentrations), once absorbed into the blood, is regulated via homeostatic mechanisms.

(618)

Response: DEP agrees that particle size can affect the absorption of manganese within the human respiratory tract. DEP would like to clarify that its analysis was not the entire respiratory tract, but only absorption into the brain via the olfactory bulb, which occurs through the cilia lining the nasal cavity. DEP would also clarify that the manganese particles contained in the fumes associated with many common occupational inhalation exposures, such as gas metal arc welding, are primarily, if not entirely, particles less than 10 microns in diameter (Zimmer et al., 2002; Sowards et al., 2010; Sen et al., 2011). The Elder et al. (2006) study found that the olfactory pathway efficiently transported ultrafine manganese particles into the central nervous system and referenced additional studies which showed manganese can be transported directly from the olfactory bulb to other brain regions such as the hypothalamus (Tjalve et al., 1995). While manganese entering through the lungs and other thoracic tissues would be circulated through the blood and possibly pass through the liver before entering the brain, manganese entering the brain through the nasal cilia are transported directly along the olfactory nerve pathway and bypass the typical body control systems that limit absorption or retention associated with other inhalation, intravenous, or oral manganese exposures.

The Schroeter et al. and Yoon et al. studies do not provide much discussion on manganese inhalation and the model parameters for inhalation. Schroeter et al. (2011) indicated that the PBPK model values for inhalation were based on calculations from another model, the Multiple-Path Particle Dosimetry Model. No other discussion is provided on the inhalation pathway or data used.

78. Comment: DEP referred to a review article by Smith et al. (2017) on the biochemistry of Mn, including its interaction with cells, enzymes, and other proteins in the human body. In a discussion of the role of manganese in dietary nutrition, Smith et al. (2017) referred to IOM's (2001) Adequate Intake Level for adult women and men (i.e., 1.8 and 2.3 mg/day, respectively) and Tolerable Upper Intake Level (UL) for manganese (i.e., 11 mg/day). Smith et al. (2017) also referred to a NOAEL of 11 mg/day and a LOAEL of 15 mg/day, as identified by IOM (2001). However, the LOAEL reported by IOM is based on changes in serum manganese and lymphocyte manganese superoxide dismutase (MnSOD) levels, which are not adverse neurological effects, following 119 days of manganese supplementation (Davis and Greger, 1992). The serum level changes are likely more consistent with a marker of manganese exposure and homeostatic regulation of manganese in the body, consistent with no discussion of this endpoint as an adverse effect by ATSDR (2012) or EPA (2002). In fact, the study that IOM cites as the basis for the manganese serum and lymphocyte MnSOD level changes (Davis and Greger, 1992) reported manganese serum levels that are all generally within the normal range: <2.15 µg/L (Mayo Clinic Laboratories, 2020) or approximately 0.4-0.85 µg/L (ATSDR, 2012). In addition, Davis and Greger (1992) did not suggest that the manganese levels in serum are adverse and in fact evaluated manganese deficiency and effects of supplementation. The authors stated that "the fairly small response of lymphocyte MnSOD activity to manganese supplementation and the long time required for significant changes (89d) in this study suggest that manganese intake of these healthy young women approximated their requirements." Therefore, the study actually suggests that 15 mg/day manganese is a healthy intake level in women. IOM (2001) also stated that higher levels (20 mg/day) of manganese are present in vegetarian diets. Therefore, there is no scientific basis for suggesting that 15 mg/day manganese would lead to adverse health effects in humans. As such, Smith et al. (2017) incorrectly stated that "such a narrow dose range between inadequate and excess intake...and only 5% oral absorption, small variation in absorption (to 2.5% or 10%) could substantially change the body burden." DEP makes similar statements on pages 7 and 11 of its Rationale: e.g., "[s]uch a narrow dose range exists between inadequate and excess intake that small variations in the body's absorption and handling of manganese could substantially change the body burden" (DEP, 2019b, p. 11). Both Smith et al.'s and DEP's statements are incorrect and not based on the available scientific evidence for safe levels of manganese intake. In addition, ATSDR (2012) stated that the average amount of manganese absorbed across the gastrointestinal tract in humans is on average 3 to 5%, and not 10%. In conclusion, DEP should not consider the LOAEL of 15 mg/day manganese that was discussed by Smith et al. (2017) and IOM (2001) as reflecting an adverse effect. (618)

Response: The relevance of the comment is not clear since the study cited (Smith et al., 2017) does not define or recommend a NOAEL or a LOAEL. Smith et al. simply noted that the IOM has set a UL for manganese of 11 mg/day for adults based on a NOAEL for western diets and that Davis et al. (1992) and Greger (1999) had calculated a LOAEL in humans to be 15 mg/day. In fact, it is stated by Smith et al. that "a defined LOAEL has been difficult to ascertain" as of the date of the 2017 publication due to the limited number of studies that were available that used an oral route for administration of manganese.

The Smith et al. (2017) study agrees with the commentator's statement that only 3%-5% of manganese is absorbed in the gut. The study states that the absorption of oral manganese in the gut is typically less than 5%, but absorption rates can vary due to disease, impaired organ function or other factors that affect and control the rate of manganese absorption or elimination. The study illustrates the point that if absorption rates vary in either direction (that is, absorption decreases or increases) from the typical range of 3-5% then levels of manganese in the body can be significantly affected. This is due to the fact that the half-life of manganese once absorbed into the body is weeks to months, which means it takes the body weeks to months to eliminate all of the manganese once it has been absorbed into the body's cells and tissues. Thus, any changes in an individual's ability to absorb or eliminate manganese can lead to decreased or increased levels of manganese in the body, which can result in adverse health effects over time.

DEP primarily cited this study in its discussion to highlight the role of manganese in the body and the oxidation states that are biologically relevant. Although DEP did not discuss other aspects of the Smith et al. (2017) paper in the rationale document, this study provides information on the negative effects associated with increased levels of manganese within the body's cells. Manganese plays an essential role in many cellular activities and has been demonstrated to have significant effects on cell function. Appropriate levels of manganese in the cell are critical. An adequate level of manganese is required for mitochondrial antioxidant defense. However, when higher amounts than those necessary are found in the cell, excess manganese can cause oxidative stress and mitochondrial dysfunction. Manganese has the ability to displace iron, calcium, and magnesium in critical enzymes; alter metals transport; and induce apoptosis, also known as programmed cell death (Smith et al., 2017). While the Smith et al. (2017) study does not attempt to establish a NOAEL or LOAEL, it does highlight the importance of manganese relative to the reduction-oxidation interface between an organism and its environment, along with the negative effects resulting from increased intercellular manganese.

79. Comment: Chung *et al.* (2015) evaluated the association between maternal blood manganese (mean: 22.5 µg/L) and mental and psychomotor development scores in 232 pairs of pregnant women and six-month-old infants in South Korea. Although the authors controlled for a number of potential confounding variables (*e.g.*, maternal age, monthly income, and birth weight), the authors did not control for other relevant confounders such as smoking, maternal intelligence, or quality of the home environment in their analyses. The authors found that blood manganese was associated with covariate-adjusted psychomotor development scores but was not associated with mental development scores. In addition, a dose response relationship was not observed between blood manganese and psychomotor development scores. The authors did not measure oral sources of manganese exposure. Because of potential uncontrolled confounding, a lack of a dose-response relationship between manganese and development scores, and inadequate information on oral manganese exposure, this study cannot be used to draw conclusions regarding water manganese and cognitive endpoints. (618)

Response: Chung *et al.* (2015) evaluated a number of possible confounding factors including maternal age/height/weight, maternal and paternal education level, marital status at

enrollment, and family income. Participants were asked to provide information about their entire food intake during the 24 hours before they were interviewed. Interviews occurred multiple times: at the time of recruitment into the study, at the visit for delivery and at each infant follow-up visit. Data collected before delivery included any exposure through passive smoking at home, parents' physical condition, medical records, and family history of diseases. Information on birth outcome was recorded (date of delivery, mode of delivery, birth weight and height, gestational age, head circumference, parity, and infant's sex). Information was also collected on variables that could affect infant growth. This study does recognize the potential for several confounding variables.

DEP is aware that a dose-response relationship was not defined by the study. DEP did not use the study to develop to a new RfD.

- 80. Comment:** Brown and Foos (2009) conducted a case study using hypothetical manganese exposure scenarios in children. The authors summarized research reporting that manganese levels in diluted powder-based infant formulas ranged from 34 to 169 µg/L manganese, with a median manganese concentration of 101 µg/L. DEP (2019b) cited this paper in relation to the manganese absorption of formula-fed infants; however, Brown and Foos (2009) did not report data on manganese absorption. Therefore, this study should not be used to determine the bioavailability of manganese in infants. (618)

Response: DEP agrees that this study was not designed to evaluate bioavailability or manganese absorption. The study relies on information contained in other studies and references including EPA's IRIS RfD summary for manganese (Mena, 1974), California's Office of Environmental Health Hazard Assessment (OEHHA) and several additional studies. DEP has removed this citation in the rationale document in reference to manganese absorption by neonates.

DEP also references the Brown study for other reasons. It identifies various manganese concentrations that neonates may be exposed to through formula and water. The scenario provided in the study uses known information on manganese levels in prepared formula, average daily consumption volumes, health reference values and other known information to calculate age-specific hazard quotients and assess drinking water exposures to manganese. Formula-fed and breast-fed infants were evaluated separately since it is likely that breast-fed infants consume minimal amounts of drinking water during the first year of life and particularly the first six months based on AAP recommendations. It should be noted that the 2019 Yoon et al. study also references this 2009 Brown and Foos study and uses a formula manganese level identified in that study.

- 81. Comment:** Bouchard et al. (2007) conducted a cross-sectional study of associations between hair manganese (mean: 5.1 µg/g, range: 0.3 to 20 µg/g) and oppositional/hyperactive behavior in 46 Canadian children aged 6-15 years. Parents and teachers reported on children's behaviors using the Revised Conners' Rating Scale. Although the authors adjusted for some potential confounders (i.e., age, sex, and income), the authors did not control for smoking, maternal intelligence, or quality of the home environment in their analyses. Children's hair manganese was associated with higher covariate-adjusted oppositional and hyperactivity

scores (i.e. indicating increased oppositional and hyperactivity behaviors) as reported by teachers. However, hair manganese was not associated with behavior scores as reported by parents. Given the difference between reporting by teachers and parents, lack of adjustment for potential confounders, and cross-sectional study design, the observed changes in behavior scores cannot be attributed to manganese. Health Canada (2019) did not include this study in its evaluation of manganese. (618)

Response: In 2005, Bouchard et al. received information regarding elevated manganese levels in the public water supply of a small community in Quebec and conducted a pilot study to assess the possible effects associated with the elevated levels of manganese. The authors reviewed the current science and literature at the time and noted a lack of data on the effects of exposure to manganese in water. The authors did evaluate and consider sociodemographic information including family structure and noted possible limitations of the pilot study including confounding factors. The study stressed that additional follow-up evaluation of the study subjects was warranted. The results of the study provided a basis for further research and nothing more. Bouchard conducted additional studies in 2007 and 2009 to further evaluate manganese in drinking water. This study is part of the collective research and information on manganese to provide support for neurotoxicity as a critical endpoint.

82. Comment: Bouchard et al. (2011) conducted a cross-sectional evaluation of associations between manganese as measured in hair (median: 0.7 µg/g, range: 0.1 to 21 µg/g) and home tap water and IQ scores in 362 Canadian children aged 6-13 years. The authors reported that children's hair manganese was associated with estimated manganese intake from water consumption but not associated with estimated manganese intake from food. When the authors adjusted for a number of potential confounders (e.g., maternal education, family income, alcohol and tobacco consumption during pregnancy, and quality of the home environment), hair manganese and estimated manganese intake from water (median: 8 µg/kg/month, range: 0 to 945 µg/kg/month) was inversely associated with full-scale IQ. However, approximately 33% of children in the study did not drink the tap water, suggesting that they were not exposed to manganese in the drinking water. In addition, there was no dose-response relationship between full-scale IQ and hair manganese or estimated manganese intake from water. Therefore, given the cross-sectional study design, lack of a dose-response relationship, and lack of a complete exposure pathway in 1/3 of the samples, the study provides limited evidence of an association between manganese in drinking water and adverse cognitive effects. ATSDR (2012) and Health Canada (2019) also discussed uncertainties of Bouchard et al. (2007, 2011), including that it was uncertain whether the observed effects were due to manganese or other drinking water or dietary components, that there was a lack of information about manganese levels in food and air, and that the study used a small sample size. (618)

Response: As was noted in the 2007 Bouchard et al. study, some of the children residing in homes receiving tap water with elevated manganese levels did not routinely drink the tap water. However, tap water was regularly used in home cooking and to prepare foods and beverages such as juice. In addition, the tap water provided by the same public water supplier was consumed by those children while at school. Some children consumed the school tap water on a daily basis. In the 2011 study, water consumption was estimated from different

sources including bottled, tap, tap pitcher-filtered and/or tap with an attached filter. All of the study subjects were exposed to manganese in water.

DEP agrees that this study does not establish a dose-response relationship. More importantly, the study was not used by DEP to develop the RfD used in the development of the criterion recommendation.

As stated in the response to Comment 69, Health Canada reviewed and cited much of the same literature used by DEP and determined that protection was warranted despite any limitations associated with individual studies. Health Canada (2019) states, "However, the results of these studies [that is, epidemiological studies including Bouchard 2011] can be used to qualitatively support the choice of the key endpoint used for quantitative assessment in animals, as similar endpoints that reflect executive function behaviors have been studied in rodents."

83. Comment: In a follow-up study of the Bouchard et al. (2011) cohort of children, Oulhote et al. (2014) conducted a cross-sectional evaluation of associations between manganese (in hair and tap water) and memory, attention, motor function, and hyperactivity scores. The authors did not evaluate correlations between manganese intake and hair manganese. After adjusting for potential confounding variables (e.g., maternal education and intelligence, family income, maternal tobacco and alcohol consumption during pregnancy, and tap water lead concentrations), the authors reported that children's hair manganese (mean: 1.4 µg/g, range: 0.1 to 20.7 µg/g) was associated with lower memory and attention scores but was not associated with motor function or hyperactivity scores. However, estimated manganese intake from water (mean geometric mean: 5.5 µg/kg/month, range: 0 to 1,059 µg/kg/month) was associated with reduced motor function but not memory, attention, or hyperactivity scores. The authors did not examine the quality of the home environment as a potential confounder. Because of the inconsistent associations reported between manganese and cognitive and behavioral function, cross-sectional study design, and lack of consideration for quality of the home environment as a potential confounder, this study provides limited evidence of an association between manganese and cognitive and behavioral outcomes. Health Canada (2019) discussed the uncertainties of both Bouchard et al. (2011) and Oulhote et al. (2014) and stated that the "risk of bias in these studies cannot be discarded." Specifically, Health Canada (2019) noted that few details on sample recruitment and retention were reported and that exposure misclassification was possible because: (1) water manganese was measured only once, (2) residing in one's current home for 3 months was sufficient for inclusion in the study, (3) hair manganese was used as a biomarker, (4) no information was reported regarding manganese in diet or soil, (5) no information was provided on the timing or duration of exposure during critical periods of development, (6) the authors did not report whether the investigators were blind to the exposure levels of the participants, and (7) the statistical error associated with effect estimates were large and borderline statistical significance was reported for many observed effects. (618)

Response: Total manganese intake, including dietary intake, was previously evaluated and discussed in Bouchard et al. 2011. Likewise, Bouchard et al. 2011 assessed the home environment using the Home Observation for Measurement of the Environment (HOME)

test. Manganese levels in the drinking water were examined multiple times in a subset of the homes. For this subset, samples were collected once per season (4 times) over a one-year period to examine if there was any seasonal variability in manganese levels. Sample results indicated minimal variability in sample results across the year.

The Health Canada comments referenced above include additional studies, such as Bouchard et al. 2018, which DEP did not evaluate. While the Health Canada evaluation noted the above concerns, they also included the following statements:

“Limitations in these studies... prevent their use in a quantitative risk assessment. However, the results of these studies can be used to qualitatively support the choice of the key endpoint used for quantitative assessment in animals, as similar endpoints that reflect executive function behaviors have been studied in rodents (e.g., behavioral hyperactivity (measured using the open arena assessment) and learning deficits (measured using the 8-arm radial maze) (Kern et al., 2010). Further, it has been suggested that the cognitive and neurobehavioral effects seen in children following exposure to manganese may be related to effects on the dopaminergic system during development (Neal and Guilarte, 2013). Mechanistic data also appear to suggest common elements between rodents and non-human primates with respect to involvement of the dopaminergic system in manganese-induced neurotoxicity (Neal and Guilarte, 2013).”

In addition to reviewing the epidemiological data, Health Canada conducted a thorough evaluation of the peer-reviewed, published animal studies on manganese. Health Canada concluded that “a number of animal studies have identified LOAELs following oral exposure to manganese. There has been concern in the published literature over the human relevance of some of the endpoints studied, and many of the studies only examine effects following a short duration without long-term follow-up. However, three animal studies in particular stand out collectively as closely assessing and quantifying neurological effects that are consistent with those reported in the epidemiology studies, with consideration of observed effects measured over a long term (Kern et al., 2010, 2011; Beaudin et al., 2013). The Kern and Beaudin studies were chosen as a basis for the current risk assessment because of their thoroughness in assessing neurodevelopmental endpoints (observed neurobehavioral effects are supported with corresponding neurochemical findings) in early life that are consistent with the findings reported in epidemiological studies (Bouchard et al., 2011; Khan et al., 2011; Roels et al., 2012; Oulhote et al., 2014).”

Additional discussion on the Beaudin et al. and Kern et al. studies can be found in responses to Comments 87-89.

84. Comment: Haynes et al. (2015) conducted a cross-sectional evaluation of associations between blood (mean: 9.67 µg/L) and hair manganese (mean: 417 ng/g) and IQ in 404 children living in Ohio, aged 7-9 years. The manganese blood concentrations reported were within the normal range of 4-15 µg/L (ATSDR, 2012), and the authors found that blood manganese was not associated with hair manganese. The authors used a voluntary method of participant selection, which likely introduced sampling bias. Although the authors controlled for a number of potential confounders (e.g., caregiver IQ, SES, serum cotinine [a marker for

smoking], and blood lead), the authors did not measure the quality of the home environment. Haynes et al. (2015) reported that the highest quartile of hair manganese (i.e., >747 ng/g) and blood manganese (i.e., >11.2 µg/L) was associated with lower full-scale IQ scores. However, the authors reported a non-linear relationship between these biomarkers of manganese and full-scale IQ scores. In addition, the authors reported an association between serum cotinine (a marker for exposure to tobacco smoke) and child cognitive function. Because Haynes et al. (2015) did not evaluate exposure to manganese in drinking water, used a cross-sectional study design, did not consider quality of the home environment as a potential confounder, observed a non-linear relationship between manganese and cognition, and reported an association between serum cotinine and cognitive function, this study cannot be used to draw conclusions regarding water manganese and cognitive endpoints. (618)

Response: Haynes et al. (2015) did consider the home environment, which they evaluated using the Parenting Relationship Questionnaire (Reynolds and Kamphaus 2004). This survey evaluates attachment, communication, parenting confidence, discipline practices, involvement, school satisfaction and relational frustration.

Since manganese is essential for normal growth, development, and function, it is not unexpected that an evaluation of manganese levels in the body across a wide range of levels would show a nonlinear, or inverted U, response. Both high and low levels of manganese may be associated with cognitive impairment. High or low levels of manganese in the body may result from disease (both), nutritional deficiency (low) or exposure to excess levels of manganese in a person's environment (high), including from air, drinking water, diet, supplements, etc. In addition, unlike the difference in IQ scores between the high blood manganese group and the average group, the authors noted that the difference between the average group and those with the lowest blood manganese levels was not statistically significant.

The measurement and evaluation of serum cotinine levels was included in the study since it could be a potential confounding factor. Cotinine is the predominant metabolite of nicotine and is used as a biomarker for exposure to tobacco smoke. In addition to cotinine, the authors measured and evaluated the serum levels of lead, a known neurotoxicant. As noted by the authors, "inclusion of multiple neurotoxicants in this study provided a robust analysis between manganese exposure and intellectual function in children because we were able to adjust for potential confounding by lead and environmental tobacco smoke."

While this study did not specifically evaluate manganese exposure in drinking water, it does provide information that supports a link between manganese exposure and impacts on neurodevelopment.

85. Comment: Khan et al. (2011) conducted a cross-sectional study of 201 Bengali children (aged 8-11 years) and examined associations between manganese and arsenic (in water and blood) and classroom behavior. Although the authors adjusted for confounding variables (e.g., maternal education, sex, and body mass index), they did not adjust for the quality of the home environment, SES, or smoking. The authors found that water manganese (median: 650 µg/L, range: 40-3,443 µg/L) was associated with covariate-adjusted negative classroom

behavior scores. Blood manganese (median: 14.6 µg/L, range: 6.3-33.9 µg/L) was not associated with classroom behavior. The median manganese blood concentration reported is within the normal range of 4-15 µg/L (ATSDR, 2012). The results of Khan et al. (2011) are limited by the cross-sectional study design, reliance on teacher reported scores (which may introduce measurement error), and potential sampling bias (i.e., children with lower water manganese were excluded due to their distance from the study region), which were also acknowledged as limitations by Khan et al. (2011). Because of these limitations, as well as not accounting for other confounders (listed above), including exposure to other chemicals in the water (i.e., arsenic), this study cannot be used to draw conclusions regarding water manganese and behavioral endpoints. (618)

Response: The participants in this study came from a larger cohort study of adults in the Araihazar region of Bangladesh. The study is known as the Health Effects of Arsenic Longitudinal Study (HEALS). As part of that study, detailed information on the smoking of tobacco products was collected and recorded. Nutritional and dietary information was also collected for the HEALS cohort via surveys.

Khan et al. examined the effects of manganese exposure through drinking water, but also attempted to evaluate the combined effects of exposure to manganese plus other neurotoxicants in drinking water such as arsenic. As part of the study, basic home environment information was collected during a home interview that included characteristics of the home (roof, wall, and floor materials), paternal and maternal education, paternal occupation, access to television or radio, and maternal intelligence. This study is related to additional similar studies published by Wasserman et al. (2006, 2011), which used the same HEALS cohort.

Khan et al. (2011) noted possible confounding factors including teacher bias and the inability to establish “geographic generalizability.” This inability, however, was not due to areas with lower water manganese being excluded due to distance from the study region. The study was conducted in rural Araihazar, Bangladesh, which is relatively well-developed. Thus, the authors stated “the study population may represent only comparable communities with similar sociodemographic characteristics. Our findings may not be generalizable to children living in urban communities.” The authors’ primary purpose for the study was to draw attention to the elevated manganese levels that are naturally occurring in the groundwater of that region. While the digging of deeper wells has greatly reduced arsenic exposure in some areas, the authors noted that the manganese levels in these deeper wells may still exceed established drinking water guidelines for manganese. As stated in many other responses to comments on the scientific studies reviewed by DEP, this study adds to the collection of data supporting a link between elevated concentrations of manganese and negative impacts to neurodevelopment in infants and children and that many of these negative effects are likely permanent.

86. Comment: Wasserman *et al.* (2006) examined cross-sectional associations between manganese and arsenic (in water and blood) and IQ scores in 142 Bengali children aged 10 years. After adjusting for confounder variables, such as maternal intelligence and house type (as a surrogate for SES), water manganese (mean: 795 µg/L) was associated with lower IQ scores. However, blood manganese (mean: 12.8 µg/L) was not associated with IQ scores. The

manganese blood concentrations reported are within the normal range of 4-15 µg/L (ATSDR, 2012). Further, the authors reported that water manganese was not associated with blood manganese in a subset of 95 children. The authors did not control for other confounding variables, such as the quality of the home environment or smoking. Further, the authors also did not measure manganese in food, which could introduce exposure measurement error. ATSDR (2012) discussed uncertainties of Wasserman *et al.* (2006), including that it was uncertain whether the observed effects were due to manganese or other drinking water or dietary components, there was a lack of information about manganese levels in food and air, and the study used a small sample size. Because of the cross-sectional study design, inadequate manganese exposure assessment, small sample size, and inadequate control of confounding variables, this study cannot be used to draw conclusions regarding water manganese and cognition. (618)

Response: As with the Khan *et al.* (2011) study, the participants in these studies came from a larger cohort study of adults in the region, known as HEALS. As part of that study, detailed information on smoking of tobacco products was collected and recorded. Nutritional and dietary information was also collected for the HEALS cohort via surveys.

The study included a total of 142 children; however, only 95 participants provided blood samples for measurement of manganese, lead, and arsenic. Of the 95 participants, no correlation was found between drinking water manganese levels and blood manganese levels. Regarding the lack of manganese measurements for food or air, the authors stated “the impact of the absence of these exposure inputs would actually bias our findings toward the null. The fact that we observed a relationship between drinking water manganese and child intellectual function in the absence of food and air manganese exposure is therefore even more compelling.”

DEP disagrees with the statement that the 2006 study used a small sample size. The 2006 study evaluated 142 children with 95 children providing blood samples.

Health Canada (2019) recently evaluated many of the same human health studies as DEP including Wasserman *et al.* (2006 and 2011). This agency concluded that although the current epidemiological studies have a number of limitations which prevent them from being used quantitatively to establish a reference dose for the protection of the children, they “qualitatively support neurotoxicity as a critical endpoint.”

87. Comment: DEP (2019b) relied on several manganese rodent studies in its Rationale (Kern *et al.*, 2010; Beaudin *et al.*, 2013; Moreno *et al.*, 2009). Overall, these studies cannot be used to draw conclusions regarding water manganese and potential health effects in humans due to a number of limitations. First, all three studies used concentrations of manganese in water that would be rarely encountered in humans. In general, the manganese exposure regimen used by these studies is associated with blood (or serum) manganese levels that are substantially higher than reported manganese levels in humans, which limits generalizability of the reported results to humans. Second, there is a lack of information about how rodent manganese requirements compare to human manganese requirements. Because of the essentiality of manganese, manganese dietary requirements in rodents would need to be

considered in order to understand what doses were actually in excess of the dietary requirements and of potential relevance to humans. Third, the authors often reported inconsistent behavioral findings. Specifically, in some cases, the authors would report that an endpoint (e.g., fear behavior) was affected by manganese exposure using one procedure, but another procedure designed to assess the same or similar endpoint did not show an effect of manganese exposure. Fourth, in some cases, the authors did not observe a dose-response relationship between manganese exposure and behavior. This suggests that observed changes in behavior were due to a factor other than manganese. Finally, all three studies used only two doses of manganese, which limits their ability to establish dose-response relationships between manganese and behavior.

The first two limitations discussed above are important to keep in mind because the doses evaluated in the rodents in these studies are much higher than what is typical in humans. Across all three studies, the doses ranged from 4.4 to 50 mg/kg-day, compared to the UL in humans of 0.14 mg/kg-day calculated by EPA (2002), based on upper intake manganese levels in the diet (10 mg/day). Further, since manganese is an essential nutrient, the oral RfD for manganese is applied based on the assumption that 50% of the intake would come from food (5 mg/day, which is a typical intake in adult humans) and that any additional manganese exposure should not result in exceedance of a total manganese intake of 10 mg/day (EPA, 2019). However, there is a lack of information on rodent dietary requirements for manganese. Thus, the doses in these studies may be very high compared to normal dietary requirements in the rodents, and the effects reported may reflect dosing that is much higher than what would be expected in humans. Application of these rodent studies to derive an oral manganese toxicity value for humans would be highly uncertain. ATSDR (2012) reached the same conclusion based on its review of the animal studies, stating, "However, inconsistencies in the dose-response relationship information across studies evaluating different neurological end points under different experimental conditions in different species, as well as a lack of information concerning all intakes of manganese (e.g., dietary intakes plus administered doses), make it difficult to derive intermediate- or chronic-duration MRLs using standard MRL derivation methodology from the animal studies." ATSDR (2012) provided an interim guideline of 0.16 mg/kg-day based on a UL of 11 mg/day in humans (similar to the EPA [2002] approach for a Mn oral RfD). (**618**)

Response: The commentator states the Kern et al. (2010), Beaudin et al. (2013), and Moreno et al. (2010) studies cannot be used to draw conclusions regarding water manganese and potential health effects in humans for four reasons. DEP disagrees that these studies are not applicable based on the reasons described below.

The commentator states that all three studies used concentrations of manganese in water that would be rarely encountered in humans, and the manganese exposure regimen used by these studies is associated with blood (or serum) manganese levels that are substantially higher than reported manganese levels in humans, which limits generalizability of the reported results to humans. As explained in greater detail in the response to Comment 88, neonatal rats received much higher levels of manganese through lactation (approximately 200-300 µg/L) than human infants receive through human breastmilk (approximately 6 µg/L). Kern et al. determined that pre-weanling rats consume approximately 100 times the amount of daily

manganese consumed by the average human infant through breastmilk. Thus, the experimental exposure levels were specifically designed to approximate equivalent human exposure levels. Beaudin et al. also noted that “the pre-weanling manganese exposure regimens were designed to approximate the relative increases in manganese exposure experienced by infants and young children exposed to manganese contaminated water or soy-based formula (or both), compared to manganese ingestion from human breastmilk.”

The commentator next states there is a lack of information about how rodent manganese requirements compare to human manganese requirements, and because of the essentiality of manganese, manganese dietary requirements in rodents would need to be considered in order to understand what doses were actually in excess of the dietary requirements and of potential relevance to humans. DEP agrees that data on the dietary requirements of rats and mice is not extensive. However, there is information available on dietary intake. The National Academies of Science (NAS), Engineering and Medicine (National Research Council) published dietary requirement information for experimental animals. The “Nutrient Requirements of Laboratory Animals, Fourth Revised Edition” (1995) identifies a recommendation of 10 mg Mn/kg diet for normal rat growth and 25 mg Mn/kg diet for reproduction. In comparison, the IRIS RfD for a 70-kg adult is 0.14 mg/kg-day based a dietary NOAEL of 10 mg/day. The publication also notes that “postnatal growth of rats is unaffected by dietary manganese intakes as high as 1,000 to 2,000 mg/kg diet, provided dietary iron is adequate.” Thus, rats and mice appear to have much higher normal dietary requirements for manganese or are less sensitive to dietary manganese than humans particularly in early life stages (as noted above). The three studies referenced above used commercially available rodent chow containing adequate levels of manganese (ranging from 10 mg/kg diet to 118 mg/kg diet) and supplemented the diet with manganese-laden drinking water at doses designed to mimic human exposures to manganese in drinking water. The NAS publication also makes the following statement regarding dietary vs. drinking water manganese and toxicity: “Although the concentrations of dietary manganese needed for overt toxicity are quite high [in excess of 3,500 mg/kg], weanling rats given water containing 55 µg Mn/mL for 3 weeks were reported to have reduced rates of brain RNA and protein synthesis (Magour et al., 1983).”

The commentator also states “the authors often reported inconsistent behavioral findings. Specifically, in some cases, the authors would report that an endpoint (*e.g.*, fear behavior) was affected by manganese exposure using one procedure, but another procedure designed to assess the same or similar endpoint did not show an effect of manganese exposure.” It is unclear to what inconsistencies the commentator is referencing, but DEP assumes the comment references Kern et al. (2010).

Kern et al. (2010) evaluated rat responses in an open arena, elevated plus maze and 8-arm radial maze. The authors found that pre-weaning exposure to manganese caused rats to travel greater distances in the open arena and spend more time in the center zone of the arena when compared to the control rats, but early exposure did not affect the response to the elevated plus maze. In the discussion, the authors explain “the elevated plus maze and the open arena are both considered screening tests for emotional reactivity (Ducottet and Belzung, 2005), but there is a fundamental difference between the two paradigms. The open area introduces a

novel environment with stressors of a wide-open unfamiliar space, as well as isolation from cage mates. Normally, animals show a preference for thigmotaxic (wall touching) behavior in response to these stress cues, but in the absence of normal inhibition of exploratory behavior in this novel environment, animals will more readily venture into the center of the enclosure (Prut and Belzung, 2003), as we observed here. The elevated plus maze also presents a novel environment and isolation from cage mates, but includes additional stress factors in the elevated open arms that are absent of thigmotaxic cues and introduce a potentially harmful situation (Carobrez and Bertoglio, 2005). Disinhibition of exploratory behavior in the open arena, but appropriate innate fear response in the elevated plus maze may suggest differential susceptibilities of dopamine systems controlling these behaviors to early manganese exposure.” Additional discussion is provided in the response to Comment 88.

Lastly, the commentator states the authors did not observe a dose-response relationship between manganese exposure and behavior. This suggests that observed changes in behavior were due to a factor other than manganese. All three studies used only two doses of manganese, which limits their ability to establish dose-response relationships between manganese and behavior. DEP disagrees the authors did not observe a relationship between exposure and behavior. While the data may be limited for use in benchmark dose modeling, Health Canada used this data in development of a new manganese guideline.

The “Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Manganese” published by Health Canada in 2019 states “the Kern and Beaudin studies were chosen as a basis for the current risk assessment because of their thoroughness in assessing neurodevelopmental endpoints (observed neurobehavioral effects are supported with corresponding neurochemical findings) in early life that are consistent with the findings reported in epidemiological studies (Bouchard et al., 2011; Khan et al., 2011; Roels et al., 2012; Oulhote et al., 2014)... In addition to demonstrating that exposure to manganese in early life can result in behavioral and sensorimotor effects, these studies provided mechanistic support by demonstrating corresponding neurostructural and neurochemical changes. Further, Kern et al. (2011) and Beaudin et al. (2013) demonstrated the ability of manganese exposure in early life to result in effects that persist into adulthood, after levels of manganese in the brain have returned to normal.”

The final 2021 WHO guidelines for drinking WQ recognize “newer data in neonatal rats (Beaudin et al., 2013, 2017) have identified neurobehavioral effects similar to those reported in previous rodent studies (Kern et al., 2010, 2011). From multiple well-documented studies in rats, a lowest observed adverse effect level (LOAEL) of 25 mg Mn/kg body weight per day can be identified based on adverse neurological changes in exposed offspring, some of which persisted into adulthood after levels of manganese in the brain had returned to normal (Kern et al., 2010, 2011; Beaudin et al., 2013, 2017).”

Additional discussion on the Kern et al. and Beaudin et al. studies can be found in Comments 88 and 89.

88. Comment: Kern et al. (2010) conducted a study in neonatal rats to examine the effects of oral administration (p.o. via micropipette) of manganese (0, 25, and 50 mg/kg-day) on

behavior and levels of brain dopamine. The authors stated that pre-weaning control rats consume approximately 70 µg/kg/day manganese from breast milk, which is approximately 100 times higher than normal human infant manganese intake from breast milk. The authors tested behavior in a number of procedures including an open arena, elevated plus maze, and radial arm maze. Kern et al. (2010) reported blood manganese concentrations of approximately 60, 150, and 210 µg/L for the control, 25, and 50 mg/kg-day groups, respectively. The authors reported that these procedures reflect fear and anxiety (open arena and elevated plus maze) and learning and memory (radial arm maze). manganese exposure dose-dependently increased fear behavior on the elevated plus maze but did not affect fear behavior in the open arena. The authors also observed that manganese exposure dose-dependently increased total memory errors upon initial testing, but after repeated testing all exposure groups demonstrated similar memory performance. This study is limited because only two doses of manganese were used, which is insufficient to generate a full dose-response curve. Further, this study is limited because the authors reported inconsistent effects on fear behavior. These inconsistent results, coupled with the reported findings that memory deficits recovered, make it uncertain whether behavior changes were due to manganese exposure in water. Finally, given that these doses are much higher than what humans would typically be exposed to in the diet, and that there is uncertainty with respect to how these doses compare to dietary requirements of manganese in rodents, the findings from Kern et al. (2010) cannot be extrapolated to humans. (618)

Response: The statement “pre-weaning control rats consume approximately 70 µg Mn/kg/day, which is ~100-times higher than normal human infant manganese intake from breast milk” was preceded by additional information regarding the comparison of rat to human milk in Kern et al. (2010). The authors made the following statements:

“Neonate rats were orally exposed to manganese doses of 0, 25, and 50 mg Mn/kg/day over postnatal day (PND) 1-21...These oral exposure levels increased manganese intake by ~350 and ~700-fold over levels consumed from lactation alone, which approximates the relative ~300 to ~500-fold increases in manganese exposure suffered by infants and young children exposed to manganese contaminated water or soy-based formulas (or both) compared to manganese ingestion from human breast milk. Human breast milk contains ~6 µg Mn/L, yielding normal infant intake rates of ~0.6 µg Mn/kg/day, based on infant daily milk consumption rates of ~0.8 L/day for a 8-kg 6-9 month old infant (Arcus-Arth et al., 2005; Dewey et al., 1991; Dorner et al., 1989; Stastny et al., 1984). By comparison rat milk manganese levels are ~200-300 µg Mn/L (Dorman et al., 2005; Keen et al., 1981), and pre-weaning rats consume an average of 260 mL/kg/day over PND 1-21 (Godbole et al., 1981; Yoon and Barton, 2008). Thus, pre-weanling control rats consume ~70 µg Mn/kg/day, which is ~100 times higher than normal human infant manganese intake from breast milk.”

As the authors explain, the doses are higher because normal manganese intake for rats is naturally higher than normal manganese intake for humans. Fordahl et al. (2012) also noted that Sprague-Dawley rats have much a higher toxicity threshold for manganese than humans and can withstand doses of 200 mg/kg/day for two years and 2,251 mg/kg/day for six months

before fatality occurs. The study doses were intentionally selected to mimic the expected human exposures as described above. Therefore, DEP disagrees with the statement made by the commentator that findings from Kern et al. (2010) cannot be extrapolated to humans based on the higher doses.

The commentator states “manganese exposure dose-dependently increased fear behavior on the elevated plus maze but did not affect fear behavior in the open area.” The authors actually reported the opposite. Manganese exposure resulted in greater exploratory behavior in the open arena, but exposure had no effect on the rats’ innate fear response in the elevated plus maze.

As stated in the response to Comment 87, Kern et al. noted a fundamental difference between these two testing models and stated the following:

“Disinhibition of exploratory behavior in the open arena, but appropriate innate fear response in the elevated plus maze may suggest differential susceptibilities of dopamine systems controlling these behaviors to early manganese exposure. Inhibitory control of exploratory behavior is governed in part by dopamine release in the accumbens and prefrontal cortex (Arnsten and Goldman-Rakic, 1998; Bandyopadhyay et al., 2005; Grace, 2000), but innate fear conditions, such as those presented by the elevated plus maze, elicit dopamine release in relatively primitive structures such as the amygdale and bypass prefrontal cortex influence, resulting in greater autonomic control of behavioral responses (Arnsten, 2000; Corcoran and Quirk, 2007; LeDoux, 2000; LeDoux, 2003). This may suggest that behavioral tests that rely only on innate or conditioned fear responses to possible injury, such as shock avoidance, may not be as sensitive for detecting effects of manganese exposure.

Behavioral disinhibition, observed as increased center zone activity in the open arena, was associated with decreased levels of D1 receptors and DAT in the nucleus accumbens and dorsal striatum, and increased D2 receptors in the prefrontal cortex of manganese-exposed animals. It is possible that these effects on dopamine-related proteins resulted in dysregulation of dopaminergic control over suppression of outward exploratory behavior in the open arena, leading to increased center zone activity. The dopamine system normally functions in the prefrontal cortex and nucleus accumbens to modulate neuronal activity to elicit appropriate behavioral responses to relevant stimuli, such as novel stressful environment, and for suppression of neuronal activity that might otherwise lead to contextually inappropriate behavioral responses (Arnsten and Goldman-Rakic, 1998; Arnsten, 2006; Russell, 2003). Alteration of the levels/functions of these dopamine-related proteins in manganese-exposed animals may have led to impairment of proper inhibitory control of contextually appropriate behavior. The lack of a manganese effect in the elevated plus maze, and the observation that manganese had no effect on dopamine receptors or DAT levels in the olfactory tubercle, both support the suggestion that early manganese exposure targets specific dopaminergic nuclei, while sparing others.”

“The pre- and early post-weaning period coincides with the development of dopaminergic pathways in brain regions such as the prefrontal cortex, nucleus accumbens, and dorsal striatum that are instrumental in the regulation of executive function behaviors involving learning, memory, and attention (Arnsten, 2006; Broaddus and Bennett, 1990a, b; Goto and Grace, 2005; Leo et al., 2003; Packard and Knowlton, 2002). The dopaminergic system is also a sensitive target of manganese exposure, based on studies in adult animals and humans (Donaldson, 1985; Eriksson et al., 1992; Guilarte et al., 2006; Huang et al., 2003; Kessler et al., 2003; Newland et al., 1989; Normandin and Hazell, 2002) and on recent studies in pre- or early post-weaning rodents (Calabresi et al., 2001; Dorman et al., 2000; McDougall, 2008; Reichel et al., 2006; Tran et al., 2002a, b).”

The commentator appears to misrepresent the findings of the 8-arm radial maze in stating that “after repeated testing all exposure groups demonstrated similar memory performance.” Kern et al. presented the following discussion in their study:

“Pre-weaning oral manganese exposure also led to significant learning deficits in the 8-arm radial maze, as evidenced by the significantly greater number of learning errors, and the significant delay or failure of manganese-exposed animals to achieve the learning criterion [≤ 4 errors over 3 consecutive session days]. These deficits may reflect lasting effects of early manganese exposure, since they were measured at a time (PND 33-46) when brain manganese levels had declined to near-control levels [being 15% and 27% higher than controls]...An animal’s normal initial response in the radial maze utilizes declarative, short-term, working memory when an environmental cue is associated with reinforcement such as a food bait reward (Packard and Knowlton, 2002). The stimulus-response associations develop and strengthen with repeated presentation of the reinforcement for long-term, reference memory applications (Packard and White, 1990; White and McDonald, 2002). Thus, the significantly greater number of reference errors and borderline greater number of working errors committed by manganese-exposed animals evidences deficits in both short and long-term learning abilities. Notably, these deficits were most pronounced during the active learning (acquisition) phase of the radial maze test period, and were not evident in the ‘performance’ phase of maze testing where manganese-exposed animals did not differ significantly from controls.

These radial maze learning deficits are consistent with the significant changes in levels of D1, D2, and DAT measured in manganese-exposed animals on PND 24. In addition to regulating reactivity to external stimuli, the ascending dopamine system is involved in the integration of external stimuli necessary for goal-directed learning (Arnsten, 2006; Goldman-Rakic et al., 2000; Grace, 2000; Grace et al., 2007; Seamans et al., 2001; Williams and Goldman-Rakic 1995; Williams and Goldman-Rakic, 1998). An intact dopaminergic cortico-striato-thalamo-cortical loop is essential for proper evaluation of external stimuli in goal-directed

behaviors, and is the main interface for the dopaminergic system's influence on behavior (Carr et al., 1999; Pattij et al., 2007). Thus, the altered D1, D2, and DAT protein levels observed here may be an underlying contributor to the significant learning deficits in manganese-exposed animals, and together suggest an impaired ability to regulate reactivity, establish appropriate contextual associations with environmental cues, and process and establish stimulus-reward associations required in learning the maze (Haber et al., 2000; Johansen and Sagvolden, 2004). The significantly increased use of stereotypic response strategy by manganese-exposed animals in the 8-arm radial maze is further evidence of disrupted learning behavior....

In summary, pre-weaning Mn exposure produced deficits in behavioral inhibition, and spatial and associative learning that were associated with significant alterations in dopamine receptors and DAT levels in selected brain regions. These results, together with animal studies showing that Mn targets the dopaminergic system (Chen et al., 2006; Donaldson, 1985; Eriksson et al., 1992; Guilarte et al., 2006; Newland et al., 1989; Newland, 1999; Yamada et al., 1986), and epidemiologic studies in children showing associations of cognitive deficits and attention deficit hyperactivity disorder (ADHD)-like behaviors with elevated Mn exposure (Bouchard et al., 2007; Collipp et al., 1983; Ericson et al., 2007; Wasserman et al., 2006; Wright et al., 2006), support the notion that early elevated Mn exposure produces behavioral deficits by targeting dopaminergic pathways of executive function. This suggestion is consistent with animal model studies linking disruption of the dopaminergic system to ADHD-like behavioral deficits in executive function (Giedd et al., 2001; Oades et al., 2005; Schrimsher et al., 2002; Swanson et al., 1998), and with recent human studies reporting altered DAT binding in striatum, substantia nigra, and ventral tegmentum in adults and children with ADHD (Jucaite et al., 2005; Larisch et al., 2006; Madras et al., 2005; Spencer et al., 2007). Together, these results support a need for further animal model and human studies to establish the causal relationship between early Mn exposure and persistent cognitive and ADHD-like deficits, and the mechanistic basis of these effects."

As noted in other related comments, DEP did not use this study to establish a dose-response curve. As described above, DEP disagrees with the commentator that the results are inconsistent and that the manganese doses used in the study prevent any extrapolation of the findings to humans.

- 89. Comment:** Beaudin et al. (2013) studied neonatal rats to determine the effects of early-life and continuous exposure to oral manganese (0, 25, and 50 mg/kg-day) on sensorimotor performance. For early-life exposure, rats were administered manganese via oral gavage for the first 22 days after birth, which corresponded to blood manganese concentrations of 23.6, 186, and 267 µg/L in the 0, 25, and 50 mg/kg-day groups (respectively). For continuous exposure, rats were administered manganese via drinking water from birth to approximately 400 days of age, which corresponded to blood manganese levels of 5.81, 9.7, and 13.7 µg/L in the 0, 25, and 50 mg/kg-day groups (respectively). Behavioral testing began at 120 days of age for all groups. Using a procedure that required the rats to navigate a staircase and gather

food pellets (the "staircase test"), the authors found that early-life exposure to 50 mg/kg-day manganese impaired fine motor control. Further, the authors observed that 25 mg/kg-day manganese delivered continuously impaired fine motor control but 50 mg/kg-day manganese did not impair behavior. This study is limited because it used only two doses of manganese, which is insufficient to generate a full dose-response curve. Further, several inconsistencies related to the exposure regimen and blood manganese concentrations introduced uncertainty in interpretation of the results. These include (1) using higher manganese water concentrations than what would be typically encountered in humans and (2) blood manganese concentrations were over 10 times lower in the rats who received manganese continuously relative to those who received manganese for 22 days in early life. This suggests a potential species difference between rats and humans that limits the generalizability of Beaudin et al.'s (2013) findings. Because of uncertainty due to the use of water manganese concentrations much higher than would be typically encountered in humans and a lack of information about rodent manganese requirements, this study should not be extrapolated to humans. (618)

Response: DEP disagrees with the commentator's assessment that the decrease in blood manganese levels over time suggests a potential species difference and there is uncertainty in the results which prevents the data from being extrapolated to humans due to the water concentration doses used in the study.

As previously described in responses to Comments 87 and 88, the drinking water manganese doses used in the study were set at the specified levels to mimic equivalent human exposure values. See the above comments for a more detailed response.

Based on the available literature on manganese, we know that the adult body's homeostatic control mechanisms have some ability to adapt to increased manganese entering the body. If a moderately-increased exposure scenario continues for a sufficient length of time, the body will begin to adjust for the increased burden and become more efficient at controlling absorption and excretion of manganese. The liver will begin excreting more manganese in the bile, the expression of metals transporters within cells will decrease and so on. Therefore, it is not surprising that blood concentrations are decreased in the long-term exposure group. However, it is important to also recognize that many factors influence an individual's ability to adapt to increased levels of manganese, and at high enough exposure levels, the body's control systems will be overwhelmed even in healthy adults.

In addition, it is recognized that neonates and infants continuing through an as-yet uncharacterized period of development, are less able to adapt. The homeostatic controls in these individuals are either not fully developed or function differently than older children and adults. Thus, the difference in blood levels is again not surprising. Furthermore, the authors did observe slightly, though significantly, elevated levels of manganese in the brain and blood of the lifelong exposure group, but not in the early-life-only exposure group.

The results of Beaudin et al. showed "that early life manganese exposure restricted to the pre-weaning period produced selective long-lasting impairment in reaching skills in adults, and that lifelong manganese exposure produced wider-spread deficits in both reaching and

grasping skills. Early (pre-weaning) exposure at the highest dose (50 mg Mn/kg/day) lead to deficits in forelimb sensorimotor function in the adults approximately 3 months after their last oral manganese dose, when blood and brain manganese levels had long since returned to background levels. The authors note “these long-lasting deficits suggest permanent or irreversible damage to the basal ganglia systems of the adult rat brain as a result of early life manganese exposure, consistent with evidence from our prior studies showing that adult (postnatal day 100) rats exposed to the same levels of pre-weaning manganese early in life exhibited increased expression of dopamine D2 receptors and activated astrocytes in frontal – subcortical neuronal circuits.”

“Lifelong oral exposure to manganese produced widespread impairment in skilled motor performance that was apparent across multiple staircase test outcomes in adult rats.” No effect was observed in the early life exposure group receiving 25 mg Mn/kg/day, but the authors did observe significant effects on behavior in the lifelong exposure group receiving 25 mg Mn/kg/day. In contrast, behavior was selectively affected in the early life group receiving 50 mg Mn/kg/day and those effects continued to be observed in the lifelong group receiving 50 mg Mn/kg/day. The lifelong group also consumed fewer food pellets. The authors concluded, “overall the continuous exposure to 50 mg Mn/kg/day in drinking water caused little *additional* impairment in skilled motor behavior beyond that produced by early life exposure at the same dose.” Additional research to examine the reasoning behind these observed effects would be helpful, but this research supports the link between manganese exposure in infants and children and developmental neurotoxicity. Beaudin et al. (2013) was funded by a grant from the National Institutes of Health.

90. Comment: Moreno et al. (2009) conducted an experiment in C57BL/6 mice to determine the effects of juvenile and adult manganese exposure on motor behavior and neurotransmitter levels. Mice were administered manganese via oral gavage (0, 4.4, and 13.1 mg/kg-day) as juveniles, adults, or as both. The authors reported serum manganese levels of 0.2-0.35 ppm (equivalent to 200-350 µg/L manganese). Motor ability was assessed using an open-field test similar to Kern et al. (2010). The authors reported that female mice behavior was not affected by manganese exposure as juveniles, adults, or both. Male mice who received 10 and 30 mg/kg-day manganese as juveniles spent less time on the periphery of the open field (i.e., showed less fear/anxiety behavior), whereas male mice who received 10 and 30 mg/kg-day manganese as both juveniles and adults spent more time on the periphery (i.e., show more fear/anxiety behavior). manganese exposure did not affect movement time in any group, with the exception of male mice receiving 30 mg/kg manganese as juveniles and adults, who displayed fewer movements per minute. Brain and serum manganese levels often did not display a dose-response relationship, such that manganese levels in controls were sometimes higher than manganese levels in manganese-exposed mice. Overall, this study is limited by (1) its use of high doses of manganese, which would not be typically encountered in humans, and (2) inconsistent behavioral findings in that manganese exposure was associated with both increased and decreased fear and anxiety behavior in male mice. These limitations, including a lack of information about rodent manganese requirements, prevent using this study to draw conclusions about manganese in water and potential health effects in humans. (618)

Response: See responses to Comments 87 and 88 for a detailed response to the comment regarding the manganese doses used in the study.

Regarding the behavioral findings, the authors stated that the observation of higher manganese levels in the control mice than those in the treatment groups for the juvenile may have been due to either stress resulting from juvenile gavage or to experimental variation between the two study groups. As this study was the first to report such findings, either possibility could not be ruled out and additional studies would be needed to confirm the findings. Nonetheless, this study provides important information on the neurobehavioral effects of ingested manganese. The study showed that the period of development in mice spanning weaning to early adulthood represents a critical window of sensitivity and that male mice are more severely affected than females. Furthermore, the study found that pre-exposed adult mice were not only more sensitive to manganese toxicity than naïve mice not exposed early in life, but this pre-exposure also resulted in greater effects on both dopaminergic and serotonergic neurochemical parameters in the brain.

Emerging studies on epigenetics and exposure to metals, including manganese, may eventually be able to explain some of the observations of studies such as Kern et al. and Moreno et al., including sex-related differences in response. Epigenetics describes the heritable changes in gene expression without mutations to the DNA sequence. In other words, the genetic code doesn't change, but how cells read and translate the code does change. Studies have been published evaluating the effects of manganese on epigenetic regulation, specifically DNA methylation.

Studies by Qiao et al. (2015) and Tarale et al. (2016) have examined the role of epigenetics in manganese induced neurotoxicity. Qiao et al. noted that "manganese has been reported to disturb dopamine metabolism via direct oxidation of monoamine oxidase activity in brain mitochondria (Shih 2004)." Qiao et al. also report that "environmental factors, biological and chemical, have long-lasting phenotypic effects without apparent underlying genetic change through epigenetic modifications. In other words, environmental factors may change the gene expression directly or indirectly through epigenetic alterations such as DNA methylation or histone modifications. These epigenetic changes in the development stages due to prenatal exposure to the environmental factors including manganese may contribute to the abnormal phenotype including neurodegeneration. It has been reported that epigenetic gene regulation may contribute to manganese-induced neurogenesis in mouse offspring after maternal exposure to manganese. Sustained promoter hypermethylation of Mid1, Atp1a3, and Nr2f1 and transient hypermethylation in Pvalb and consequent down regulation of these genes were found in mouse offspring after maternal exposure to manganese (Wang et al., 2013)".

Human studies by Maccani et al. (2015) and Appleton et al. (2017) found that prenatal exposure to increased levels of manganese and other neurotoxic metals changes DNA methylation patterns in the placenta. Maccani et al. stated "these results suggest that in utero manganese exposure may result in potentially harmful disruption to normal placental and fetal growth and development, which is important considering existing links between placental methylation patterns and fetal growth (Wilhelm-Benartzi et al., 2012; Banister et al., 2011) and neurobehavior (Bromer et al., 2013; Lesseur et al., 2014).

91. Comment: There is no conclusive evidence to suggest that manganese bioavailability differs between food or water ingestion. In fact, EPA's own assessment (EPA, 2002) includes discussion of an unpublished study by Ruoff (1995) that evaluated the relative bioavailability of manganese in food and water and found no significant differences. Although EPA (2002) discussed possible increased manganese uptake in fasted individuals as a source of concern and additional basis for the MF of 3, there are no published studies that provide support for this concern. (3, 618)

Response: DEP disagrees with the statement that there is no evidence to support differences in the bioavailability and absorption of manganese when manganese is ingested with food/meals versus drinking water only (i.e., a fasted state). Although the 1995 EPA IRIS Chemical Assessment Summary for manganese, in reference to the study by Ruoff (1995), does state that “the relative bioavailability of manganese from food compared with that from drinking water was determined to be 0.7 and not statistically significantly different”, the IRIS summary also states that “when the data were reanalyzed to include only the ingestion of manganese in drinking water by fasted individuals, the relative bioavailability was 0.5, indicating roughly a 2-fold greater uptake of manganese from drinking water compared with uptake from food.”

WHO (2020) noted that reliable quantitative data comparing bioavailability and absorption of different chemical forms of manganese from drinking water was not found. The report referenced absorption studies by Johnson et al. (1991) and Schwartz et al. (1986). Schwartz et al. found that adult male volunteers on a high-fiber diet containing 12-17.7 mg of manganese per day absorbed an average of between $7.6\% \pm 6.3\%$. Johnson et al. (1991) studied “the absorption of radiolabeled manganese from various plant foods in adult men and women and reported that absorption ranged from 1.4% to 5.5% and was significantly lower than the mean values of 7.8%-10.2% from controls receiving Mn(II) Chloride dissolved in water.” WHO found that oral studies in animals generally yielded similar results with respect to absorption and cited Pollack et al. (1965), Davis et al. (1993), Finley et al. (1997) and Zheng et al. (2000). Thus, there is evidence that absorption rates vary in adults for fasted vs. non-fasted states.

It is also recognized by WHO (2020) and Health Canada (2019) that there are additional factors that can influence the bioavailability of manganese from food sources that would generally not be present in drinking water including dietary fiber, oxalic acids, phytate/phytic acids, tannins and other minerals. WHO cited to Chen et al. (2018), Gibson (1994), IOM (2001), USEPA (2002), Aschner et al. (2005), ATSDR (2012), and Freeland-Graves & Llanes (1994). WHO also mentioned absorption of manganese being closely linked to iron absorption and noted that iron-deficient diets lead to an increased absorption of both iron and manganese (Thompson et al., 1971; Sandstrom et al., 1986; Finley, 1999).

92. Comment: Unlike other substances for which EPA has derived oral RfDs based on studies of adverse health effects, the manganese RfD derived by EPA in 1995 and last reviewed in 2002 is not based on a study of adverse health effects, but instead is based on a UL of manganese that is considered safe. The EQB’s proposed manganese WQ criterion relies on this RfD, and on an MF of three applied to that RfD that is also recommended by EPA for evaluating risk

from non-food exposure pathways, including drinking water. The main reasons EPA describes as supporting the need for application of the modifying factor are:

- 1) some studies suggested possible adverse health effects in humans following a lifetime consumption of 2 mg/L manganese in water, and
- 2) there was concern for possible increased uptake of manganese from water compared to food, particularly in infants.

However, our review of the studies available at that time indicates that there was no conclusive evidence to support either of these concerns. In fact, EPA described a number of limitations in the human drinking water studies and noted that none of the human studies were of sufficient quality to use to derive an oral manganese RfD.

EPA's lifetime HAL for manganese in drinking water of 0.3 mg/L includes an MF of 3 to account for these concerns (EPA, 2004). Similarly, WHO also has established a health-based value for Mn of 0.4 mg/L, which includes an MF of 3 to account for possible increased manganese bioavailability from water (WHO, 2017). However, EPA's (2002) reasoning for including an MF of 3 is now 17 years old and not consistent with the current science for manganese. Since EPA's (2002) assessment, several important studies have been published that assuage concerns related to possible increased bioavailability of manganese in drinking water. These studies also apply to WHO's (2017) health-based value and other state regulatory bodies that applied an MF of 3 for manganese drinking water values based on similar reasons of concern to those stated above. (3, 618)

Response: DEP disagrees with the commentators' assertions that the PBPK model studies and Foster et al. (2015) study assuage any concerns related to increased bioavailability of manganese in drinking water and with the suggestion that EPA's 1995 IRIS recommendation and 2003 update for oral exposure was inappropriate. See responses to Comments 58, 59, 65, 75 and 91 for additional discussion on the PBPK models, bioavailability, and EPA's IRIS recommendation/2003 update.

Manganese Toxicity and Effects on Aquatic Life, Agriculture and Other Water Uses; Opposition to the Proposed Manganese Criterion of 0.3 mg/L

93. Comment: EPA does not identify manganese in its “national-recommended-water-quality-criteria-aquatic-life-criteria-table” as a pollutant of concern (not listed). (862)

Response: EPA's lack of a national manganese criterion recommendation does not imply that manganese is not toxic or a pollutant of concern. Much like the States, EPA does not have infinite resources to develop criteria recommendations for every possible pollutant in existence. Thus, they tend to focus their limited resources on developing recommendations for pollutants that are of national concern and priority. Elevated levels of manganese in surface waters are not an issue for many states. Manganese tends to be a regional problem. Regardless of whether or not EPA has a national recommendation for a particular pollutant, States still have the responsibility to develop WQ criteria necessary to protect their State's designated uses. The federal regulations, at 40 CFR § 131.11(a)(2), state the following:

“States must review water quality data and information on discharges to identify specific water bodies where toxic pollutants may be adversely affecting water quality...or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use.”

94. Comment: Manganese is generally not considered toxic to aquatic organisms when concentrations are below 2 mg/L. In the commentator's experience, when treated wastewater effluent containing manganese is subjected to whole effluent toxicity testing (WETT), neither acute or chronic toxicity is observed at levels much greater than 2 mg/L. There is no risk or benefit to the receiving streams by lowering the manganese discharge limit. (8)

Response: WETT does not necessarily account for or predict how an effluent will react once it mixes with the receiving water and begins to travel downstream. The presence of other substances and characteristics of the effluent may reduce the toxicity of the manganese at the point of discharge and cause the manganese, along with other metals, to be in a biologically unavailable form. However, the manganese is still present in the effluent and is discharged. A receiving water may experience significant changes in WQ as the water travels downstream. The behavior of manganese in surface waters is complex, and the bioavailability of manganese is affected by pH, salts/total dissolved solids (TDS) and other factors, which can fluctuate significantly in streams, especially as tributaries of different WQ enter into the receiving water.

Furthermore, WETT is typically conducted using only two species of organism (Daphnia and fathead minnow) and doesn't consider possible impacts to potentially more sensitive species, such as mayflies or freshwater mussels.

95. Comment: The proposed rule states that because the proposed human health criterion for manganese is more stringent than the current criterion for protection of use as a potable water supply, its application to all surface waters would be protective of other uses. However, the human health criterion is far more restrictive than is necessary to protect other surface water uses and would require dischargers to install costly upgrades to their effluent treatment systems with no benefit to the receiving stream. Rather than relying on the human health criterion to be protective of other surface water uses, an in-stream WQS should be developed for the specific protection of aquatic life and other designated uses, which is likely to be well above the 0.3 mg/L proposed human health criterion. An example of this, brown trout (*Salmo trutta*) a widespread, recreationally important, and sensitive cold water fish species, has a reported growth and survival effect concentration (IC₂₅) of 4.95 mg/L for manganese. This indicates a WQS for the protection of aquatic life would be well above the proposed 0.3 mg/L; and therefore, the proposed criterion is far more restrictive than is necessary to protect aquatic life and other designated uses. (497)

Response: DEP disagrees that the application of the proposed human health criterion for manganese in all surface waters would provide no benefit to the stream. DEP does not generally develop single pollutant criteria for every protected water use. DEP evaluates the available scientific data and literature and develops a criterion for the most sensitive statewide use. The federal regulations, at 40 CFR § 131.11(a) state: “For waters with

multiple use designations, the criteria shall support the most sensitive use.” In doing so, all other uses are afforded protection. DEP’s review of the available peer-reviewed data has indicated that people, specifically infants and children, are the most sensitive organism to be protected.

It is not uncommon for data gaps to exist in the scientific literature that is available for criteria development, and the extent of the data gaps will vary for different uses and different criteria. Adopting the most protective criterion for a statewide use is appropriate because DEP is obligated to establish criteria to protect all of the designated water uses. If a protected water use applies statewide in all surface waters, then the criterion should likewise apply in all surface waters. In addition to numeric criteria, Chapter 93 specifies in § 93.6 that “waters may not contain substances attributable to point or nonpoint source discharges in concentrations or amount sufficient to be inimical or harmful to the water uses to be protected or to human, animal, plant or aquatic life.” These general WQ criteria also recognize that chemical mixtures can have synergistic effects that lead to toxic conditions where such conditions would otherwise not exist. Most toxicology studies test a single pollutant under controlled, laboratory conditions, which may not always reflect actual exposure conditions.

In line with these general WQ criteria, a statewide application of a criterion for a specific use or user assists in protecting other water users, including aquatic organisms, wildlife, livestock and others, that may not be as well-studied as the organisms upon which the criterion is based. For example, freshwater mussel research has increased significantly in recent years. These organisms represent one of the most imperiled groups on the planet, and until recently, were largely unstudied. Newer research has demonstrated that mussels, particularly juvenile and young mussels, are very sensitive to many pollutants. Thus, these organisms may not be adequately protected by some of the existing aquatic life criteria due to the data gaps that existed at the time of criteria development. As such, and in this example, the more stringent criteria necessary to protect human health may also provide additional protections for these aquatic organisms.

The commentator suggests that aquatic life criteria would be much less stringent based on data for one fish species; however, aquatic life criteria development is complex. In following EPA’s approved guidelines, DEP would need to review all of the available peer-reviewed literature for every relevant aquatic organism in developing an aquatic life criterion for manganese. Aquatic life criteria development requires a certain amount of data, including a minimum number and variety of species, and the criterion will always be based on a grouping of the most sensitive species. In addition, metals criteria development is beginning to utilize more complex modeling, such as Biotic Ligand Models, rather than more simple hardness-based equations. It is unclear at this time what an aquatic life criterion would look like and whether it would be much less stringent than the proposed human health criterion.

Furthermore, all of the existing 122 toxics criteria in Table 5 that were developed for the protection of human health currently apply in all surface waters consistent with DEP’s regulations and policies. In addition, the Potable Water Supply use is a statewide protected use, applicable in all surface waters except where specifically removed in §§ 93.9a-93.9z.

96. Comment: *The human health criterion is overly protective of aquatic life and other uses based on other States' criteria and toxicity data:*

- If DEP requires “that this criterion should apply in all surface waters (i.e., at the point of discharge),” as stated in their 2019 executive summary to the EQB (DEP 2019) the human health manganese AWQC would be overprotective of aquatic life, livestock, recreational, and fish-ingestion uses. In the proposed rulemaking DEP also states that “the adoption and implementation of a human health criterion in all surface waters in accordance with the proposed regulation should also provide adequate protection to aquatic life and livestock from the toxic effects of manganese” (DEP 2020). While this statement that the proposed criterion “should also provide adequate protection to aquatic life and livestock” is a true statement, it is actually overprotective of both of the mentioned designated uses. EPA has not developed nationally-recommended aquatic life criteria for manganese, so a comparison to a federal criterion is not possible. However, multiple states have developed their own aquatic life criteria, and all are substantially higher (i.e., less stringent) than the proposed DEP criteria. For example, Wyoming has adopted acute and chronic aquatic life criteria of 3.1 and 1.5 mg/L, respectively (WAR Chapter 1, ref. # 020.0011.1.04242018). Other states have developed hardness-based aquatic life criteria to account for the ameliorative effect hardness has on manganese toxicity. Colorado (5 CCR 1002-31), Illinois (35I.LCS §302.208), and New Mexico (20.6.4.900 NMAC) have developed hardness-based aquatic life criteria for manganese. The hardness-based criteria adopted in Colorado and New Mexico are the same equations, which were derived using a toxicity database developed in May 2000. The most sensitive species in the acute database is rainbow trout (*Oncorhynchus mykiss*), with a species mean acute manganese value of 5.3 mg/L (acute value normalized to 50 mg/L hardness; ENSR 2000). The most sensitive species in the chronic database is brook trout (*Salvelinus fontinalis*), with a species mean chronic manganese value of 2.7 mg/L (chronic value normalized to 50 mg/L; ENSR 2000). As noted, these acute and chronic values are normalized to a hardness of 50 mg/L to allow for direct comparisons to other studies and represents a conservative estimate on manganese toxicity. A more recent literature search conducted on behalf of the PA Coal Alliance identified five additional/newer toxicity studies (Tetra Tech 2020). The studies they identified acute toxicity effect thresholds ranging from 8.6 to over 1,300 mg/L, and chronic toxicity effect thresholds ranging from 4.6 to 20.7 mg/L. Therefore, the toxicity studies used to derive the aquatic life criteria in Colorado and New Mexico still represent the most sensitive species tested to date. To further illustrate how these hardness-based aquatic life criteria would relate to PA surface waters, we identified hardness concentrations in the Conemaugh River, near the [commentator’s] permitted outfall. The average hardness concentration from the most recent 5 years of data from DEP monitoring Site #810 on the Conemaugh River, results in a hardness concentration of 159 mg/L (NWQMC 2020). Applying this hardness concentration to the Colorado and New Mexico hardness-based manganese aquatic life criteria equations would result in acute and chronic manganese criteria of 3.5 mg Mn/L and 1.9 mg Mn/L, respectively. In another example, applying the same hardness value to the Illinois hardness-based equations would result in even less stringent criteria at an acute value of 5.1 mg Mn/L and a chronic value of 2.21 mg Mn/L.

Applying DEPs proposed human health criterion to all waters thus is not necessary to protect aquatic life, given that even the most stringent acute and chronic aquatic life criteria for manganese are 10x and 5x, respectively, higher than the proposed 0.3 mg Mn/L value. Therefore, there is no need to adopt a lower manganese criterion of 0.3 mg/L to protect aquatic life because the existing 1.0 mg/L Potable Water Supply use criterion is already more stringent than is needed to protect this use. (832)

- The proposed change to the manganese critical use and criterion is unnecessary on account of the adequacy of the existing 1 mg/L criterion to protect aquatic life. In their review of aquatic life toxicological information, Tetra Tech (2020) found that manganese is not toxic to aquatic life at concentrations less than the existing criterion. The most sensitive species with acute toxicity to dissolved manganese was found to be the freshwater scud with an acute toxicity concentration of 8.6 mg/L, while the most sensitive species with chronic toxicity to dissolved manganese was found to be the brown trout with a chronic toxicity concentration of 4.6 mg/L. This analysis demonstrates that these species, and by extension the species less sensitive than they, are already protected by the existing criterion. (935, 951)
- If DEP requires “that this criterion should apply in all surface waters (i.e., at the point of discharge),” as stated in their 2019 executive summary to EQB (DEP 2019), the human health manganese AWQC does not need to be lowered from 1.0 to 0.3 mg /L to be protective of aquatic life, livestock, recreational, and fish-ingestion uses. In the proposed rulemaking DEP also states that “the adoption and implementation of a human health criterion in all surface waters in accordance with the proposed regulation should also provide adequate protection to aquatic life and livestock from the toxic effects of manganese” (DEP 2020). While this statement that the proposed criterion “should also provide adequate protection to aquatic life and livestock” is accurate, the existing 1.0 mg/L manganese criterion is protective of both the mentioned designated uses.

The commentator has reviewed, and supports, comments filed for this rulemaking by the North American Coal Corporation (NA Coal) which include a technical memorandum from GEI Consultants, Inc. (GEI) regarding the overprotective nature of the proposed human health criterion for other surface water uses. This memorandum (GEI 2020) conclusively demonstrates that lowering the human health criterion to 0.3 mg /L is far more stringent than is required to protect aquatic life uses. This is because the existing aquatic toxicity literature shows that even the most sensitive aquatic species (brook trout [*Salvelinus fontinalis*]) would be protected from chronic exposures at as low as 2.7 mg/L. Furthermore, other states with manganese aquatic life protection standards (e.g., New Mexico, Colorado, Illinois, and Wyoming) use criteria up to 5x to 10x higher than DEP’s proposed criterion of 0.3 mg/L. Therefore, the commentator concludes it is not necessary to reduce the human health criterion from 1.0 to 0.3 mg/L to protect aquatic life (and other uses; see GEI 2020). (880)

- There are no “Quality Criteria for Water” for manganese established by EPA to protect aquatic life, which is due to the near absence of manganese toxicity to fish and aquatic life. An evaluation was conducted to obtain, review and summarize published peer

reviewed manganese aquatic life toxicity information. Pollutants, such as dissolved metals, can be either acutely toxic causing mortality or have long term effects related to survival, growth and reproduction. The EPA publishes criteria documents that States may choose to adopt as WQSs. These documents recommend criterion maximum concentrations (CMC) to prevent short term or acute toxicity impacts and criterion continuous concentrations (CCC) to prevent long term chronic toxicity impacts to aquatic life (or human health) in surface water. In the case of manganese, EPA has not published any criteria document for manganese. A literature search was conducted for publicly available publications related to manganese toxicity to aquatic life. The information available was somewhat limited. This is, in part, due to the relatively low toxicity of manganese to aquatic life and therefore lack of interest on the part of researchers.

The commentator summarized chronic aquatic life toxicity data from toxicological information obtained from journals, reports, and theses. Only moderate hardness test water conditions are provided in the table, which represents mid-range manganese toxicity as manganese toxicity is highly hardness dependent. Several studies documented this hardness dependency that indicates the aquatic life toxic concentration of manganese increases as hardness increases. The available aquatic life toxicity information included acute toxicity (e.g., 96-hr LC50) and chronic toxicity (e.g., lowest observed effect concentration (LOEC)) for a number of aquatic species including mollusks, crustaceans, insects and fish. A number of these aquatic species are known to be sensitive to pollution. While the vast majority of research in EPA'S ECOTOX database for aquatic life toxicity was conducted on species not native to Appalachia or in some instances the United States and not appropriate for use in a criteria calculation, ECOTOX does indicate that manganese has low toxicity to aquatic life.

The most sensitive reported aquatic species with acute toxicity to dissolved manganese is the freshwater scud (*Hyalella azteca*) with an acute toxicity concentration of 8.6 mg/L. Manganese in a concentration range of 13 to 20 mg/l has been reported to have acute toxic effects on some salmonid species. The aquatic species with the most sensitive chronic toxicity to dissolved manganese is brown trout (*Salmo trutta*) with a growth effect concentration of 4.6 mg/L. This species was followed closely by an algae (*Scenedesmus quadrangularis*) with a growth effect of manganese at 5.0 mg/L. Because the hardness concentration of surface water affected by mine drainage is much greater than the laboratory test conditions reported in these studies, the concentration at which manganese is acutely toxic to aquatic species in that environment will be greater than shown in Table 1. Overall, it is evident that the BAT effluent limits of 2.0 mg/L average monthly and of 4.0 mg/L daily maximum, as total manganese, provide adequate protection for freshwater fish and aquatic life, even at the low hardness concentrations of the laboratory test water. (618)

Response: The 0.3 mg/L is a human health criterion, which was developed to protect the most sensitive endpoint. The current criterion of 1.0 mg/L is not a human health criterion or aquatic life criterion. It is unclear at this time what an aquatic life criterion would look like for Pennsylvania. While it is not uncommon for States to examine other State's criteria, each State must develop and adopt WQ criteria that are appropriate for the protection of their

designated uses and surface waters. DEP disagrees that EPA's lack of a national recommended criterion is due to overall low toxicity and lack of researcher interest.

DEP is aware that some States have adopted hardness-based aquatic life criteria for manganese. DEP is also aware that metals criteria development is generally moving away from hardness-based equations to more complex modeling, such as the Biotic Ligand Model. The commentators reference criteria adopted by Colorado, Illinois, Wyoming and New Mexico. DEP is not developing aquatic life criteria, but if DEP were to develop aquatic life criteria, it would be based on the most current peer-reviewed scientific data and literature. It would also need to follow the current criteria development recommendations, including any guidance and recommendations from EPA, and consultation with the National Marine Fisheries Service or U.S. Fish and Wildlife Service.

As previously stated, DEP has not conducted an extensive review of aquatic life toxicity literature at this time because the most sensitive protection needed was identified as the protection of human health.

See the responses to Comments 97 and 98 for additional discussion.

97. Comment: Other states have acknowledged, and EPA has concurred, that an aquatic life criterion for manganese is not necessary. Until the mid-1990s, West Virginia maintained a WQ criterion of 1.0 mg/L for manganese in streams classified as either public drinking water supplies or aquatic life uses. In 1997, after an exhaustive review of technical information and supporting scientific data, the West Virginia Environmental Quality Board deleted the aquatic life criterion for manganese. EPA Region III subsequently approved the deletion of the aquatic life criterion for manganese. (618)

Response: DEP has concluded that the most sensitive protection needed is for the protection of human health, and therefore is not pursuing the development of an aquatic life criterion. Based on EPA's preliminary review and public comment on the proposed rulemaking, EPA Region 3 supports the development and the science of this final-form rulemaking and, specifically, the human health criterion.

98. Comment: The proposed 0.3 mg/L criterion is unnecessary to protect fish and aquatic life because manganese is not toxic to aquatic life at concentrations expected to be encountered in PA. EPA has not developed criteria to prevent acute or chronic toxicity to aquatic life in surface water. The Tetra Tech report summarizes data indicating that the federal coal industry BAT limits of 2 mg/L (monthly average) and 4 mg/L (daily maximum) protect fish and aquatic life, including the most sensitive aquatic species. At [the commentator's] mine site, we re-mined a previously abandoned site under a Sub-Chapter F permit using the manganese exemption in 25 Pa. Code § 87.102(c)(2). Even without manganese treatment, the instream manganese concentration at our downstream monitoring point has not exceeded 1 mg/L since 1990. Our operations have contributed much-needed alkalinity to the watershed, the receiving streams are no longer impaired, and aquatic life is thriving as evidenced by regular macroinvertebrate sample data. Our experience confirms manganese does not threaten aquatic life at concentrations encountered in PA. (901)

Response: As stated in the response to Comment 95, DEP does not generally develop single pollutant criteria for every protected water use. DEP evaluates the available scientific data and literature and develops a criterion for the most sensitive statewide use. In doing so, all other water uses are afforded protection. DEP has concluded that the most sensitive protection needed is for the protection of human health. DEP must protect statewide water uses and users in accordance with all applicable laws and regulations. Fishing, Water Contact Sports, and Potable Water Supply uses are all statewide protected water uses, and thus, criteria to protect these uses generally apply in all surface waters. In addition, all 122 human health toxics criteria contained in Table 5 currently must be met in all surface waters.

Manganese levels in surface waters vary widely across this Commonwealth. While DEP generally agrees that natural background levels of manganese are low in many regions, toxic concentrations are known to occur in areas impacted by AMD or by significant anthropogenic disturbances. Additionally, the existing Potable Water Supply use criterion for manganese limits the amount of manganese that can be legally discharged. Unlike the mining industry, not all dischargers have other regulations in place to limit discharges of manganese. If the point of compliance for the criterion would have been moved to the nearest downstream potable water supply withdrawal, there would be no technology-based limits in place for many permitted industries and dischargers to ensure that their discharges of manganese would not create toxic conditions for aquatic life or other protected uses.

DEP recognizes that the remining efforts of present-day coal companies play an important role in remediating the historical environmental pollution that has resulted from past mining companies abandoning their mine lands. DEP supports these beneficial projects and is working to ensure that the regulation will have minimal impact on remining.

99. Comment: In 1995, a Penn State University professor, Dr. Dean Arnold, assisted by Penn State graduate students, began monitoring the benthic macroinvertebrate community in Otter Run in Lycoming County for impairment from exposure to manganese. Later, in 1998, Normandeau Associates took over monitoring, and in 2000 a new sampling and data analysis methodology was developed by a work group that included consultants, the Pennsylvania Fish and Boat Commission (PFBC), and USGS, which was put in effect in August 2000 and continues today. This methodology, which is used in determining a significant loss of biota, has resulted in the determination that the benthic macroinvertebrate community is not considered impaired at the manganese levels measured, which frequently exceeded 2 mg/l, often by more than double. (618)

Response: DEP received and reviewed a copy of the Otter Run report during the public comment period of the ANPR for manganese.

DEP develops and implements assessment methodology to satisfy reporting requirements of CWA sections 303(d), 305(b), and 314 (33 U.S.C.A. §§ 1313(d), 1315(b) and 1324). Section 303(d) requires states to develop a list of waters that will not meet all WQS after implementation of discharge controls; and for each water identified on the list, DEP must develop a TMDL. DEP assessments are developed, publicly participated, finalized and

compiled in accordance with the *Assessment methodology for rivers and streams* (Shull and Pulket 2018).

In addition to the data DEP collects, DEP readily accepts and values all data from outside agencies and the public for use in making assessments. However, different data types and levels of quality assurance determine how exactly those data are used. DEP's tiered data acceptance strategies follow the same general tiered framework as described by the Chesapeake Bay Monitoring Cooperative's Prioritization Report (Chesapeake Bay Monitoring Cooperative 2017). Tier 1 data is generally defined as educational or environmental screening data that has known quality and a study plan, but does not follow DEP or EPA quality assurance plans. These data will not be used for assessment determination purposes, but can be used by DEP to highlight areas of interest for future monitoring efforts. Tier 2 data have clearly defined quality assurance plans and procedures, but may not have followed DEP monitoring protocols described in the *Water Quality Monitoring Protocols for Streams and Rivers* (Shull and Lokenbill 2018). These data may not be used for assessment determination purposes, but can be used for other purposes such as trend or performance analysis. Tier 3 data are assessment level data that have approved quality assurance plans, follow appropriate study designs, and follow DEP monitoring protocols (Shull and Lokenbill 2018). Individuals seeking to provide DEP with Tier 3 data should also be trained and audited by DEP staff before submitting data.

The Otter Run report received during the public comment period of the ANPR for manganese:

- Describes multiple data collection protocols that are inconsistent with DEP data collection protocols,
- Describes an evaluation or assessment approach that is inconsistent with approved DEP assessment methodology,
- Does not include a Quality Assurance Project Plan,
- Includes data that was collected by individuals that were not audited by DEP staff, and
- Would not be appropriate for making assessments for 303(d) listing purposes.

100. Comment: Manganese treatment is dangerous to aquatic life:

- Manganese treatment is difficult and dangerous. While manganese has low toxicity to aquatic life, its treatment and removal can be highly dangerous for fish and invertebrates due to the tremendous increase in pH required for manganese removal. This is evident based on review of an Eh-pH diagram for manganese as compared to iron. Removal of manganese from mine drainage requires either high pH (generally greater than 9.0) or strong oxidation combined with near-neutral pH. Because of the difficulties in obtaining strong oxidation sufficient to remove manganese, pH adjustment is the primary form of manganese removal. Treating manganese to achieve a limit of 1mg/l requires significant caustic addition to achieve high pH levels in treatment ponds. High pH levels in the discharge can cause a more significant adverse harm to the receiving stream's aquatic life

than a manganese concentration in the discharge of up to 2 mg/l, which is the BAT standard. Therefore, the current point of compliance at or prior to the potable water supply withdrawal prevents treatment activities at the point of discharge that could overall cause harmful effects on the water chemistry of the receiving streams. (905)

- While manganese has low toxicity to aquatic life, its treatment and removal can be highly dangerous for fish and invertebrates due to the tremendous increase in pH required for manganese removal. This is evident based on review of an Eh-pH diagram for manganese as compared to iron. Removal of manganese from mine drainage requires either high pH (generally greater than 9.0, often at 10.5 or 11.0) or strong oxidation combined with near neutral pH. Because of the difficulties in obtaining strong oxidation sufficient to remove manganese, pH adjustment is necessary.

Treating manganese to accomplish a limit of 1 mg/l requires significant caustic addition to achieve high pH levels in treatment ponds. High pH levels in the discharge can cause a more significant adverse harm to the receiving stream's aquatic life than a manganese concentration in the discharge of up to 2.0 mg/l, which is the BAT standard. The national recommended criteria for pH is limited to 6.5 to 9.0 due to the impact on aquatic life. A pH range of 6.5 to 9.0 protects fish and aquatic life, which Pennsylvania has adopted as a WQ criterion in Chapter 93. Outside of this range, fish suffer adverse physiological effects increasing in severity as the degree of deviation increases until lethal levels are reached. Further, while aluminum is relatively insoluble at pH 6 to 8, the solubility of aluminum increases under alkaline conditions. Thus, increase in pH for treatment of manganese at 1.0 mg/l results in soluble aluminum, Al+4(OH)4, which is toxic to aquatic life. (618)

Response: The WQS regulations found in 25 Pa. Code Chapter 93 contain criteria for many pollutants, including pH and aluminum. For the protection of aquatic life, aluminum may not exceed 750 µg/L as an acute criterion, and pH must be maintained between 6 and 9. Permitted discharges must comply with these regulations, and an effluent limitation should be included in any NPDES permit where reasonable potential to exceed criteria has been demonstrated. If treatment processes would raise the pH of the effluent above 9 or result in an unacceptable level of aluminum in the effluent, additional treatment would be required prior to a discharge to surface waters to comply with the WQ criteria for pH or aluminum.

The current point of compliance for the manganese criterion is not at the point of downstream potable water supply withdrawal as indicated by Commentator 905. The current point of compliance for the manganese criterion is in all surface waters (that is, near the point of discharge). The point of compliance is not changing with this rulemaking.

101. Comment: The regulatory analysis of the proposal should be limited to an evaluation of the critical water use issues. The proposed change should not be expanded to develop new manganese criteria for aquatic life, especially in the absence of criteria recommended by the EPA or surrounding Appalachian states. Using the proposed rule as an opportunity to develop a new WQS that is protective of aquatic life seems to be beyond the scope of this rulemaking. First, there is no federal aquatic life standard for manganese, largely because

the EPA acknowledged that there is not adequate science to support the development of such a standard. While manganese has low toxicity to aquatic life, its treatment and removal can be highly dangerous for fish and invertebrates due to the tremendous increase in pH required for manganese removal. (862)

Response: DEP is required to protect all designated water uses and users of the surface water. This protection is generally achieved through the adoption and implementation of WQ criteria. As it has been explained in responses to other comments, DEP generally develops a criterion for the most sensitive statewide protected water use or user. At this time, human health has been determined to require the most stringent protection. Thus, DEP is not currently proposing an aquatic life criterion for manganese.

However, if a WQ criterion were needed to ensure aquatic life uses were protected, DEP would be obligated to develop a criterion. DEP disagrees that EPA acknowledges there is no science to support the development of an aquatic life criterion. As has been noted by other commentators, several states have aquatic life criteria for manganese, and EPA reviewed and approved the criteria for those states.

102. Comment: The other designated use DEP claims to protect from “toxic effects” is livestock. The EPA addressed “toxic effects” of manganese to livestock in the 1972 Water Quality Criteria, stating that “it is doubtful that setting an upper limit of acceptability is necessary for manganese, but as with iron, a few milligrams per liter in water can cause objectional deposits on stock water equipment” (EPA 1972). While the EPA has published recommended manganese concentrations for a broader agricultural designated use, the recommended value of the 0.2 mg Mn/L is specific to land applications of irrigation water for continuous use (EPA 1972). To summarize, the EPA recommends keeping manganese concentrations to “a few milligrams,” not because of potentially toxic effects, but rather to minimize “objectionable deposits.” (832)

Response: DEP is aware of this information from EPA regarding manganese and agriculture, and the information being referenced is now nearly 50 years old. During the rulemaking process, DEP met with the Department of Agriculture to discuss the proposed criterion. In response to DEP’s request for information, Dr. Kevin Brightbill, the state veterinarian, provided statements and information on the possible impacts of elevated manganese on livestock, including information from Dr. Robert Van Saun, DVM, MS, PhD, a large animal veterinarian with PSU and PennState Extension.

DEP agrees that manganese in drinking water is generally not directly toxic to livestock but, nonetheless, its presence can have negative consequences, especially in dairy cattle. The current recommended level of manganese for livestock watering, which is a statewide protected water use, is less than 0.05 mg/L due to palatability issues at higher levels. Information on the PennState Extension website indicates that when water contains greater than 0.05 mg/L of manganese, water intake in dairy cattle may decrease which may lead to a reduction in milk production. Information from Dr. Van Saun also indicated that higher than recommended levels of dietary manganese, whether from feed or water, have the potential to interfere with the absorption of other necessary dietary cations (such as, zinc, cobalt, iron and

copper) in the small intestine of cattle. For these reasons, the Department of Agriculture supports DEP's recommended manganese criterion of 0.3 mg/L applied in all surface waters.

General Support for the Second Alternative Point of Compliance (that is, Compliance at the Point of Discharge)

103. Comment: *Maintain the point of compliance at the point of discharge:*

- The commentator urges the EQB and DEP to protect human health and all uses of our streams by requiring that the discharge point remains the point of compliance for the proposed manganese standard. (16, 18-59, 62-72, 75, 79-88, 90-92, 94, 96-102, 104-496, 499, 501-588, 590-591, 598-610, 612-614, 616, 617, 619, 640, 687, 722, 765, 816, 836, 856, 868-870, 882, 898, 914, 928)
- The commentator requests that the manganese WQS's point of compliance remain at the point of discharge in order to hold dischargers accountable for manganese control and treatment and to protect waterways from excessive manganese pollution. (589, 699-700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 873-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 934, 937, 939-940, 945, 947, 949-950)
- The commentator requests the EQB maintain the current point of compliance. The discharger of pollution must be responsible for limiting the amount of pollution they dump into our waterways. Dilution is not the solution for this pollution. We should not have to clean up after polluters. The commentator is asking the EQB to adopt the new numeric human health criterion for manganese and require that the discharge point remain the point of compliance for this standard. (500, 593-594, 596, 620-639, 641-686, 688-697, 705, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)
- The point of compliance for the manganese effluent limit must remain where the pollution occurs – at the point of discharge. This is the only way that Pennsylvania can ensure that our streams and aquatic life – indeed, all uses of the river – are protected. (93, 864, 929-931, 942)
- The commentator strongly urges DEP to apply the proposed manganese standard at the point of discharge, making the companies releasing manganese into our water supplies responsible for treatment prior to potentially hazardous discharge. (863)
- The commentator wholeheartedly supports the change in the manganese criterion, but applied at the point of discharge, not at the point of public water supply withdrawal. Don't go halfway, lower it from 1.0 mg/L to 0.3 mg/L at the point of discharge. (60)
- The commentator supports the continued application of point of compliance for toxic substances to be the point of discharge. (925)

- The commentator supports maintaining the current point of compliance for manganese, in all surface waters (that is near the point of discharge), as stated in § 96.3(c). **(6, 13, 14, 74, 595, 615, 702, 870, 917, 918)**
- Reducing pollution into our waterways should be the responsibility of the generator of that pollution, at the point of discharge, and not the public water supplier at the point of water supply intake. **(13, 74)**
- Please adopt the second point of compliance alternative (at the point of discharge). The entity, company, or operation emitting the manganese should be fully responsible for its levels in the water, so let's test for levels right at the point of discharge. **(95)**
- The commentator supports the second alternative point of compliance to maintain the existing point of compliance in all surface waters (that is, at the point of discharge). This will protect existing and designated surface water uses and would afford aquatic life an appropriate level of protection from deleterious effects of manganese. **(597, 867)**
- The point of compliance must be measured at the discharge point – just as it has always been. **(701)**
- Maintaining the discharge point as the point of compliance protects all water uses between the point of discharge and the point of a downstream potable water supply withdrawal. **(936)**
- The commentator has reviewed both alternatives and believes the second alternative (that is, at the point of discharge) is more protective of residential ratepayers. The commentator opposes the first alternative. **(902)**
- The commentator believes the most optimal option is to regulate manganese at both the point of discharge and point of withdrawal. If the application of only one option is feasible, regulating manganese at the point of discharge would be more protective of human health. **(907)**
- The commentator supports the proposed regulation to update the WQ criterion for manganese with the understanding that the new criterion will be applied to all discharges into surface water in the same way that the existing 1 mg/L WQ criterion. **(938)**

Response: DEP appreciates the commentators' support for the second alternative point of compliance. The final-form regulation maintains the manganese human health criterion at the point of discharge.

104. Comment: *Compliance at the point of discharge protects the Potable Water Supply use and other water uses:*

- The point of compliance for the revised manganese WQS must remain at the point of discharge and not the point at which water is taken from the stream. Maintaining the existing point of compliance (at the discharge point) will protect all water uses including municipal, industrial and agricultural water supplies, and recreational and aquatic life uses in all surface waters. (929)
- The second alternative point of compliance maintains the existing point of compliance in all surface waters (i.e., at or near the point of discharge). The current science indicates that the human health criteria proposed in this rulemaking will afford adequate protection for aquatic life if it is applied in all surface waters. Under this alternative, additional protections will be provided to the Potable Water Supply use and other protected water supply uses (e.g., Irrigation, Livestock Water Supply and Wildlife Water Supply). (707)
- Representative (now Senator) Comitta concurs with the Pennsylvania Environmental Council and supports “maintaining the current point of compliance for manganese to all surface waters (that is, at the point of discharge). The alternative would be to allow the unregulated discharge of manganese in Commonwealth waters after the point of discharge until it reaches a public water supply intake. Whether it be agricultural, municipal, or industrial water supplies, recreational uses, or the web of aquatic life in these waters, all would benefit from maintaining the current point of compliance. (920)
- The commentator supports maintaining the current point of compliance for manganese to all surface waters (that is, at the point of discharge). The alternative [at the point of potable water supply intake] would be to allow for the unregulated discharge of manganese in Commonwealth waters after the point of discharge until it reaches a public water supply intake. Maintaining the current point of compliance will protect all water uses, including municipal, industrial, and agricultural water supplies, and recreational and aquatic life uses, between the point of discharge and the point of a downstream drinking water intake. (536)
- The commentator requests that the proposed manganese standard of 0.3 mg/L apply at the point of discharge to ensure that dischargers are the ones protecting the public from their own activities, not municipal water systems. Point of discharge designation is best in protecting stream health and aquatic life. The only way to prevent manganese from reaching downstream sections is to enforce effluent limits at the point of discharge. Under this point of discharge alternative, the manganese criterion for the protection of human health would be applicable in all surface waters to protect all relevant uses. Because of this, this alternative would afford aquatic life an appropriate level of protection from the negative impacts of manganese. This option also ensures that all streams are protected from the discharge of manganese whether they have a downstream water intake or not. (36)

- The only way to prevent manganese from reaching downstream sections is to enforce effluent limits at the point of discharge. Under this point of discharge alternative, the manganese criterion for the protection of human health would be applicable in all surface waters to protect all relevant water uses. Because of this, this alternative would afford aquatic life an appropriate level of protection from the negative impacts of manganese. This option also ensures that all streams are protected from the discharge of manganese whether they have a downstream water intake or not. (16, 18-31, 33-59, 62-72, 75, 77, 79-88, 107, 276, 574, 589, 882)
- The commentator strongly supports the second alternative point of compliance. Under this alternative, the manganese criterion for the protection of human health would be applicable in all surface waters to protect all relevant water uses. The threshold at which manganese needs to be maintained in the surface water to avoid toxicity to humans is lower than the level necessary to afford appropriate protection for aquatic life. Because of this, this alternative would afford aquatic life an appropriate level of protection from the negative impacts of manganese. Additional protections would be provided to the Potable Water Supply use and other protected water supply uses such as irrigation, wildlife water supply, livestock water supply, aesthetics, fishing, boating, and water contact recreation. If the proposed manganese criterion of 0.3 mg/L is adopted and the second point of compliance alternative is adopted, all users of surface waters will benefit. These regulations are a necessary step to protect the health of all Pennsylvania residents while simultaneously protecting aquatic life and the natural resources that we depend on. (5, 103)
- We request that DEP reject the change in the point of compliance and focus on implementing WQ criteria at the point of discharge that is appropriately protective of aquatic life and human health for all surface waters. (928)
- Water suppliers rely on source water protection to provide safe and adequate drinking water to their customers. (14, 595)

Response: DEP appreciates the commentators' support for the second alternative point of compliance. The final-form regulation maintains the manganese human health criterion at the point of discharge in order to provide protection to all water uses.

105. Comment: Under the second alternative point of compliance, there would also be cost savings by public water systems because manganese levels in source waters would be lower and less treatment would be necessary to meet drinking water regulations. (5, 16, 18-31, 33-59, 62-72, 75, 77, 79-88, 103, 107, 276, 574, 589, 882)

Response: DEP acknowledges that the second alternative point of compliance may provide cost savings to some public water systems through an overall improvement in surface water quality.

106. Comment: It is the commentator's strong opinion that the second alternative point of compliance (at the point of discharge) would be in the better interest of the Commonwealth

of Pennsylvania as a whole. It is irresponsible to make a decision based on what the cheaper option is knowing that that decision will not be of long term benefit. That is what alternative one and its supporters are asking the EQB to do. Alternative one benefits to those who contribute to manganese pollution. Alternative two benefits public health and the environment. When deciding which alternative to implement, remember that it is the duty of the EQB to protect human health and natural lands. The task of balancing public interest with environmental stewardship can be achieved in this by implementing the second alternative. (76)

Response: DEP appreciates the commentator's support for the second alternative point of compliance. The final-form regulations retain the point of compliance at the point of discharge.

107. Comment: DEP has proposed to reduce the limits on the amount of manganese pollution that can enter our streams. As noted in our other comment, the standard needs to be for all industries including coal. Do not place the burden on the citizens, those whom have a right to clean water but to the polluter. As you address this standard, please ensure you address the issue of manganese discharge across all regulations. (592)

Response: DEP appreciates the commentator's support for the second alternative point of compliance. The final-form regulations retain the point of compliance at the point of discharge.

108. Comment: *Duty to protect the environment and citizens from pollution:*

- Pollution from industrial uses such as quarrying and mining activity has historically been detrimental to the health of our waterways in the Delaware River Watershed as well as throughout the Commonwealth. It is critical for DEP and the EQB to hold the entities discharging manganese accountable for their pollution, rather than allow them to further harm our waterways and place the additional burden of cost on the public. (918)
- Alternative two benefits public health and the environment. When deciding which alternative to implement, remember that it is the duty of the EQB to protect human health and natural lands. The task of balancing public interest with environmental stewardship can be achieved in this by implementing the second alternative. (76)

Response: DEP agrees that some historical activities and practices have been detrimental to waters of the Commonwealth. It is the EQB's duty and responsibility to adopt regulations that protect the environmental resources of this Commonwealth. DEP appreciates the commentator's support for the second alternative point of compliance.

109. Comment: While the second alternative point of compliance [at the point of discharge] would not remediate the full cost, as this appears impossible due to the mandates of Act 40, it will nevertheless alleviate some of the cost burden from public water utilities, thereby reducing the likely cost burden to public water utility customers. (902)

Response: As discussed in the response to Comment 134, DEP does not expect this regulation to affect the NPDES permits of many public water systems. These NPDES permits currently contain a BPJ-based TBEL for manganese that is applied at the end-of-pipe and is more stringent than the application of the current potable water supply use criterion of 1.0 mg/L modeled at the point of discharge. When the new criterion of 0.3 mg/L is applied at the point of discharge, public water systems discharging to larger, unimpaired receiving waters will likely remain unaffected. The greatest potential for a public water system to be affected would involve discharges to small, low-flow receiving waters or waters that are impaired for metals/AMD.

110. Comment: The commentator asks the EQB to maintain the current point of compliance [at the point of discharge]. The discharger of pollution must be responsible for limiting the amount of pollution it dumps into our waterways. Dilution is not the solution to pollution. The commentator finds it unconscionable that the mining companies (and other industries) have essentially asked the ratepayers to pay for removing a toxin that they have discharged. If the compliance point and treatment for manganese shifts to the point of withdrawal, the likelihood of the cost of treatment and technology needed to comply with safe drinking water standards would be passed onto the ratepayer. (500, 593-594, 596, 620-639, 641-686, 688-697, 705, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)

Response: DEP recognizes that moving the point of compliance under the first alternative would have had the potential to increase treatment needs at downstream public water systems. DEP appreciates the commentators' support of the second alternative point of compliance. The final-form regulations retain the point of compliance at the point of discharge.

111. Comment: Enforcing the rule change at the point of discharge into surface waters may lead to the reduction of anthropogenic-sourced levels of manganese in Commonwealth surface waters, which would provide protection of multiple uses of surface water. Additionally, a lower criterion for manganese enforced at discharge would allow for easier compliance to the safe drinking water standard of 0.05 mg/L for the various end-users of surface water, which fall under EPA/FDA/USDA regulation. A potential drawback of this application is that the unregulated entities which produce food products that enter the human diet might not control for manganese levels in the surface water they withdraw. However, a potential 66% reduction in surface water levels of manganese combined with dilution effects and bio/metabolism/sequestration may minimize these risks. Without a regulation to control for manganese at the discharge into publicly accessible water, it is possible citizens and the aquatic wildlife they might harvest and consume could be exposed to unknown levels of manganese at discharge locations. The commentator believes that the most optimal option which provides the highest level of protection to humans from hazardous levels of anthropogenic sources of manganese in surface waters is to apply the reduction of manganese to discharge and withdrawal sources. If only one application can be applied, regulating manganese at discharge would be more protective of human health in the Commonwealth. (907)

Response: DEP agrees that reducing source water concentrations of manganese has the potential to assist some public water systems in complying with the SMCL for manganese in potable water, which is 0.05 mg/L. As DEP does not regulate the water intakes of food production facilities unless those facilities are also identified as public water systems, it is not known if the scenario described in the comment above is likely to occur. Food manufacturing facilities have their own standards and regulations to ensure quality and safety of their food products and would likely be monitoring for pollutants and treating any surface waters used in food production.

It is largely unknown at this time whether manganese levels in wildlife or aquatic organisms utilizing surface waters with elevated manganese represent a concern with respect to human consumption. DEP is not aware of any studies or research to evaluate manganese levels in waterfowl, deer, or other game animals.

DEP appreciates the commentator's support for the second alternative point of compliance.

Opposition to the First Alternative Point of Compliance (Movement to the Point of Downstream Potable Water Supply Withdrawal) Because It Is Not Protective of WQ or Water Uses

112. Comment: *The first alternative point of compliance is not protective of water uses and the second alternative is protective:*

- If this policy is approved, you will be allowing the point source of pollution to be even greater than it already is. Aquatic life will be affected in a negative manner. (77)
- Changing the point of compliance to the intake for drinking water supplies would endanger those who use streams for recreation and would threaten the ecological health of our streams. Maintaining the point of compliance at the point of discharge ensures that all waterways are protected from excessive manganese pollution regardless of whether or not a drinking water supply intake is downstream. (918)
- Changing the point of compliance to the point of intake for drinking water supplies would strip Pennsylvania's waterways of valuable protections that have been in place for decades. Aquatic life would be threatened because stream segments would not be subject to manganese limits unless they are located close to a drinking water supply intake. Furthermore, these standards wouldn't even apply to streams where no potable water supply intake exists. Changing the point of compliance to drinking water intakes would also fail to protect those who use waterways for recreation. Human health and our aquatic ecosystems should not have to be jeopardized. (589, 699, 700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 873-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 934, 937, 939-940, 945, 947, 949-950)

- Manganese can cause negative impacts to human health and aquatic life, as well as other uses of water such as for agriculture and recreation. Because of these impacts, changing the point of compliance to the intake for potable water supplies would not protect human health and the environment throughout our streams. Maintaining the point of discharge compliance ensures that our waters are protected whether or not a drinking water supply is downstream. **(864, 918)**
- Setting the standard for manganese to the point of water supply intake does not protect aquatic uses, depriving me, as a citizen, of the aquatic use of surface waters of the Commonwealth, a use I currently enjoy. **(73)**
- Manganese can cause negative impacts to human health and aquatic life, as well as other uses of water such as for agriculture and recreation. Because of these impacts, changing the point of compliance to the intake for potable water supplies would not protect human health and the environment throughout our streams. Maintaining the point of discharge compliance ensures that our waters are protected whether or not a drinking water supply is downstream. **(93, 930, 931, 942)**
- The commentator opposes the alternative to change the point of compliance from the point of discharge to the point of drinking water intake. The point of compliance for the manganese effluent limit must remain where the pollution occurs – at the point of discharge. This is the only way that Pennsylvania can ensure that our streams and aquatic life – indeed, all uses of the river – are protected. **(918)**
- If the point of compliance is moved to any downstream potable water supply intake, the manganese criterion will not apply and therefore, will not protect other water uses between the discharge location and the downstream water supply intake. It would allow for the unregulated discharge of manganese in waters of the Commonwealth after the point of discharge until it reaches a public water supply intake. Shifting the point of compliance to downstream public water supply intakes jeopardizes thousands of miles of streams and the aquatic life and recreational uses they support. It ignores the fundamental mandate of the CSL and the CWA to protect and maintain uses, and flies in the face of DEP's obligations under Section 27 to prevent degradation of public natural resources. **(929)**
- Not only will the shift in the point of compliance away from the discharger have an adverse impact on public water suppliers (and their customers and ratepayers), but it will likely also have unintended WQ consequences. If the point of compliance is moved, the manganese criteria would not apply to the discharger and, as a result, there would be absolutely no protection of either Pennsylvania streams or the water uses therein between the point of discharge and the point of the downstream public water supply intake. In addition, by allowing more manganese to be deposited into the Commonwealth's surface water sediments, the result may be that manganese will become a legacy pollutant in the Commonwealth's surface waters, likely to impact generations of future Commonwealth residents. **(938)**

- This proposed change [moving the point of compliance] is most troubling since it would allow for the unregulated discharge of manganese in Commonwealth waters after the point of discharge until it reaches a public water supply intake. (930)
- The EQB should reject any change in the point of compliance as it is deleterious to the health of the Commonwealth's citizens and aquatic life. (78)
- This alternative gives no consideration for the potential impacts this change will have on fish, other aquatic life, and recreational uses when moving the point of compliance for manganese from the wastewater discharge to the existing or planned surface potable water supply withdrawal. Manganese will precipitate or settle onto stream substrates under certain stream conditions as a black, sticky coating on streambed substrates which could most certainly interfere with the ability and desire to boat, fish, and enjoy a stream. (597)
- The first alternative would change the point of compliance for manganese to being met "at the point of all existing or planned surface potable water supply withdrawals." Under this alternative, no water-quality based effluent limits will apply to the surface water if no potable water supply withdrawal exists or is planned. This is not acceptable. Aquatic life would not be granted adequate protection under this alternative because stream segments and aquatic ecosystems would not be subject to the manganese effluent limitations unless they are located close to a potable water supply withdrawal. There could be long stretches of open water from the point of discharge to the nearest potable water supply withdrawal that would be left completely vulnerable. The only way to prevent manganese from reaching downstream sections is to enforce effluent limits at the point of discharge. (5, 103)
- The commentator opposes moving the point of compliance from the point of discharge to the point of potable water supply intake. It does not provide protection for aquatic life in the length of water between the discharge point and the point of withdrawal for human consumption. (932)
- The first alternative, consistent with Act 40 of 2017, moves the point of compliance to the point of all existing or planned surface potable water supply withdrawals and would create a delta of water containing higher levels of manganese, compromising aquatic life between the point of discharge and intake. (867)
- The proposed amendment would make stream segments and aquatic ecosystems between points of discharge and downstream water supplies vulnerable to potentially dramatic WQ changes from higher manganese loadings, which could ultimately result in their impairment. (890)
- The commentator strongly opposes the proposed alternative which would change the point of compliance to the point of potable water supply withdrawals. This change

would endanger Pennsylvania's waterways and jeopardize human health and aquatic life. The commentator respectfully requests that the EQB reject the proposed alternative to change the point of compliance **(870)**

- The surface water in Pennsylvania needs to be valued holistically, not just for its Potable Water Supply use. A study done in 2019 found that a general trend for aquatic ecosystems, specifically lakes and rivers, is that the parts of these ecosystems we use most for goods/services, are the most at risk for being negatively impacted by human activities (Culhane et al., 2019). The same study also concluded that protecting these areas alone was not enough to protect all the areas at high risk. The only way to use natural resources sustainably is by protecting the whole resource. **(76)**
- Shifting the point of compliance to public water supply intakes imperils hundreds if not thousands of miles of streams and the aquatic life they support. Moving the point of compliance would adversely impact public water suppliers and other downstream users and raises concerns about aquatic and public health impacts. **(536)**
- The commentator is opposed to eliminating the long-standing requirement for polluters to the state's waterways to maintain a minimum amount of manganese at the point of discharge and instead allowing the measurement to occur at the point of downstream public water system withdrawal. As detailed in our February 26, 2018 comments on the ANPR, this proposed change in the point of compliance does not ensure protection of drinking water and may harm aquatic life over time. **(928)**
- The EQB must reject the proposed alternative to change the point of compliance from the discharge point to the intake point for drinking water supplies. In accordance with federal and state laws and regulations, the discharger of pollution must be responsible for limiting the pollution it dumps into our waters. **(32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 501-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)**
- Dilution is not the solution to pollution! Requiring compliance at the point of discharge protects all of Pennsylvania's waters, regardless of whether water is a safe environment for aquatic life, used for recreation or as a source of drinking water. **(32, 90-92, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 502-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)**
- Manganese can travel far downstream meaning the compliance at the point of discharge protects all water uses of our streams, including human drinking water sources, our food supply, and aquatic life. Requiring compliance at the point of discharge protects all of Pennsylvania's waters, regardless of whether there is a drinking water supply downstream. **(32, 90-91, 94, 96-102, 104-106, 108-275, 277-496, 498-499, 501-535, 537-573, 575-588, 590-591, 598-610, 612-614, 616-617, 619, 640, 687, 722, 765, 816, 836, 856, 868-869, 898, 914)**

Response: By requiring the achievement of WQ criteria in all surface waters at least 99% of the time in accordance with §96.3(c), protection is provided to all water uses and conversely, that moving the point of compliance for the manganese criterion from the point of discharge to the point of downstream potable water supply withdrawal would have had the potential to result in increased discharges of manganese to surface waters. Since permit effluent limitations would have only been modeled to the nearest downstream potable water supply withdrawal, permitted discharges to surface waters where the nearest intake is far downstream or where one does not exist would have been unlikely to receive an effluent limitation because reasonable potential to violate the WQS would not have been triggered even if manganese was present in the discharge. For the mining industry, federal and other state regulations currently limit, and would have continued to limit, the amount of manganese at the point of discharge. However, most other categories of discharge lack these additional backstops. In some of these cases, a discharger may not have received a manganese effluent limitation in their permit until aquatic life or other water uses would have been negatively impacted or even severely degraded. The final-form regulations retain the point of compliance at the point of discharge.

113. Comment: The EQB should reject any change in the point of compliance as it is based on bad science. (78)

Response: The final-form regulation retains the current point of compliance for the manganese criterion based on its toxicity to human health. Furthermore, no scientific data or information was submitted to the EQB or found to support moving the point of compliance.

114. Comment: The change in compliance point should address the relationship of pH to manganese. The toxicity of manganese is determined by the pH of the water. Therefore, it is best tested and corrected at the source. (92)

Response: DEP is aware that pH will influence the state of manganese in water (dissolved vs. particulate forms) with lower pH waters having greater dissolved concentrations of manganese. For aquatic life, dissolved manganese is expected to be more toxic since it will exhibit greater bioavailability. Such is the case with most metals. DEP generally agrees that the prevention of toxic conditions to aquatic life is best achieved at the point of discharge.

115. Comment: If compliance is moved to water intakes, how does the EQB plan to protect the public's exposure while utilizing the waterways for recreation, fisheries, and agricultural irrigation? I urge you to not adopt the mining industry's plea to move the point of compliance to public water supply intakes, due not only to aquatic environmental concerns, but also concerns for human health. (702, 956)

Response: DEP has considered the public comments received from approximately 920 commentators in support of both the new criterion of 0.3 mg/L and the second alternative point of compliance. Based on these comments and DEP's review of all of the relevant information, DEP is recommending to the EQB that the new criterion be adopted with

maintenance of the current compliance point consistent with all other existing toxic criteria (that is, at the point of discharge).

116. Comment: The exception to meeting WQ criteria described in 25 Pa. Code § 96.3(d) only exists for "designated surface water uses" since WQ criteria are developed for the purpose of meeting those uses. Existing uses are not associated with WQ criteria. Instead, those uses are associated with the Commonwealth's Antidegradation Policy. Measuring for compliance with existing use requirements in the antidegradation policy as described in 25 Pa. Code § 93.4a, whether the water segment is subject to mere existing use protection, protection for high quality waters, or protection for exceptional value waters, must be met at all locations within the water body segment. Creating an exception for manganese (much like the current exceptions for TDS, nitrite-nitrate nitrogen, phenolics, chloride, sulfate and fluoride) presents a scenario where a permittee can be in compliance with a designated use WQ criterion and subject to governmental and citizen suit enforcement for violating the antidegradation policy's protection of existing uses, high quality waters and exceptional value waters. The Department should not create such confusion for the public or industry in its implementation of WQSs. (863)

Response: DEP protects both designated and existing water uses through the application of WQ criteria, except for HQ or EV waters.

Section 93.3 identifies and defines the protected water uses for Pennsylvania surface waters, and the water quality criteria in § 93.6, § 93.7 and § 93.8c apply to those uses whether they represent the designated or existing use for a specific waterbody. There is no difference in the criteria that apply to designated or existing uses unless the designated or existing use of a waterbody is HQ or EV. In the cases of special protection uses (that is, HQ and EV), the water quality criterion required is the maintenance of the existing WQ of that stream (or an appropriate reference stream). The numeric criteria are generally not applicable to HQ and EV with a few exceptions, such as approved social or economic justifications (SEJ) for less stringent protections in HQ waters. These protections will not be changed by this final-form rulemaking. In addition, discharge permits must protect all existing and designated uses of the receiving water, including any more stringent downstream water uses such as HQ and EV.

The final-form regulation retains the current point of compliance for the manganese criterion based on its toxicity to human health. Maintenance of the point of compliance in all surface waters will protect existing and designated uses between the point of discharge and downstream uses.

Impacts on Public Water Systems; including the Economic Hardships associated with the First Alternative Point of Compliance as described in the Proposed Rulemaking

117. Comment: About 11% of the Commonwealth's population is served by individual private drinking water wells. Changing the compliance point to the intake of public water systems would not protect those citizens on private water wells from the dangerous impacts of manganese. (930)

Response: DEP agrees. The WQSs only apply to surface waters of the Commonwealth and are not applicable to groundwater. While public water systems are regulated under 25 Pa. Code Chapter 109, private drinking water wells are not regulated by the Commonwealth. Management of private wells is the responsibility of individual homeowners.

118. Comment: *The first alternative point of compliance shifts the burden and costs of treatment to public water systems:*

- This alternative would also inappropriately place the burden of treating the pollution on the public water systems, rather than the polluter. The public should not have to be forced to bear the costs of treating this pollution in order to create a windfall for the mining industry. (864)
- The EQB should reject any change in the point of compliance as it places the financial burden on water suppliers and citizens rather than the polluters. (78)
- The public should not be forced to bear the costs of treating manganese pollution in order to save the mining industry money on compliance costs. (589, 699-700, 703-704, 706, 708-709, 731-764, 766-812, 814-815, 817-827, 829-831, 833-835, 837-844, 846-855, 857-858, 865-866, 873-879, 881, 883-884, 886-889, 891-896, 899-900, 903-904, 906, 908-913, 915-916, 919, 921, 923-924, 926-927, 934, 937, 939-940, 945, 947, 949-950)
- The commentator does not support changing the point of compliance to the point of withdrawal which will shift the burden of treatment and control to downstream users such as public water suppliers and customers. (597)
- The first alternative, consistent with Act 40 of 2017, moves the point of compliance to the point of all existing or planned surface potable water supply withdrawals, essentially shifting responsibility for maintaining manganese limits from the discharger to the first downstream public water supply intake. That change would result in the customers of the water supplier picking up the tab for increases in treatment and compliance costs because higher levels of manganese would be released into the water supply. (867)
- The commentator opposes moving the point of compliance from the point of discharge to the point of potable water supply withdrawal. Movement of the point of compliance with a WQS from the point of discharge to a stream to the point of public water intake shifts the cost of compliance from the discharger to the downstream users. (932)
- The commentator strongly opposes the proposed alternative which would change the point of compliance to the point of potable water supply withdrawals. This change would shift the cost of pollution control from the polluters to the public. The commentator respectfully requests that the EQB reject the proposed alternative to change the point of compliance. (870)

- It is irresponsible to make a decision based on what the cheaper option is [for industry] knowing that that decision will not be of long term benefit [to the environment]. That is what alternative one and its supporters are asking the EQB to do. (76)
- Fundamentally, the prevention and reduction of pollution entering our waterways should be the responsibility of the generator of that pollution and not the public or other downstream users. Moving the point of compliance would adversely impact public water suppliers and other downstream users, increasing treatment capacity and costs (which, for public water suppliers, are ultimately borne by the citizens of the Commonwealth). (536)
- The commentator is opposed to eliminating the long-standing requirement for polluters to the state's waterways to maintain a minimum amount of manganese at the point of discharge and instead allowing the measurement to occur at the point of downstream public water system withdrawal. As detailed in our February 26, 2018 comments on the ANPR, this proposed change in the point of compliance threatens to increase the cost of clean water and is likely to cost Pennsylvania's business dependent upon healthy water. In short, it shifts the cost of manganese pollution from the discharger to the public. The commentator believes that shifting the point of compliance for the manganese WQS is not in the best interest of DEP, Pennsylvania's businesses, water suppliers and citizens. (928)
- The EQB must reject the proposed alternative to change the point of compliance from the discharge point to the intake point for drinking water supplies. The cost of pollution belongs to the shareholders not the stakeholders. This change will shift responsibility and cost to the consumer. The standard needs to apply to all industries, owners and polluters. (92)
- Changing the point of compliance to the drinking water intake would also inappropriately place the burden of treating manganese pollution on public water suppliers and customers, rather than on the companies discharging into our waterways. The public should not be forced to bear the costs of treating this pollution in order for mining companies to save money on compliance costs. (93, 918, 930, 931, 942)
- Changing the point of compliance would threaten private water supplies that are fed by midstream water supplies. Pollution from industrial uses such as quarrying and mining activity has historically been detrimental to the health of our waterways in the Youghiogheny River Watershed as well as throughout the Commonwealth. It is critical for the DEP and the EQB to hold the entities discharging manganese accountable for their pollution, rather than allow them to further harm our waterways and place the additional burden of cost on the public. (942)
- Pennsylvania communities can no longer bare more sacrificed areas and pollution due to these powerful industries of the extraction business that continue to pressure many elected officials to waste time and resources by putting public health at risk as they bend

to the polluter's wishes to undermine strong protection laws that have been in place for decades. (931)

- The commentator has concerns over putting the financial burden on the public if the point of compliance is moved and sees no reason why residents of the watershed should have to pay for the pollution caused by specific industrial point sources. The commentator understands that the EQB must often weigh the impact on economic growth with concerns over environmental health, but this is now an issue of human health as well and thinks regulatory changes should strongly consider the best available scientific research. (702, 956)
- Moving the point of compliance serves no purpose other than to shift the cost of treatment from the discharger to the water supplier and its customers. (615, 917)
- The first alternative would shift the burden of manganese removal onto public water suppliers instead of the dischargers. This alternative is harmful and only benefits entities holding or seeking permits to discharge manganese into the surface waters of the Commonwealth (mostly quarries and mining operations). (103)
- Movement of the point of compliance to any downstream public water supply intake would shift the treatment costs onto public water suppliers (which are ultimately borne by the ratepayers) and other downstream users. The prevention and reduction of pollution in our waterways is the responsibility of the generator of that pollution, not downstream users or the public. Coalfield residents are not interested in picking up the industry's tab for the cost of wastewater treatment. (929)
- Representative (now Senator) Comitta comments that the unregulated discharge of manganese is the responsibility of the generator of that pollution and not the public or other downstream users. Not only would shifting the point of compliance contaminate Pennsylvania waters, but it would shift costs to those downstream, to public water suppliers and thus to customers. (920)
- [Moving the point of compliance] shifts costs to water purveyors, many of which serve small, rural communities located in low income areas, and passes the cost of business compliance on to citizens. Shifting environmental compliance onto ratepayers is unacceptable. (932)

Response: DEP acknowledges the commentators' opposition to the first alternative point of compliance and generally agrees that moving the criteria compliance point to the point of downstream potable water supply withdrawal is not protective of statewide water supply uses and has the potential to shift the burden of treatment away from the dischargers of manganese. The final-form regulations retain the point of compliance at the point of discharge.

119. Comment: If DEP applies the manganese standard at the point of water withdrawal, the burden for treating manganese would pass to water utilities, and ultimately this cost will be borne by Pennsylvania residents and ratepayers. Further, the overall cost of addressing this contamination of Pennsylvania water resources is multiplied through the need for treatment systems at each downstream water withdrawal. It is far more efficient and lower in overall cost to require companies discharging manganese to properly treat their wastewater. Additionally, setting a standard of 0.3 mg/L at the point of water supply withdrawal, could result in violations of state and federal drinking water standards, which is set at 0.05 mg/L. DEP should not set a standard that will result in violations that water utilities will be legally required to address. Any standard set at the point of a water withdrawal must minimally meet any federal or state MCL set for that contaminant. (863)

Response: DEP agrees that moving the point of compliance for the manganese criterion would have had the potential to impact downstream water users. As the commentator notes, allowing the discharge of increased levels of manganese might have affected multiple downstream water users on a particular waterbody and treatment at the point of discharge is more efficient.

DEP does not agree that the WQ criterion for manganese should be set at the current SMCL of 0.05 mg/L. This drinking water standard was established for control of objectional taste and staining issues rather than to protect public health. Furthermore, natural background levels of manganese across the Commonwealth often exceed this level. However, DEP has developed and is recommending a WQ criterion recommendation that is consistent with natural background levels of manganese observed in the Commonwealth as well as current EPA recommendations for the protection of human health.

120. Comment: Don't even think about making this act a law unless you increase the standard by 70% [like the act calls for the potable drinking water industry] across the board on all industries that contribute manganese to our waterways. The water authority that supplies the water for our community has abandoned mines, active mines and who knows what else or who else contributes manganese to our source water. This act would only add to the cost of drinking water. So why should the people pay, in their water bill, for the big mess that the passage of this act would enhance. There are people in Appalachia coal country Kentucky that cannot afford city water. I don't think the sponsors of this act care about the people. They just care about themselves and their campaign contributions from the energy and natural resource industries. In 2016, Sen. Yaw received \$149,000 from them and Sen. Scarnati received OVER 1.5 million. Do I need to say anything else. It stinks. (1)

Response: The Department acknowledges the commentator's concerns with Act 40 of 2017.

121. Comment: The commentator (municipal water authority) would need to add an alternative treatment process with a projected construction cost of \$2.1 million and a 20-yr operating cost of \$15.8 million plus \$540,000 per year in increased treatment chemical costs; and \$6,530 annually for increased monitoring after a start-up cost of \$13,000. These costs would be passed on to the rate paying public, essentially taxing them for the otherwise private concern of pollution generating businesses. With our service population being one of the poorest in the state, this is wholly indefensible. (74)

Response: DEP appreciates and thanks the commentator for providing this treatment cost estimate information.

122. Comment: In February 2018, the commentator was one of 15 organizations that responded to the Department's ANPR published at 48 Pa. B 605 (January 27,2018). The ANPR requested information ranging from scientific data to financial impact and analysis. Under the proposed first alternative (Act 40 of 2017) - which moves the point of compliance – the commentator estimates that change would result in a \$40-\$60 million price tag for public water suppliers that would ultimately be paid by our customers through higher rates. With 68 permitted water supply systems [owned by the commentator], the commentator identified 16 plants which would be challenged if confronted with increased levels of raw water manganese. At least eight (8) of those plants would have a higher probability of occurrence and would be negatively impacted to the point of requiring treatment plant modifications. The aggregate capacity of the eight (8) identified plants is in the range of 40 MGD. The estimated costs for plant upgrades ranged in the \$1-\$1.5 million per MGD, equating to an overall one-time capital investment in the \$40-60 million range (that figure does not include the anticipated 5-10 percent (\$700,000 - \$1.4 Million) annual increase in chemical costs or monitoring. (867)

Response: DEP appreciates and thanks the commentator for providing this treatment cost estimate information.

123. Comment: Under current regulations, public water systems are to receive raw water at their intake. Only by using conventional treatment can these systems remove residual pollutants. These systems are currently not set up to either endure increased costs for more chemical use or increased cost related to more sensitive technology to remove higher levels of manganese. A municipal water authority treatment plant operating at one million gallons per day (MGD) would face an additional estimated \$20,000 per year increase in chemical usage to meet manganese compliance levels. To put that into perspective, the Pittsburgh Water and Sewer Authority averages 70 MGD in finished water, which equates to an increase of \$1.4 million in operating costs. It was also reported in the EQB's rulemaking that the City of Lancaster's Department of Public Works and Pennsylvania American Water would incur capital costs upwards of tens of millions of dollars to comply with such a proposal. This cost would be associated with increased needs of chemicals and additives, additional system maintenance, increased sludge removal, flushing and cleaning of the system, and increased compliance monitoring. Thus, allowing upstream polluters to purposefully discharge untreated manganese into our waterways would place an undue burden on water authorities and their ratepayers. (500, 593-594, 596, 620-639, 641-686, 688-697, 705, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)

Response: DEP appreciates and thanks the commentators for providing this treatment and cost estimate information.

124. Comment: Moving the point of compliance from dischargers to downstream water suppliers would shift the logistical and financial burden of removal from those parties

responsible for manganese pollution to suppliers of public drinking water. Many downstream water utilities may not be equipped to remove the contaminant and would need to upgrade their publicly-financed facilities at significant cost in order to maintain drinking water quality standards. Potential compliance costs for this commentator could prove immense. Manganese is a persistent contaminant that can be carried long distances. Due to the current regulatory safeguards provided by the existing ambient WQSs, manganese has not been a priority drinking water concern for this commentator's water treatment plants. But as the farthest downstream water supplier in the Schuylkill River watershed, relaxing limits on dischargers by taking dilution effects into consideration during permit development could have a measurable impact on manganese concentrations at Philadelphia's drinking water intakes. Any increase in ambient manganese could necessitate that these plants incorporate treatment technologies or management practices that are currently neither needed nor budgeted for. The current ambient WQS of 1 mg/L is already 20 times greater than the current SMCL of 0.05 mg/L, which has been instituted to prevent aesthetic issues in drinking water. However, research has shown that even this SMCL requires reevaluation as customer complaints due to the visual effects of manganese presence are cited at concentrations less than or equal to 0.02 mg/L manganese dioxide. Therefore, even without exceeding the SMCL, an increase in manganese levels could weaken consumer confidence in public water supplies. (890)

Response: DEP acknowledges and appreciates the commentator's perspective and concerns.

125. Comment: EPA requires states to address levels of manganese above 0.3 mg/L, due to the EPA HAL which includes a 10-day limit of 0.3 mg/L for infants. EPA also requires states to implement corrective actions, including public notification (PN). To address this requirement, DEP is currently in the process of updating its guidance document "Situations Requiring One-Hour Reporting to the Department of Environment Protection" to clarify that a water supplier shall notify DEP within 1 hour of discovery if there is an exceedance of an EPA HAL for a secondary or unregulated contaminant in the finished water including:

"Manganese: Manganese has a lifetime advisory level of 0.3 mg/L, and a 1-day and 10-day health advisory level of 1 mg/L. For bottle-fed infants younger than six months, EPA has established a 10-day health advisory level of 0.3 mg/L." (14, 595, 615)

Response: DEP is aware of the PN requirements associated with violations of safe drinking water standards or HALs, and agrees that, if the final-form criterion of 0.3 mg/L is only required to be met at the point of the nearest downstream potable water supply withdrawal, some public water systems could be faced with the additional costs and challenges associated with providing PN to their customers. Furthermore, these facilities may not be equipped to handle increased manganese levels at the point of withdrawal. The final-form regulations retain the point of compliance at the point of discharge.

126. Comment: *Increased capital, operations and monitoring costs for public water systems are expected if the point of compliance is moved:*

- Increasing the level of manganese at public water supply intakes by moving the point of compliance will require public water suppliers to install specific manganese removal technologies at substantial increases in capital, operating and monitoring costs. (14)
- Water suppliers monitor for manganese in their source water to make sure they can properly treat it before it becomes a problem. Moving the point of compliance for manganese would result in higher levels of manganese in the source water causing water systems to experience increases in monitoring costs and increases in treatment costs due to the need to modify existing treatment processes or to provide additional treatment. (13, 74, 595, 615, 917)
- DEP determined that 280 of the 340 surface water treatment plants in Pennsylvania would need to evaluate treatment changes if the manganese compliance point were moved, without the addition of a stricter standard upstream. (14, 13, 74, 595, 615, 917) This would be particularly burdensome on small water systems, such as manufactured housing communities, as they lack the resources necessary to make capital improvements to their treatment processes. (615, 917)
- Shifting the point of compliance from the point of discharge to the intake of potable water supplies unfairly shifts the burden of treating manganese from industrial dischargers to water suppliers and ultimately the public. This will create a significant financial windfall for the mining industry and other industry dischargers, while water suppliers and the public pick up the tab for treating industry pollution. Water suppliers may require additional monitoring for manganese or costly facility upgrades for manganese treatment. These types of additional costs for water suppliers will likely result in increased fees for consumers. Other industries that require surface water intakes, such as food and beverage industries, may also bear the cost of additional monitoring or treatment. This system runs counter to the framework of water protection law which is intended to place the onus for pollution control on the polluters themselves rather than the public. (870)

Response: DEP recognizes that moving the point of compliance for the manganese criterion to downstream potable water supply withdrawals may increase costs to public water systems. The final-form regulations retain the point of compliance at the point of discharge.

127. Comment: *Public water systems will be impacted by the proposed criterion in their NPDES permits, but it is generally easier and less expensive to treatment on the NPDES side:*

- As water suppliers remove manganese in the treatment process, the manganese accumulates in the sludge generated in the treatment process which is then discharged in accordance with the facility's NPDES permit. This means that water suppliers will be faced with complying with the change in the manganese discharge standard at both ends

of the treatment process (at the point of the water treatment plant and at the NPDES point of discharge). However, meeting the standard in their NPDES permit would not be as costly to water suppliers as it would if the Act 40 change to 1.0 mg/L at the point of water supply intake was implemented. (595)

- Even the 0.3 mg/L standard proposed by the EQB would still be significant and water suppliers also have an NPDES permit so they will be discharging the manganese that they remove and it will get solidified in their sludge – costing them on both ends of the treatment process. However, meeting the proposed 0.3 mg/L standard in their NPDES permit would not be as costly to water suppliers as it would be if the Act 40 change were done alone. It is also important to note that it is easier and less expensive to treat manganese on the NPDES site of the equation, whether it be the water supplier's wastewater or solids. However, the NPDES permit will not automatically be changed to 0.3 mg/L – it will be reviewed when the NPDES permit is renewed and it will depend on the level of manganese in the source water. In addition, DEP does not expect this to impact many wastewater treatment plants; thus, in no way reducing the costs of treatment for the public water suppliers. (74)
- Even the 0.3 mg/L standard proposed by the EQB would still be significant for water suppliers who also have an NPDES permit and must be in compliance with the 0.3 mg/L standard for manganese when they filter backwash and discharge under their permit. However, meeting the standard in their NPDES permit would not be as costly to water suppliers as it would if the Act 40 change to 1 mg/L at the point of water supply intake was implemented. (615, 917)
- The second alternative, also not without significant cost, proposes a lower standard (0.3 mg/L), maintains the current point of compliance, deletes manganese from Table 3 in §93.7 (relating to specific water quality criteria) and adds manganese to Table 5 in §93.8 c (relating to human health and aquatic life criteria for toxic substances. The lower standard is in line with EPA's HAL of 0.3 mg/L and is based on EPA's "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health" (2000). Monitoring and treatment costs associated with the EQB's proposed 0.3 mg/L standard will be significant for water suppliers who also have an NPDES permit as they must comply with manganese standards when they filter backwash and discharge under their permit. However, meeting the standard in the NPDES permit would not be as costly to water suppliers and their customers as it would be under Act 40 of 2017 with the change in the point of compliance. (867)
- Setting the point of compliance at the intake to a water treatment plant would represent a fundamental change in Pennsylvania, because it shifts the point of compliance from discharger to public water supplier. Significantly, foisting the entire economic burden of meeting the proposed criterion on public water suppliers will translate to a significant and substantial cost to customers and ratepayers of such entities. Not to be overlooked is the fact that public water suppliers must also meet a SMCL for manganese of 0.05 mg/L in finished water (see 40 CFR § 143.3); therefore, public water suppliers will be required

to meet a manganese criterion or standard at both their intake and their point of discharge. (938)

Response: As noted in the responses to Comments 109 and 134, DEP does not expect most public water system NPDES permits to be affected by the proposed regulation due to the current TBELs that apply to these wastewater discharge permits. DEP concurs that these public water systems must meet both safe drinking water standards as required by their public water supply permit while also meeting the required NPDES effluent limitations for their wastewater discharges of filter backwash water. Since these public water systems must operate under both a public water system permit and an NPDES permit, DEP appreciates the commentators' statements indicating that treatment of their wastewater (the second alternative point of compliance) would be less costly than the costs associated with removing additional manganese in their source water on the potable water supply end (the first alternative point of compliance).

128. Comment: The commentator is concerned with the proposed rulemaking's impact on water affordability, particularly the impact on low-income users. Water unaffordability is increasingly problematic across the Commonwealth, as rates for service have risen precipitously to meet the ever-increasing need for costly infrastructure investment and upgrades. The commentator opposes the first alternative point of compliance [at the point of public water supply withdrawal], as it places the cost burden squarely on public water suppliers and would result in a significant cost to water utility customers, exacerbating the existing water affordability crisis. It is critically important to ensure that all Pennsylvanians – including the millions of households living at or near the poverty level – can afford to access and maintain water and wastewater services to their homes. The loss of water service due to the inability to pay can have far-reaching and devastating impacts to individuals, families, and the community as a whole.

Involuntary termination of water service due to the inability to pay immediately results in unsanitary and dangerous conditions in the home – and can and does trigger eviction and foreclosure proceedings, and often results in forced removal of children from the home. The inability to pay for water service also has long-term impacts on a consumer's credit, and has a destabilizing impact on the ability of families to remain housed over the long term – often triggering periods of homelessness. Indeed, the mere existence of utility debt often disqualifies households from public and private housing alike. Importantly, increased unaffordability for water service has a devastating impact on communities with high concentrations of poverty, as it causes increased blight, erodes the tax base, and destabilizes revenues for municipally owned water authorities in disadvantaged communities across the state. Each of these impacts are intensified in the context of the current public health and economic crises, as the ability to remain stably housed and access running water to wash hands and sanitize surfaces is critical to prevent further spread of the COVID-19 virus. Given the current and ongoing water affordability crisis in the Commonwealth, it is unacceptable to add any additional financial burden on public water utilities and authorities, as these costs will be passed directly on to ratepayers. (902)

Response: DEP appreciates the commentator's concern and recognition of the potential impacts of moving the point of compliance on public water systems serving lower-income areas of the Commonwealth. The final-form regulation retains the point of compliance at the point of discharge.

General Support for the First Alternative Point of Compliance; Movement of the Point of Compliance to Downstream Potable Water Supply Withdrawals Benefits Industry; No Impact on Public Water Systems

129. Comment: The House and Senate Environmental Resources and Energy Committees and other commentators urge EQB to apply the current manganese WQ criterion of 1 mg/L at the point of intake of existing and planned public water supplies pursuant to Act 40. (9, 861, 901, 922, 935, 952, 953, 955)

Response: DEP acknowledges the comment to move the point of compliance to the nearest downstream potable water supply withdrawal. For reasons detailed in the responses to Comments 202 and 212, the final-form rulemaking maintains the point of compliance in all surface waters (i.e., at the point of discharge). For reasons detailed in the responses to Comments 54-58 and in the criterion rationale document, "Development of the Human Health Criterion for Manganese", the final-form rulemaking replaces the existing Potable Water Supply criterion for manganese of 1.0 mg/L with a new human health criterion for manganese of 0.3 mg/L.

130. Comment: The commentator supports the points of compliance as being at the intake to the first downstream public water supply, consistent with Act 40 of 2017 and recommends that the EQB adopt the first alternative point of compliance. (2, 7, 8, 9, 10, 11, 12, 618, 698, 728, 859, 860, 862, 880, 905, 951)

Response: DEP acknowledges the comment to move the point of compliance to the nearest downstream potable water supply withdrawal. For reasons detailed in the responses to Comments 202 and 212, the final-form rulemaking maintains the point of compliance in all surface waters (i.e., at the point of discharge).

131. Comment: DEP has identified this WQS for manganese is needed for the protection of public water supplies but has conducted no studies assessing manganese (dissolved and total) concentrations at these existing and potential water supplies. (861)

Response: DEP has developed a manganese water quality criterion for the protection of human health which includes, but is not limited to, protection of the Potable Water Supply use. More than 21,000 statewide water quality (SWQ) samples were collected by DEP from surface waters throughout Pennsylvania between 2008 and 2018, including at Water Quality Network (WQN) stations, continuous instream monitoring (CIM) sites and other monitoring sites, such as public water systems. Additional public water system data were received by DEP in 2019 from a Pennsylvania public water system (SUEZ). An evaluation of the data can be found in Appendix A.

It is not relevant whether the form of manganese present is dissolved or total. When manganese levels exceed the EPA HAL of 0.3 mg/L, public water systems cannot treat the manganese using sequestration since this process only chemically binds the manganese into complexes that keep it in a dissolved state to prevent taste and staining issues. Sequestration does not physically remove the manganese from the water, so if consumed, it would become bioavailable to humans upon ingestion due to stomach acid having a pH in the range of 1 to 3. Manganese levels above the HAL also trigger public notification requirements for public water systems.

132. Comment: Changing the point of compliance to be within all surface waters or at the point of effluent discharge unnecessarily expands the 0.3 mg/L to be applicable for designated uses beyond human health. DEP choosing to apply a Human Health-based manganese WQS for the protection of all designated surface water uses is contrary to decades of the balanced environmental protection of PA surface waters. Given that the proposed manganese standard was developed based on intake, consumption, and human health only, it is inappropriate and overprotective to apply the proposed standard as an ambient standard that must be achieved in all surface waters, or at the point of all discharges. Rather, the standard should be applied where it will ensure the protection of intake and consumption – in those surface waters classified as “Potable Water Supply [use].” (9, 618, 859, 861).

Response: Human health toxics criteria have always been applied at the point of discharge in accordance with Chapter 93, 96 and 16. Furthermore, the development of criteria specific to each designated use is not generally necessary if more stringent statewide criteria already exist. DEP must protect the most sensitive water use(s) in all cases, and protection of those uses extends protection to all other applicable uses. Furthermore, with few exceptions, all surface waters of the Commonwealth are designated as and protected for Potable Water Supply use (25 Pa Code § 93.4. Statewide water uses.). The final-form regulation retains the point of compliance at the point of discharge. See also the responses to Comments 48 and 52.

133. Comment: In adopting the proposed regulation, Pennsylvania would be regulating manganese in a manner inconsistent with the surrounding coal mining states who have all adopted less restrictive manganese standards. Many of these states utilize the potable water supply withdrawal as the point of compliance for certain parameters. Ohio, Kentucky, Illinois, Indiana and West Virginia all base their manganese standard on the concentration at the potable water supply withdrawal, and there is no evidence that the health of the residents is affected by this point of compliance. In Virginia, the manganese human health criterion for Potable Water Supply use was removed, in part, because the state’s narrative criteria ensure full protection of the designated uses, including Potable Water Supply use.

In West Virginia, “*the manganese human health criterion shall only apply within the five-mile zone immediately upstream above a known public or private water supply used for human consumption.*” W. Va. Code § 47-2-6.2.d.

In Kentucky, all streams are designated for warm water aquatic habitat and primary and secondary contact recreation. “*The designation for domestic water supply is applicable only at points of intake.*” Section 401 K.A.R. 5:026. Kentucky does not have a Potable Water

Supply standard, an aquatic life standard, or a human health standard for manganese. Rather, it regulates mine discharges consistent with 40 C.F.R. §434.

In Indiana, “*all waters that are used for public or industrial water supply must meet the standards for those uses at the points where the water is withdrawn.*” 327 IAC 2-1-3(3). Indiana does not have a Potable Water Supply standard or an aquatic life standard for manganese. Rather, it regulates mine discharges consistent with 40 C.F.R. §434.

In Illinois, “*...waters of the State shall meet the public and food processing water supply standards . . . at any point at which water is withdrawn for treatment and distribution as a potable supply or for food processing.*” 35 ILCS §303.202.

In Ohio, “*all surface waters within five hundred yards of an existing public water supply surface water shall be classified as ‘Public Water Supply.’*” OAC 3745-1-07(B)(3)(a). Ohio does not have a Potable Water Supply standard, an aquatic life standard, or a human health standard for manganese. Rather, it regulates mine discharges consistent with 40 C.F.R. §434.

If EQB adopts the proposed rulemaking, Pennsylvania’s regulation of manganese will be at odds with and more stringent than every neighboring coal mining state. **(9, 15, 618, 728, 859, 862, 880, 901)**

Response: Every state must evaluate and adopt WQSs to protect surface waters from pollution. While every state must follow the requirements of the CWA, individual states also have their own laws, statutes, regulations, and policies that must be followed in adopting WQSs. In addition, the timeline on which individual states evaluate and adopt or revise their WQSs, including any evaluations of specific WQ criteria, can vary significantly from state to state.

DEP reviewed the WQS regulations for Ohio, Kentucky, Illinois, Indiana and West Virginia. All of these states currently base their WQS for the protection of Potable Water Supply use on the concentration at the potable water supply withdrawal. Ohio, Kentucky, and Indiana do not have WQ criteria for manganese to protect *any* water uses. Illinois and West Virginia are the only states listed in the comment with a Potable Water Supply use criterion for manganese. To the best of DEP’s knowledge, none of these states has evaluated the need for a human health criterion in at least the past decade. West Virginia has not evaluated manganese since the early 2000s when the “5-mile” rule was formally adopted by EPA in 2005. Illinois changed their WQS for manganese in 2012 by adopting hardness-based aquatic life criteria and increasing their Potable Water Supply use criterion from 0.15 mg/L to 1.0 mg/L. The rationale behind the change in Potable Water Supply use criterion stated that manganese levels in Illinois’s surface waters often exceeded the 0.15 mg/L criterion and the manganese appeared to be due to natural sources and conditions (that is, not from point source discharges related to industrial and mining wastewater effluent discharges, or other anthropogenic sources).

As described throughout this comment and response document, updated scientific data and literature on the toxicity of manganese has become available in the last decade. None of the

states listed in this comment have evaluated the more recent science on manganese. This statement generally holds true for States throughout the country. With the assistance of the Association of Clean Water Administrators (ACWA), DEP conducted a poll of the participating states to determine if any States had evaluated manganese recently and adopted human health criteria. The results indicated that a few states had Potable Water Supply criteria or drinking water HALs, but many States did not have criteria for manganese. It is important to recognize that manganese in surface waters is not a problem for many States due to the geology of the region, lack of mineral mining activities and other related factors. Furthermore, when states implement WQS, they are not required to collect health effects data from their residents, and therefore, it is not known if negative health effects have resulted from the point of compliance being located at the point of potable water supply withdrawal. A lack of health effects data does not equate to an absence of negative health effects.

Virginia's removal of its manganese WQ criterion was based, in part, on the 2003 EPA "Health Effects Support Document for Manganese", which reviewed the health effects data available at the time. In 2003, EPA's Safe Drinking Water program made a determination not to regulate manganese with an MCL. This information is now nearly two decades old and not consistent with the current science on manganese. As noted in the response to Comment 60, EPA Safe Drinking Water is currently reevaluating the science and data on manganese in drinking water.

134. Comment: The commentator owns and operates a surface water treatment plant in Mercer County. The commentator also has a NPDES permit to discharge treated filter backwash into the Shenango River. The commentator does not support reducing the manganese limit from 1 mg/L to 0.3 mg/L for all dischargers. It is unlikely the commentator would be able to meet this limit without significant plant upgrades. These upgrades would not impact or improve the finished WQ for its customers. Reducing the manganese discharge levels from the plant to 0.3 mg/L would likely have no impact on manganese levels in the Shenango River given the minimal discharge quantity relative to the river's flow rate. There is no benefit to justify the cost burden to the commentator's customers. Discharge limits should be based on actual WQ impacts on receiving streams. (6)

The commentator owns and operates a water treatment plant (WTP) with both groundwater and surface water sources. The WTP also has an NPDES Permit for discharge of filter backwash, which is treated to reduce sediments, to the Ohio River. The NPDES Permit currently includes a manganese limit of 1 mg/L. The commentator is concerned with DEP's proposed second alternative for manganese WQS revisions. Implementation of the second alternative would potentially result in the NPDES Permit manganese limit decreasing from 1 mg/L to 0.3 mg/L. It is unlikely that this limit would be met without incurring significant cost for WTP upgrades. These plant upgrades would have no impact on finished WQ and would likely be unnecessary to protect downstream surface water sources, and therefore the financial impact to the commentator's customers cannot be justified. With the goal of protecting water supplies from high levels of manganese in mind, the commentator requests that DEP consider the first alternative as a more practical regulatory change. Point source discharges such as the commentator will likely have no impact on the Ohio River's manganese concentration given how low the discharge rate is relative to the River's flow

rate. However, if the discharge did have an impact, it would be reasonable to justify NPDES changes that are based on actual receiving stream WQ modeling, with the intent of ensuring that manganese concentrations remain below 0.3 mg/L at water supplies, as compared to imposing a conservative limit uniformly on dischargers to all receiving streams. (2)

Response: DEP is aware that some public water systems, such as Commentators 2 and 6, are concerned that the proposed criterion will impact the NPDES permits they hold for the discharge of filter backwash water. While DEP recognizes that certain discharge situations have the potential to result in more stringent effluent limitations for this permitted sector, it is important to understand that nearly all public water system NPDES permits currently include TBELs of 1.0 mg/L. While this value is equivalent to the existing Potable Water Supply use criterion magnitude of 1.0 mg/L, they represent different protections and are not applied in the same way. The TBELs were developed by DEP using its BPJ. Application of these TBELs in permits requires public water systems to achieve manganese levels of no greater than 1.0 mg/L at the end of the discharge pipe and do not factor in the compliance travel time (i.e., dilution or mixing zone) typically used when calculating WQBELs. At this time, DEP is not proposing to change these TBELs for public water systems. Since DEP must implement the more stringent of TBELs or WQBELs, DEP must evaluate both types of effluent limitations during a permit application review. Public water systems, such as Commentator 6, that discharge into large unimpaired waterbodies are not likely to be affected by the proposed change in the manganese criterion from 1.0 mg/L to 0.3 mg/L. The TBEL of 1.0 mg/L will likely continue to apply.

135. Comment: Pennsylvania already has a water supply SMCL that is more stringent than the proposed human health criterion. Pennsylvania, and states such as Alaska, California, Colorado, Massachusetts, Minnesota, Nebraska, New Hampshire and Wyoming have adopted an SMCL for drinking water of 0.05 mg Mn/L (USEPA 2020). The SMCL, which is based on an EPA guideline for taste and color rather than protection of human health, is a limit targeted at the primary exposure route that all public water systems in Pennsylvania are already required to meet. In other words, whether the EQB adopts the proposed human health criterion of 0.3 mg/L or retains the existing 1.0 mg/L for designated Potable Water Supply uses, all public water systems would still need to supply drinking water that meets the more stringent manganese SMCL as written in 25 Pa. Code § 109.202(b)(1). This would not change if Act 40 were enacted as proposed. DEP would be setting a precedent that is not needed to protect human health or the environment and seems to not offer any actual benefit to supplied drinking water. (9, 12, 832, 859, 880)

Response: DEP agrees with the commentators that public water systems would still be required to comply with the SMCL of 0.05 mg/L manganese in treated, potable water regardless of whether the WQ criterion for manganese is 1.0 mg/L or 0.3 mg/L or where the point of compliance is located. DEP is not setting precedent by establishing the point of compliance for human health toxics criteria in all surface waters. Currently, the point of compliance for the manganese criterion of 1.0 mg/L is at the point of discharge and all Table 5 human health toxics criteria are applied at the point of discharge. DEP disagrees that applying a more stringent manganese criterion at the point of discharge does not provide any benefit to public water systems. By reducing the amount of manganese in surface waters,

public water systems may be able reduce their monitoring and treatment costs or eliminate them all together in some cases. See also the responses to Comments 48 and 52.

136. Comment: Water treatment facilities are generally more capable of handling water treatment of this kind than wastewater treatment facilities. Wastewater facilities tend to only use biological treatment not specialized for manganese. (12)

Response: DEP generally agrees that wastewater treatment facilities, such as domestic wastewater or sewage treatment plants, rely heavily on biological processes to remove nutrients and certain pollutants or pathogens typical of domestic wastewater. However, industrial wastewater is very different than domestic wastewater. Industrial wastewater treatment does not strictly, or even primarily, rely on biological treatment processes to remove pollutants unlike the treatment of domestic wastewater. Industrial wastewater treatment is more similar to water treatment in many ways. Both sectors use similar treatment techniques to remove pollutants that may include chemical addition, settling, and filtration. Industrial treatment systems are just as capable of removing manganese as water treatment systems such as those operated by public water systems.

137. Comment: Contrary to DEP's ANPR, SMCLs are not enforceable, and public water systems only test for SMCLs on a voluntary basis. Manganese is listed as an SMCL for aesthetic reasons such as laundry staining, and organoleptic effects like taste. Commentator believes that EPA's conclusions are sound and that there is no reason to revisit the SMCL or the underlying data on which it is based. (618)

Response: DEP is not proposing to change the Safe Drinking Water SMCL for manganese. While SMCLs are voluntary at the Federal level, SMCLs are required to be adopted and met in Pennsylvania, according to the Pennsylvania Safe Drinking Water Act and the regulations promulgated thereunder. *See* 35 P. S. § 721.4 and 25 Pa. Code §109.202(b). Although routine monitoring and reporting for manganese is not currently required, achievement of the 0.05 mg/L limit in finished water is not voluntary; it is a regulatory requirement. The SMCL is applicable to all public water systems in Pennsylvania.

138. Comment: 25 Pa Code, Chapter 93 establishes criteria for Potable Water Supply use which, for manganese, is 1.0 mg/l. It is important to note that Potable Water Supply use is defined in 25 Pa Code Chapter 93 as "Used by the public as defined by the Federal Safe Drinking Water Act, 42 U.S.C.A §300F, or by other water users that require a permit from the Department under the Pennsylvania Safe Drinking Water Act (35 P.S. §631-641), after conventional treatment, for drinking, culinary, and other domestic purposes, such as inclusion into foods, either directly or indirectly." Thus, the 1.0 mg/l manganese criterion is not a human health criterion, it is taste and odor criterion that applies after conventional treatment of water. Therefore, there should not be additional WQ-based permitting for manganese, beyond what is regulated in 25 Pa Code, Chapters 86 - 90 and 40 CFR Part 434 in discharges of water from an area disturbed by coal mining activities that do not have a reasonable potential to interfere with a public water supply intake. However, at present, DEP is applying the aforementioned Potable Water Supply use standard, a standard for drinking water, directly at the outfalls from permitted coal mining treatment facilities and sedimentation ponds. (618)

Response: DEP agrees that the current Potable Water Supply use criterion of 1.0 mg/L is not a human health criterion, but the Potable Water Supply use criterion also was not established for taste and odor purposes nor is it intended to be applicable after conventional treatment of water. The definition referenced in the comment above describes what Potable Water Supply use means in relation to the designated use that is to be protected. Finished water standards are entirely regulated by the Safe Drinking Water program under 25 Pa. Code Chapter 109, which is separate from the WQSs regulations. The WQSs regulations do not regulate finished water. Rather, the Potable Water Supply use and criterion that have been adopted are intended to protect surface waters of the Commonwealth such that the surface waters are available for present and future use as potable water supplies and should require only conventional treatment to make the water potable (that is, drinkable). While manganese may be removed through conventional treatment processes without modification in some public water systems, metals removal is not the purpose of conventional treatment, and many systems require either adjustments to existing processes or the addition of new treatment systems. Conventional treatment generally involves the use of coagulation, flocculation, sedimentation, filtration and disinfection to remove pathogens that can cause illness and organic matter that can cause esthetic issues.

DEP currently applies the Potable Water Supply use manganese standard in all surface waters, which is at the point of discharge. However, the standard is typically not included in permits as an end-of-pipe effluent limit unless the receiving water has no assimilative capacity to accept more of the pollutant or an approved TMDL requires implementation of a more stringent waste load allocation. In these cases, a discharger may receive an effluent limitation that is equivalent to WQ criteria. In most other cases, the discharger receives a water-quality-based effluent limitation that factors in a compliance travel time (that is, a mixing zone).

139. Comment: The EQB's analysis of the two alternatives is silent on the very important concept of mixing. Most industrial discharges are located a substantial distance from the nearest public water supply intake. Mixing is a recognized construct in the NPDES permitting program. Many permittees rely on a permitted mixing zone for compliance with WQ-based effluent limitations. If the human health criteria are applied at the point of discharge, these mixing zones arguably will no longer be allowable, as all State waters are treated as a public water supply. The commentator is unaware of any rulemaking effort to classify all Pennsylvania streams as drinking water supplies. (905)

Response: The implementation of the manganese criteria at the point of discharge follows current DEP regulations and policies. Compliance travel times (i.e. mixing zones) do currently apply to manganese and would continue to be used by DEP in the development of permit effluent limitations. WQ criteria are generally not applied at the end-of-pipe unless the waterbody has no assimilative capacity or an approved TMDL is being implemented. All Pennsylvania surface waters with a few exceptions are designated for the Potable Water Supply use, and this statewide designated use has been in place for many years. See also the responses to Comment 138 for more discussion on mixing zones and Comment 132 for discussion on Potable Water Supply use designations.

140. Comment: The proposed change to the point of compliance for manganese WQ criteria will not impact the protection afforded to surface potable water supply withdrawals. As part of the NPDES permitting process, DEP evaluates the proposed discharge and assigns effluent limits that are intended to not only protect the designated use of the receiving streams, but also to protect the nearest downstream potable water supply withdrawal. DEP consistently employs its Penn-tox program, which is a quantitative assessment of the reasonable potential for a discharge to cause an excursion above the applicable WQSs. This process applies to all dischargers and NPDES permit holders across the state – regardless of industry classification. The analysis is completed under conservative theoretical conditions that assume an elevated concentration of manganese is discharged at a maximum flow rate under drought conditions in the receiving stream, to ensure adequate protection of designated uses and downstream water supplies at all times. This analysis includes a comparison of industry specific effluent limit guidelines, to other guidelines and standards such as WQ-based effluent limits and TMDLs developed at the watershed level – an approach that is consistent with DEP’s WQ management and pollution control duties at the watershed level under the CSL. In this analysis, the most protective category of effluent limit is applied – and to reiterate, even in circumstances where industry specific federal effluent limit guidelines have been developed for specific industrial source categories. This analysis is routinely repeated during the permit renewal process to ensure continued protection and antidegradation of the Commonwealth’s water resources and associated designated uses.

If a potable water supply withdrawal does exist downstream of a manganese discharge, the discharger’s point of compliance will be modelled from the upstream point of discharge to the point of potable water supply withdrawal, allowing for attenuation of the effluent as it travels downstream. The discharger’s effluent limitation would be determined based on achieving the proposed manganese criterion of 0.3 mg/L at the point of potable water supply withdrawal. DEP should clarify that the change to the point of withdrawal mandated in Act 40 of 2017 will not result in the complete elimination of manganese effluent limits in NPDES permits issued by the state. Rather, the development of technology-based manganese effluent limits would still apply at the point of discharge, such as in circumstances where the applicable jurisdiction of an overarching federal ELG applies, or where reasonable potential analysis completed as part of the permitting process indicates negative impact to a nearby potable water supply withdrawal. For instance, the federal ELG’s for the coal mining industry 40 CFR §434 prescribe best available, technology- based effluent limitations for various mine drainage categories. These ELGs are also found in 25 Pa. Code Chapters 87-90. The federal ELG limitations of 2.0 mg/L monthly average and 4.0 mg/L daily maximum have been in place since 1985 and would continue to apply as end-of-pipe effluent limitations. As the permitting authority, DEP would maintain the right to define and reassess alternative criteria for facilities classified as post mining areas under 40 CFR §434.11(k). If concern exists for non-coal mining industries, DEP should regulate those industries through BAT standards or develop effluent limitations on a case-by-case basis using its BPJ. In addition, the EQB could establish a human health criterion for manganese applicable at the point of potable water supply withdrawal and a second criterion protective of aquatic life applicable at the point of discharge (or at the end of an appropriate mixing zone). **(9, 15, 497, 618, 728, 859, 862, 897)**

Response: DEP disagrees that the first alternative point of compliance does not have the potential to impact the protection afforded to public water systems that withdraw surface water.

DEP assesses reasonable potential and develops permit effluent limitations for specific pollutants. While DEP agrees that this process requires implementation of the most stringent, protective limit, there are several potential concerns with moving the compliance point for manganese to the downstream potable water supply withdrawal. In most cases, implementing either the current 1.0 mg/L Potable Water Supply use criterion or the proposed 0.3 mg/L human health criterion at the point of withdrawal would allow for increased discharges of manganese as dischargers must currently comply with the 1.0 mg/L criterion near the point of discharge. Furthermore, the Federal ELGs for the coal mining industry do not apply to other dischargers of manganese, and none of these other industries are subject to a Federal ELG for manganese.

141. Comment: Amending 25 Pa. Code 96.3(d) to include manganese will have no noticeable impact on public drinking water supplies, if implemented appropriately using existing regulatory mechanisms. At most, adding manganese to the group of constituents for which the WQ criterion must be met at the point of all existing or planned surface potable water supply withdrawals found in 25 Pa Code §96.3(d) raises the manganese limit for coal mining discharges from 1.0 mg/l to the federally allowable limit of 2.0 mg/l at the point of discharge, which will provide a positive economic benefit to the coal industry, watershed associations, and other organizations that treat mine water or acid mine drainage from abandoned legacy sites. DEP has not conducted any treatment cost analysis for either the discharges or the public water systems to demonstrate the benefits versus the costs of the proposed regulation. Since the benefit to the environment and the public is not demonstrated with the proposed rulemaking package, the substantial cost and effort to achieve compliance is inappropriate. (7, 9, 15, 618, 728, 859, 862)

Response: DEP disagrees with the statement that the movement of the point of compliance to the point of downstream potable water supply withdrawal has no potential to impact public water systems. See the response to Comment 147 for discussion on potential impacts to downstream public water systems. As stated by DEP throughout this comment and response document, the mining industry is the only regulated industry that has Federal ELGs for the discharge of manganese. There are no limitations for any other category of dischargers, and DEP has identified hundreds of NPDES permits for non-mining activities that currently contain manganese limits. WQSs apply to all activities that impact surface waters and are not written for specific categories of industry.

DEP solicited economic impact information from those potentially affected by the proposed rulemaking throughout the rulemaking process. Prior to the proposed rulemaking, DEP published an ANPR to collect data and information on manganese including potential economic impacts. DEP received comments through the ANPR and on the proposed rulemaking from several public water systems regarding the economic impacts to public water systems as a result of moving the point of compliance to the nearest downstream potable water supply withdrawal. One commentator owns and operates 68 permitted water treatment plants in PA. The commentator identified 16 plants that would be challenged if

manganese levels increased, and eight of those plants would be impacted to a point of requiring treatment plant modifications. The total capacity of the eight plants is approximately 40 MGD. The estimated costs for plant upgrades ranged between \$1-\$1.5 million per MGD, equating to an overall one-time capital cost of \$40-\$60 million. This estimate does not include anticipated increased annual operations and maintenance costs of \$700,000-\$1.4 million. See the response to Comment 165 for more information on estimated economic impacts to public water systems. See also Comment 169 and the response to Comment 215 for more information on estimated economic impacts to the coal mining industry.

DEP has also met with multiple technical advisory committees, individual mining companies and associations, public water system associations, Federal and State agencies, consultants, academics and others throughout the process to better understand the potential economic impacts. DEP continues to collect information and evaluate potential impacts of the proposed regulation on all entities potentially affected.

DEP disagrees with the statement that the proposed regulation does not demonstrate any benefit to the environment or the public. Through its work on stream redesignation rulemakings, DEP has presented information demonstrating the benefits and values of clean water. See the response to Comment 153 for more discussion on the benefits of clean water. DEP did review implementation costs associated with this final-form rulemaking. However, water quality criteria development does not center on economic factors. The Federal Clean Water Act emphasizes scientific considerations for criteria development that protects water uses.

142. Comment: There is an SMCL for manganese in drinking water at 0.05 mg/L, which public water systems are required to meet. With this being the case, it is highly unlikely that public water system operators will see any increases in operating costs as a result of this proposed regulation insofar as any manganese concentration increase in the raw intake water resulting from the proposed regulation will be negligible. Water entering the withdrawal point currently has to be 1.0 mg/L or lower and would stay 1.0 mg/L or lower even if the point of compliance were to be moved. Nothing will change for water suppliers. Should the point of compliance for a standard of 0.3 mg/L move to the point of nearest water supply intake, increased treatment costs would only theoretically occur in situations where dilution does not reduce instream concentrations of manganese to at or below the current instream criterion of 1.0 mg/L.

With respect to the costs of regulatory change, there have been numbers thrown around that water suppliers would have to spend \$60 to \$80 million in treatment upgrades if the point of compliance would be moved. However, no upgrades should be needed since there will be no change in protection as public water system operators currently have a 1.0 mg/L of manganese protection standard since DEP has placed the point of compliance within the stream. Additionally, the majority of the instream manganese is solid and should be removed at the potable water supply withdrawal by already standard filtration techniques. (728, 862, 897)

Response: DEP disagrees with these statements regarding the current protections to public water systems and that nothing would change as a result of moving the point of compliance to the downstream water supply intake. With the current point of compliance being established at the point of discharge, the raw water levels of manganese observed by many downstream public water systems are presently much lower than 1.0 mg/L. If public water system operators begin to receive higher amounts of manganese in their raw water, up to 1.0 mg/L, many are likely to be affected by the increased amount. The commentator oversimplifies the ability of public water systems to remove manganese using existing treatment processes. See the response to Comment 147 for additional discussion.

- 143. Comment:** DEP is proposing the new 0.3 mg/l standard be applied to all reaches of the stream to protect human health, especially for children and infants under the very unlikely scenario that children and infants drink directly from a stream. DEP has not identified the necessity for the proposed WQS for manganese by evaluating the current human health concerns to the public and the actual risk associated with incidental and voluntary consumption of “untreated” surface waters containing manganese. By this logic, all streams should be drinking WQ, which is impracticable and unachievable. This is why Chapter 93 states the definition of a potable water supply is “after conventional treatment.” (728, 861)

Response: DEP has extensively evaluated the toxicological data and science on the human health effects of manganese. DEP agrees that most individuals do not regularly consume untreated surface water for drinking water purposes; however, it is important to note that Pennsylvania does have several public water supplies that still use an unfiltered surface water (or groundwater under the direct influence of surface water) as their sole, or primary, source of water. Incidental or intentional ingestion can also occur during swimming and water recreation, particularly in children. In addition, the human health protections encompassed by human health criteria generally extend to more than drinking water consumption, and may include other exposures such as fish consumption and water contact sports.

Furthermore, while DEP agrees that it would be unachievable for all streams to be of potable drinking WQ without any treatment, the Potable Water Supply use protects present and future water supplies by maintaining water quality so that only conventional treatment is necessary to make the water potable. As specified in 25 Pa. Code § 93.4. Statewide water uses., “except when otherwise specified in law or regulation, the uses set forth in Table 2 apply to all surface waters.” Table 2 contains the Potable Water Supply use as well as WWF, Industrial Water Supply, Livestock Water Supply, Wildlife Water Supply, Irrigation, Boating, Fishing, Water Contact Sports and Esthetics.

- 144. Comment:** Adopting manganese as a toxic substance and establishing a much more stringent human health criterion would unnecessarily burden those wastewater utilities under the purview of NPDES permits or practicing residuals management. In 2016, EPA included manganese in the UCMR4 as a part of the Safe Drinking Water Act. The agency’s collection of that occurrence data remains ongoing through the end of 2020. As no national primary drinking water standards yet exist for manganese, it would be inappropriate and excessive to apply a concentration limit equivalent to the current, highly protective 10-day drinking water HAL for infants to the ambient WQ of Pennsylvania streams. Furthermore, elevated

manganese in drinking water may often be attributed to premise plumbing issues that would not be alleviated by the implementation of the proposed ambient WQS. (890)

Response: It is important to recognize that safe drinking water regulations and WQS regulations stem from independent programs with their own goals and requirements. As noted by the commentator, EPA included manganese in the UCMR4 and is currently evaluating the science on the toxicity of manganese. It is unclear at this time when, or if, EPA will establish a primary MCL for manganese or what the value will be. However, as stated in the response to Comment 62, the lack of regulation for a specific parameter by the SDW program does not imply that it is inappropriate for the same parameter to be regulated under the WQSSs program.

DEP disagrees with the statement that it would be excessive and inappropriate to protect surface waters at a level that is protective of infants. As described in the response to Comment 57, a human health AWQC “should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water- or fish intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects.” Although the values of the proposed criterion and EPA’s HAL are both 0.3 mg/L, the proposed WQ criterion is not based on EPA’s drinking water HAL. Both values rely on the EPA IRIS reference dose. Regarding the establishment of HALs, EPA generally develops HALs for one-day, ten-day and lifetime exposures if adequate data are available. EPA did not have sufficient information to develop a one-day advisory for any age group, but recommended use of the ten-day advisory for a child (1.0 mg/L) as a conservative estimate for the one-day exposure for both children and adults. EPA further indicated that the ten-day advisory for a child should also be protective of adults. Calculation of the lifetime health advisory of 0.3 mg/L utilized adult exposure inputs for body weight and drinking water consumption rates. EPA did not develop specific advisories for infants, but rather chose to apply the lifetime health advisory of 0.3 mg/L for both acute and long-term exposures “because of concerns for differences in manganese content in human milk and formula and the possibility of a higher absorption and lower excretion in young infants.”

DEP also disagrees with the statement that manganese in drinking water is often attributed to premise plumbing issues. The commentator provided no water supply data or scientific studies to support this claim. According to the National Academies of Sciences, Engineering and Medicine (NAS), premise plumbing includes that portion of the potable water distribution system associated with schools, hospitals, public and private housing, and other buildings. It is connected to the main distribution system via a service line. Premise plumbing systems most commonly use pipes made of copper, plastics, brass, stainless steel and galvanized iron. DEP agrees that some manganese leaching could occur where galvanized iron or steel has been used in premise plumbing. However, manganese problems in Pennsylvania’s public water systems are most often due to the presence of manganese in the source water (both surface and groundwater). While amounts greater than 0.05 mg/L cause noticeable taste and staining issues, smaller amounts can also cause problems such as manganese scaling within the distribution system pipes. According to a 2011 WHO document (WHO/SDE/WSH/03.04/104/Rev/1), manganese can form coatings on water pipes

that may later slough off at water concentrations as low as 0.02 mg/L. While this manganese might appear to be a plumbing/piping issue, it is actually caused by the presence of manganese in the water entering the distribution system. DEP does agree that any issues arising directly from premise plumbing (that is, leaching from pipes) would not be addressed by the rulemaking.

145. Comment: Following the signing of Act 40 into law, the commentator submitted a written request to the EQB requesting that 25 Pa. Code 96.3(d) be amended to include manganese as an exception to subsection (c). In the comment letter, the commentator points out that the WQS found in 25 Pa. Code 93 is a Potable Water Supply use standard and not an effluent limitation. As such, it is a WQS that must be attained after treatment. The discrepancy between effluent limitations for mining criteria and Potable Water Supply use results in the misapplication of the Potable Water Supply use criteria when an operator seeks an NPDES permit. Chapter 87 and 88 mining regulations only require mine operators to treat manganese to 2.0 effluent standard. Holding mine operators to the more stringent Chapter 93 standard in areas that will have “zero impact” on any potable water source creates an unnecessary cost burden on operators while providing no noticeable environmental or consumer protection. Additionally, once the regulation is amended, manganese will still be regulated and treated but on a more site-specific basis. Companies, like the one in Tamaqua who want to treat manganese to a 2.0 will still be required to update and amend their TMDL plans. At that point, potable water supply withdrawal sites can be identified and those mining and treatment operations which may be located at an unsafe distance may still be required to continue to meet the 1.0 [mg/L] standard or somewhere in between. (15)

Response: DEP agrees that the current WQ criterion in Chapter 93 is for the protection of Potable Water Supply use and is not equivalent to an effluent limitation. WQSs are used to develop effluent limitations that are protective of all surface water designated uses and water users. DEP disagrees that the current application of the Potable Water Supply use criterion at the point of discharge is a misapplication of the criterion and does not provide environmental or consumer protection. The existing manganese WQ criterion provides protection for the Potable Water Supply use, but it also provides protection for other, intervening designated uses (such as aquatic life, recreation and irrigation uses) between the point of discharge and downstream potable water supply withdrawal. Furthermore, the manganese criterion is currently applied to the development of effluent limitations in accordance with 25 Pa. Code § 96.3(c), which requires that the criterion be met at least 99% of the time in all surface waters.

Whether a WQ criterion applies at the point of discharge or the point of downstream potable water supply withdrawal, DEP follows approved guidelines and procedures to develop permit effluent limitations, which includes the evaluation of TBELs, WQBELs, TMDLs, and antidegradation, as appropriate. Waste load allocations specified by TMDLs must be implemented in all NPDES permits issued by DEP unless an evaluation of other factors, as described above, would result in more stringent limits.

DEP is tasked with the responsibility to establish TMDLs for impaired waterbodies.. It is important to note that, where a waterbody has been determined to be impaired and effluent limitations have been established based on a TMDL approved by EPA, the antibacksliding

provisions of the CWA (33 U.S.C.A. §§ 1342(o) and 1313(d)) and the Federal NPDES regulations may prohibit a relaxation of the existing effluent limitations. In all cases, existing permitted dischargers would be required to comply with any existing wasteload allocation in a TMDL, if it is more stringent than TBELs, until the TMDL is revised.

146. Comment: Coal mine discharges are located mostly in remote extreme headwater reaches far away from public drinking water supplies. Based on a survey of PCA operating members and consultants, discharge sites are on average greater than 40 miles from a potable water supply withdrawal. In some cases, the mine sites contribute only a very small amount of water in comparison to the size of the receiving waterbody.

For example, one anthracite mining company located in Tamaqua, Schuylkill County is treating for manganese at its mine discharge to the 1.0 standard. It is placing its treated discharge into the Little Schuylkill River which is one of numerous tributaries of the Schuylkill River. According to the USGS from 2013 to 2017 the average daily mean water flow in the Little Schuylkill River averaged between 64.5 and 84.9 cubic feet per second (CFS). However, by the time it reached its nearest potable water supply withdrawal, 73 driving miles from the treated discharge, the flow had increased to an average daily mean ranging from 2,276 to 3,245 CFS. By the time it reaches the first potable water supply withdrawal we have been able to identify downstream, the water flow has increased by a factor of more than 38 times the flow in Tamaqua. Additionally, the average daily manganese treated water flow exiting the Tamaqua mine site during the same period of time has averaged 12.1 CFS. By the time it reaches the point of the first potable water supply withdrawal on the Schuylkill River, the treated discharge represents about 0.0053 percent of the entire system's flow volume. We have not been able to find any testing figures for manganese at the potable water supply withdrawal. However, at 73 driving miles distant, we believe it is safe to say that any water treated for manganese in Tamaqua will have dropped out of suspension or long been diluted by the time it reaches the potable water supply withdrawal. In fact, given the distance and the volume of water diluting the treated manganese discharge from its introduction in Tamaqua until its first withdraw 73 miles away, it is highly unlikely that even if treated to the Federal standard of 2.0 mg/L that it would have any noticeable impact on the public water system drawing from the Schuylkill River.

When factoring for the federal discharge limit of 2.0 mg/l, assimilation, and with the added protection of the required reasonable potential analysis found in 40 CFR §122.44 and incorporated at 25 Pa. Code §92a.44, the discharge of this naturally occurring element from mining facilities will not affect any potable water supply withdrawals. Therefore, the point of compliance should be at the point of potable water supply withdrawal. Furthermore, given that all waters of the State do not serve, either legally or practically, as public drinking water supplies, the application of the Potable Water Supply use standard at such distances is overly restrictive and nonsensical. (15, 618, 698, 954)

Response: Almost all surface waters of the Commonwealth legally serve as potential potable water supplies. In fact, the Potable Water Supply use is a statewide protected use listed in 25 Pa Code § 93.4, Table 2. Potable Water Supply use applies in all surface waters of the Commonwealth except where the Potable Water Supply use has been specifically removed in

§§ 93.9a-93.9z. There are only a few exceptions in the Chapter 93 WQSs regulations where the Potable Water Supply use has been removed. Those exceptions include the Delaware estuary found in Drainage Lists E and G and several tributaries to the Allegheny River near Pittsburgh found in Drainage List U.

Since the final-form manganese criterion was developed as a toxics criterion for the protection of human health and is not specific to the Potable Water Supply use, the appropriate application of the criterion is in all surface waters. At the present time, all 122 human health toxics criteria are applied at the point of discharge and must be met in all surface waters at least 99% of time. As such, the distance of the discharge from potable water supply withdrawals is not relevant to the application of a human health criterion.

In addition, the comment states that mining discharges are generally located in extreme headwater reaches of streams, which raises other concerns outside of Potable Water Supply use and human health. If a manganese criterion was to be applicable only at downstream potable water supply withdrawals, it is unlikely that there would be adequate protection of aquatic life, the other water supply uses, recreational uses and esthetics in these headwater reaches, which are by their nature very sensitive to ecological disturbances. Conservative pollutants, such as manganese, do not normally breakdown into non-toxic substances through physical, chemical or biological processes in the receiving water and, therefore, would have the potential to increase in streams as a result of movement of the compliance point. Furthermore, these substances tend to be long-lived, stable compounds that can persist within the environment. Even if dischargers are releasing insoluble or “particulate” manganese into neutral pH receiving waters at the point of discharge, downstream tributaries and other influences can change WQ, including pH, which could convert particulate manganese to dissolved and result in the transport of manganese farther downstream than has been suggested. While it is recognized that mining activities are regulated, in part, by Federal ELGs which limit the discharge of manganese as a 30-day average to 2.0 mg/L, mining discharges may contain up to 4.0 mg/L as a daily maximum and 5.0 mg/L as an instantaneous maximum. These higher values are not protective of aquatic life or other protected water uses.

- 147. Comment:** As part of the ANPR, DEP requested information on the financial and economic impact of compliance with the manganese WQS, including costs associated with adding manganese treatment to public water supply facilities, and manganese treatment process information. A comment from the PA Public Utility Commission (“PUC”) states that the 1.0 mg/L standard established in Act 40 will “require a significant financial investment for affected treatment systems.” In a separate comment, PA American Water estimates \$40-60 million in compliance costs associated with the Act 40 revision to the WQSs. Both sets of comments assume, but do not substantiate, the adoption of Act 40 will significantly increase manganese concentrations at the point of intake into the water treatment facility. It is apparent DEP relied heavily on the assumed increase in treatment costs to support the proposed lowering of the manganese limit to 0.3 mg/L; however, as stated in the TetraTech report, there are additional considerations that should be factored into the analysis. The previously mentioned comments from the PUC and Pa American Water do not assess the

sources of manganese in their raw intake water, rather they carte blanche predict Act 40 will result in increased concentrations which will result in increased costs.

Manganese in raw intake water comes in two chemical forms, dissolved or insoluble. Insoluble forms of manganese are typically associated with high flow events that scour particulate manganese from stream beds and banks. Insoluble manganese is removed by conventional filtration and would not add to chemical costs. In explaining the history of the current 1 mg/L Potable Water Supply use criterion, the DEP BCW Rationale document states that, in 1979, an “average up-to-date water plant can probably handle soluble manganese concentrations without too much difficulty. A well-designed plant can handle 1.5 to 2 parts per million.”

The treatment of surface water for drinking water must comply with the EPA Surface Water Treatment Rule, which generally requires conventional treatment of the raw water. Overall conventional water treatment consists of: 1) screening of the intake to remove large debris; 2) chemical feed of oxidants, disinfectants, pH adjustment chemicals (e.g., lime), coagulants and flocculants; 3) rapid mix to disperse the chemicals into the water; 4) flocculation to increase the size of the coagulated particles; 5) sedimentation to remove the large flocculated suspended solids; 6) filtration to remove fine particles and provide removal of pathogens (e.g., cryptosporidium oocysts); and 7) post-chlorination of the treated drinking water to maintain a disinfectant residual throughout the distribution system. The overall objective of conventional treatment is to provide a clean water free of suspended solids and pathogens. One of the components in the initial treatment is the addition of primary oxidant/disinfectant chemicals. This chemical for surface waters often includes chlorination (or ozone), known as pre-chlorination, and is a component in the initial disinfection of the raw water and to prevent slime growth in the treatment systems including flocculators, pipes, clarifiers, and filters. While the primary function is disinfection and slime control, these chemicals will also act as oxidants to oxidize inorganics, such as sulfurs, iron and manganese.

TetraTech assessed a worse-case scenario (i.e., no dilution from fate and transport) for treatment systems that rely on chlorination to address dissolved manganese. Their results show it is expected the regulation “would result in a maximum treatment savings of less than \$0.0007 per 1,000 gallons water treated at the treatment plant. The average household cost savings created by the 0.3 mg/L WQS would be only about \$0.40 to \$1.00 per year.” The final point made by TetraTech likely speaks directly to the ANPR commentator’s concerns about increased costs associated with chemical treatment of dissolved manganese. As pointed out by TetraTech, however, the source of manganese “is likely from upstream historic mining activities, but unrelated to NPDES discharge points from mining.” Gross assumptions about manganese concentration increases without a fate and transport assessment of permitted NPDES discharges upstream of any particular drinking intake is bad science at best and negligence at worst. As TetraTech points out, should the rule be finalized as promulgated, the cost of compliance with the new manganese standard from legacy sources will fall to the State of PA and her taxpayers.”

Also worth pointing out are two comments currently on the docket from two municipal water authorities. Both groups oppose adoption of the new standard because of the costs associated

with treating NPDES permitted filter backwash discharges to meet the new standard. It is clear DEP neglected to conduct a fulsome cost/benefit analysis and merely assumed the costs of lowering the standard would transfer to dischargers rather than drinking water providers. **(618, 832, 901, 954)**

Response: DEP does not agree with various statements and analyses presented in this comment and in the Tetra Tech report, which appears to make a number of incorrect assumptions and overly simplifies drinking water treatment processes with respect to manganese removal.

Cost information submitted by drinking water facilities as part of the ANPR considered the potential impacts of moving the current 1.0 mg/L criterion for manganese to the point of potable water supply withdrawal, in accordance with Act 40. At that time, DEP had not proposed a change to the criterion magnitude. Public water systems have no ability to accurately predict the future levels of manganese that will be found in their raw water samples. The cost information that was provided considered the impacts to public water systems if the systems received raw water containing manganese at concentrations of 1.0 mg/L, the maximum allowable limit at the point of intake.

Manganese, like all metals, is a conservative pollutant. Conservative pollutants do not normally breakdown into non-toxic substances through physical, chemical or biological processes in the receiving water. These substances tend to be long-lived, stable compounds that can persist within the environment. Manganese has the potential to increase in streams as a result of movement of the compliance point and to be carried downstream. It would be difficult to accurately predict the levels of manganese that would be encountered by public water systems. If a potable water supply withdrawal isn't located near a discharge, NPDES permittees other than the mining industry will potentially be able to discharge significant quantities of manganese into the environment. In addition to the increased amount of manganese, many factors affect the behavior of manganese in the aquatic environment including, but not limited to, pH, frequency of high flow/scouring events, salinity/TDS and the presence of other metals. Manganese is unlikely to be present in particulate form and settle out in low pH waters. As has been noted in many comments by industry, manganese removal typically requires very high pH levels to quickly precipitate it out of solution. Many streams, particularly in coal-mining areas, tend to have lower pH levels (<6 and as low as 3 in some localized areas) and elevated levels of other pollutants, such as iron or sulfates. Even if dischargers are releasing insoluble or "particulate" manganese into neutral pH receiving waters at the point of discharge, downstream tributaries and other influences can change WQ, including pH, which could convert particulate manganese to dissolved and result in the transport of manganese farther downstream than has been suggested.

Public water systems must adjust their treatment processes based on the raw WQ of the surface water entering their facilities. Raw water levels of manganese currently reflect a compliance point for manganese at the point of discharge. If dischargers are allowed to release more manganese into the environment to the point of achieving 1.0 mg/L at the closest downstream potable water supply withdrawal, public water systems will need to increase source water monitoring to ensure their treatment plant continues to achieve the

SDWA regulatory limits. Currently, the raw water levels of manganese at many public water systems' intakes are much lower than 1.0 mg/L, and even 0.3 mg/L, so if instream concentrations rise to 1.0 mg/L at the point of withdrawal, many of these systems would be impacted. Some of them to the point of requiring updated treatment processes to remove the extra manganese.

While DEP's 1979 rationale document for the existing 1.0 mg/L statewide Potable Water Supply use criterion discusses some testimony from a water treatment plant operator regarding the ability of a public water system to remove manganese, it must be recognized that there have been many regulatory changes in the safe drinking water program since that time. Some of these changes restrict the use of certain types of chemicals and limit other operational practices in order to safeguard the public from exposure to toxins and diseases. For example, regulations have been passed to limit the formation of toxins in the water distribution system after treatment (that is, the Disinfection By-Products (DBP) Rule) or reduce the concentration and possible breakthrough of pathogens (that is, the Filter Backwash Recycling Rule). The Tetra Tech report ignores these regulatory changes in the program and assumes that all systems can pretreat with chlorine. In fact, many public water systems currently do not have the ability to pre-chlorinate due to DBP formation or are otherwise limited in their ability to feed certain chemicals prior to sedimentation and filtration.

The Tetra Tech report also assumes that the majority, if not all, of the surface water public water systems in the Commonwealth use conventional filtration. In fact, more than one-third of the 337 permitted surface water public water systems use processes other than conventional filtration, including direct filtration, diatomaceous earth filtration, membrane filtration, slow sand filtration, and other filtration technologies.

In addition to the assumption that all surface water treatment plants use conventional filtration, Tetra Tech appears to have assumed that all systems use chlorine gas for disinfection or pre-treatment. While chlorine gas is two to four times cheaper than liquid sodium hypochlorite, chlorine gas was largely abandoned by public water systems as the preferred disinfectant following the events of September 11, 2001. Chlorine gas is extremely toxic if it is inhaled or comes in contact with skin and can react explosively. Since the density of this gas is approximately 2.5 times that of air, it will tend to remain near ground level if there is little air movement. Thus, the use of this chemical presents greater potential dangers to public water system operators and the public. Of the 216 public water systems that still use conventional filtration, 125 systems are currently identified in DEP's drinking water inventory system (PADWIS) as using chlorine gas in their treatment processes. However, based on consultation with the SDW program, it is clear that public water systems are generally moving away from the use of chlorine gas and even from the use of conventional filtration.

DEP consulted and collaborated with Drexel University to better understand manganese removal treatment options and the challenges associated with manganese removal for public water systems. An analysis completed by Drexel University (Hamilton et al., 2022) identified additional challenges for public water systems regarding the treatment and removal of

dissolved manganese from surface waters that conflict with some of the statements made by Tetra Tech. The Tetra Tech report states that chlorine will oxidize inorganics, such as sulfurs, iron and manganese. The Tetra Tech report further states that chlorine is frequently used for the oxidation of dissolved manganese prior to greensand filters and the same principle would also apply to conventional treatment systems. Tetra Tech writes, “At most, any slight increase in dissolved (or reduced) manganese in intake water would require a modest increase in chemical (chlorine) use as part of pre-chlorination.” Drexel found that manganese is not readily oxidized by chlorine at pH values typical of water treatment. As stated in the Drexel report, “Tobiason et al. (2016) report that oxidation of manganese by chlorine is not effective until pH 9, which is well above the range in which most water supply treatment plants operate. Thus, the equation given on page 15 of the Tetra Tech report, which shows the oxidation of manganese by chlorine, while not incorrect, would not occur to a substantial degree under typical water treatment conditions per Tobiason et al.” Drexel also noted Tetra Tech’s comments about the difficulties of removing manganese when aluminum is present may be applicable to drinking water treatment. The Drexel report states, “Difficulties with simultaneous removal of aluminum and manganese from coal mine drainage are noted in Tetra Tech’s comments and clearly warranted careful consideration with respect to conventional drinking water treatment process. Aluminum salts are widely used as a water treatment additive [i.e., coagulant] and at favorable pHs can precipitate readily.”

Furthermore, the Tetra Tech report fails to address the impact of manganese on the filter beds. Conventional filtration plants typically use mixed media filters which contain layers of anthracite followed by layers of sand. The mining industry has repeatedly stated that treatment of manganese is very difficult because manganese removal requires pH adjustments and can be challenging to settle out of the water. Public water systems face similar challenges and manganese can negatively affect the downstream processes in the water treatment plant due to adsorption, scaling, etc. As noted in the response to Comment 144, WHO found that manganese can form coatings on water pipes at water concentrations as low as 0.02 mg/L. This coating of surfaces can also occur in the filters. If manganese oxide is present even in low levels in the water being delivered onto the filter beds, a coating of manganese will form on the anthracite possibly reducing the life of the filter media and the functioning of the filter bed. Unlike bacteria and other such particles found in the water leaving the sedimentation basin(s), not all of the manganese is simply trapped by the filter and disposed of in the waste sludge. Regarding the effects of particulate forms of manganese on filters, any additional loading of solids onto the filter bed would decrease filter run times and necessitate more frequent backwashing. Other types of filtration plants, such as membrane plants, would be faced with similar challenges and costs including increased backwashing and chemical cleaning of the membranes, possible need for pre-treatment to prevent fouling of the membranes and/or increased membrane replacement costs. The Tetra Tech report did not consider or evaluate these other impacts and associated costs.

DEP does not anticipate increased costs to taxpayers to address legacy mining issues as result of this final-form rulemaking. Legacy discharges are generally managed using available funding, including any existing bonds that were forfeited and grants obtained through OSMRE’s Abandoned Mine Reclamation Fund. See also the responses to Comments 51 and 175.

DEP has conducted a thorough review and comprehensive evaluation of the issues. DEP is aware that a couple of public water systems commented in support of the point of compliance at the point of potable water supply withdrawal. There is currently misunderstanding among some of the public water systems regarding the basis for their existing NPDES discharge effluent limitations for manganese. The public water system sector has a TBEL of 1.0 mg/L applied at the end-of-pipe, which was developed by DEP using its BPJ. Implementation of the proposed 0.3 mg/L criterion would require an evaluation of WQBELs modeled at the point of discharge. While the adoption of the final-form criterion at the point of discharge could potentially result in an end-of-pipe limitation of 0.3 mg/L for a public water system, there are only limited situations in which that is likely to occur. Particularly for public water systems on larger waterbodies, the current BPJ-based TBEL of 1.0 mg/L would likely continue to be the most stringent limit, and as such, there would be no change to the current NPDES discharge limitations for manganese. See also the response to Comment 134.

148. Comment: In the first alternative, “if a potable water supply is located on the stream, a discharger’s point of compliance with the proposed manganese criterion will be modelled from the upstream point of discharge to the point of potable water supply withdrawal, allowing for attenuation of the effluent as it travels downstream. The discharger’s effluent limitation would be determined based on achieving the proposed manganese criterion of 0.3 mg/L at the point of potable water supply intake.” This suggests that the financial burden of compliance will not rest solely upon the public water system, as the DEP will have the ability to apply individual limits based on modeling. Additionally, industries such as power generation and mining will still be subject to the existing BAT manganese limitations. Enforcing an effluent limitation based on a downstream requirement and supported by WQ modeling is a more reasonable regulatory approach than uniformly applying a conservative limitation to all upstream dischargers. Furthermore, this approach would not place the full financial burden of meeting the 0.3 mg/L limitation solely on the public water supply systems, since WQBELs could still be applied to upstream dischargers with the potential to impact downstream WQ. **(860)**

Response: DEP agrees that movement of the point of compliance would not provide relief to NPDES dischargers where a discharge would have the potential to impact a public water system. These NPDES dischargers would be required to protect the downstream potable water supply withdrawal. It is unclear at this time how many dischargers would be impacted. However, it is important to note that public water systems are still likely to be impacted even if the manganese WQ criterion becomes more stringent and upstream NPDES permits require more stringent effluent limitations.

DEP agrees that the mining industry would still be subject to the Federal ELGs. However, the steam electric power generation industry does not have an ELG for manganese.

149. Comment: Public water systems in the Commonwealth are required to meet drinking water standards (MCLs) established under the federal SDWA, including the SMCLs. The SMCL for manganese is 0.05 mg/L. Significantly, neither the proposed rule nor the supporting documentation cites any examples of public water systems in the Commonwealth that

currently are not able to meet the SMCL for manganese or of individuals experiencing neurological disorders from excessive intake of manganese from drinking water. The proposed standard for protection of human health is 0.3 mg/L – six times higher than the drinking water standard. Because of the difference between the two standards, treatment to remove manganese will still be required at public water system treatment plants to achieve the SMCL. Thus, imposing the proposed standard at the point of discharge for users upstream of a potable water supply withdrawal would likely improve downstream manganese concentrations, but not to the extent where treatment to meet the SMCL could be reduced or eliminated. (497)

Response: DEP agrees that public water systems are required to meet the SMCL for manganese in finished drinking water, independent of WQSs. As previously discussed by DEP, WQSs for human health are not specific to the Potable Water Supply use, and WQSs serve a different role than the Chapter 109 Safe Drinking Water requirements. When establishing WQSs for the protection of human health, it is irrelevant whether or not public water systems are currently achieving SDW MCLs or SMCLs. With respect to health effects, DEP is not aware of any efforts in Pennsylvania to identify or track negative developmental health outcomes in children that have been associated with exposures to elevated manganese through drinking water, including memory and behavioral issues. With that stated, a lack of study and examination in Pennsylvania does not imply that negative health effects are nonexistent. Recent studies have been conducted in other states, including Ohio, and other countries to examine the effects of manganese exposure on neurodevelopment in children. The results of those studies continue to support the link between excessive manganese and negative neurodevelopmental outcomes in children.

DEP agrees that treatment will still be needed at various public water system treatment plants to achieve the SMCL regardless of the final WQ criterion or point of compliance. However, it is possible that public water systems will be able to reduce the amount of treatment needed and, in some cases, may be able to cease treatment all together. The commentator did not provide any data or information to support the claim that no public water systems would be able to eliminate treatment for manganese as a result of the proposed criterion of 0.3 mg/L being met at the point of discharge. See the response to Comment 143 for more discussion.

150. Comment: The current criterion, total manganese not to exceed 1.0 mg/L, was established in 1967 by the Department of Health, Sanitary Water Board, for only certain waterbodies in the Commonwealth. This standard was adopted statewide in 1979. This standard was to ensure that public water systems receive water at their intake structures that can achieve compliance with Safe Drinking Water standards using only conventional treatment. An “average up-to-date plant can probably handle soluble manganese without too much difficulty. A well designed plant can handle 1.5 to 2 parts per million [mg/L] ...” If a well-designed plant in 1967 could treat 1.5 to 2 mg/L of manganese to meet the SMCL of 0.05 mg/L, it is again difficult to understand why the WQS needs to be reduced to 0.3 mg/L for a “newer” conventional water treatment plant to meet the SMCL of 0.05 mg/L. (497)

Response: It must be recognized that there are a number of considerations that need to be taken into account with respect to the above reference. First, the testimony quoted in the

comment was initially used to develop a WQS only for this one facility's water source, the Allegheny River. DEP could not locate any additional files or information related to the 1967 site-specific manganese criterion. Thus, it is unclear whether the claims in the testimony were supported or validated by any additional scientific study or additional treatment plant operational data. In fact, DEP's 1979 rationale document for the manganese criterion noted discrepancies between the literature and testimony from the Wilkinsburg Joint Water Authority.

It should also be noted that EPA did not establish the SMCL for manganese until 1977, and Pennsylvania did not have primacy over its SDW program until 1984. There have been many regulatory changes in the SDW program since 1967 when the above testimony was obtained from Mr. Adams, superintendent of the Wilkinsburg Joint Water Authority. See also the response to Comment 147. Some of these more recent regulatory changes restrict the use of certain types of treatment chemicals and limit other operational practices in order to safeguard the public from exposure to toxins and diseases. For example, regulations have been passed to limit the formation of toxins in the water distribution system after treatment (that is, the Disinfection By-Products (DBP) Rule) or reduce the concentration and possible breakthrough of pathogens (that is, the Filter Backwash Recycling Rule). As a result of many of these newer regulations, few surface water treatment plants pre-chlorinate or add oxidants to the beginning of the treatment process. Also, if manganese is present in the water entering the filtration stage, it can affect the filter bed media and necessitate more frequent replacement and maintenance among other problems.

In addition, EPA published a HAL for manganese of 0.3 mg/L in 2004. If raw water levels of manganese are at or above this level, corrective action requirements are triggered for the public water system, including additional monitoring and the potential need for the public water system to issue public notification. Furthermore, they can no longer treat the manganese in the raw water using sequestration.

151. Comment: The proposed rule expresses concern that moving the point of compliance to the potable water supply withdrawal could burden facilities with surface water intakes that require a certain level of WQ and cites certain industrial sectors as examples. However, the proposed rule fails to identify any examples of potentially impacted facilities, what the current WQ is to those facilities, what their required levels of influent WQ are, how current WQ compares to the required levels, what treatment is already required in addition to conventional water treatment, as defined by the EPA Surface Water Treatment Rules, or what additional treatment might be required. Without such information, the potential impacts are speculative. (497)

Response: In addition to Potable Water Supply use, all of the other water supply uses are protected statewide, including Industrial Water Supply, Livestock Water Supply, Wildlife Water Supply and Irrigation. Moving the point of compliance to the nearest downstream potable water supply withdrawal does not provide protection for the other statewide water supply uses.

PFBC submitted comments to this effect during the ANPR regarding manganese levels and fish culture. PFBC indicated that the desirable range for manganese is between 0-0.01 mg/L

with an acceptable range up to 1.0 mg/L. If manganese concentrations are higher than 1.0 mg/L then pre-treatment is necessary to remove manganese to an acceptable level to raise fish. Both State and private hatchery operations could be impacted by moving the point of compliance to the point of downstream potable water supply withdrawal.

The Penn State Extension is an educational organization that provides practical information to the public on topics such as agriculture, forest management, food safety, 4-H and WQ. According to the Penn State Extension, manganese levels in irrigation water above 0.05 mg/L can cause clogging of irrigation equipment and above 2.0 mg/L may be toxic to sensitive plants. EPA also noted in their WQ criterion recommendation for manganese (Gold Book edition, 1986) that at levels of slightly less than 1.0 mg/L to a few milligrams per liter, manganese may be toxic to plants from irrigation water applied to soils with pH values lower than 6.0. EPA also stated that most industrial users could operate where the 0.05 mg/L public water system SMCL was observed, but some industries may require more stringent criteria to protect or ensure product quality.

152. Comment: There are no potable source waters in Moshannon Creek downstream of the Rushton AMD Treatment Plant, and the closest downstream water intake is over 100 miles away. It becomes difficult to understand the purpose of applying the proposed 0.3 mg/L manganese standard to a surface water of such poor quality as Moshannon Creek and that does not serve as a potable water supply. It also becomes highly unlikely whether any person would consider using the Moshannon Creek as a potable water, intentionally or unintentionally, which raises concerns as to the purpose of implementing the proposed 0.3 mg/L manganese standard uniformly either at all discharges or in all streams, particularly where upstream background manganese concentrations are far in excess of the proposed standard.

With respect to surface water potable treatment, EPA has developed Surface Water Treatment Rules that generally require minimum levels treatment (conventional) that involve filtration to protect the public from microbial pathogens known to be contained in surface waters. This pathogen content in surface waters again raises a concern of risk and why a surface water should be drinkable for manganese when it is not drinkable based on pathogen risk. With respect to potable water treatment, conventional treatment described by the American Water Works Association includes screening, primary oxidant/disinfectant, coagulation/flocculation, sedimentation, and filtration before a final disinfectant is added for distribution of the water to the public. This conventional process train would easily capture particulate manganese that is in the surface water sediment load (e.g., total suspended solids) with no additional costs or operational requirements. In addition, dissolved manganese, at concentrations less than 2.0 mg/L (BAT limit for the coal mining industry), can be removed in conventional treatment with primary oxidants forming particulate manganese that will be captured in the subsequent treatment processes.

There are two important conclusions based on the above considerations for surface waters potable water treatment. First, if the manganese in the surface water reaches the potable water intake as a particulate form with other suspended solids, there is no implication on the water treatment plant operation as this manganese would be captured as part or required treatment of the Surface Water Treatment Rules. Second, if the manganese reaches the

treatment plant intake as dissolved manganese, which can be no more than 1.0 mg/L under current TMDL effluent limits and 2.0 mg/L under BAT limits, the conventional treatment will be able to remove this manganese through slight increases in primary oxidant, with subsequent removal similar to capturing of particulate manganese discussed above. Therefore, the current BAT limit for manganese, if achieved across all discharges, would be sufficient for potable water treatment.

Our final comment on potable water treatment is that it is likely that the major cost increases at potable water treatment systems will not be the treatment of water for potable water but instead will be for treatment of various waste water streams (e.g., filter backwash and sludge decant) that may contain “captured” particulate manganese that originate from surface waters withdrawn. Treatment of these flows to comply with the proposed regulation are likely and could be a significant increase in capital and operating costs for the surface water potable water treatment plant.

DEP should withdraw the proposed manganese WQS until such time that they have evaluated total and dissolved manganese in surface water potable water supplies. This is needed for DEP to better understand the cost implications of manganese and its removal in surface potable water supplies and treatment plants. DEP should also conduct cost evaluations to determine the costs of treatment at the potable water supplies versus the costs of treatment at the private and public sector discharges, including implications on discharges from potable water treatment plants. **(861)**

Response: Regardless of whether or not a public water system currently exists on Moshannon Creek, the Potable Water Supply designated use is a statewide protected use and is applicable to this waterbody. Furthermore, DEP has explained that human health toxics criteria can be applicable to multiple protected water uses and are not specific to the Potable Water Supply use. DEP disagrees with statements that public water systems would easily be able to treat to remove additional manganese from the source water. See the response to Comment 147 for more discussion on public water system impacts.

In addition, while DEP recognizes that BAT limits exist for certain mining discharges, there are no other regulatory-based TBELs for other dischargers. Otherwise, public water systems with NPDES-permitted discharges are the only other dischargers that have effluent limitations based on something other than WQ. These facilities typically have a BPJ-based TBEL developed by DEP that is applicable at the end of pipe. There are hundreds of non-mining, non-drinking water NPDES permits with manganese limits. See also the responses to Comments 51 and 52.

Many public water systems are unlikely to see any change in their NPDES effluent limitation for manganese because this industry currently has a BPJ-based TBEL of 1.0 mg/L applicable at the end of pipe. See response to Comments 134 and 147 for more discussion.

- 153. Comment:** There is the issue of substantially raising costs for the permitted industries without a significant tangible benefit for the citizens of the Commonwealth. The primary argument put forth to justify the reduction in the criterion is to reduce the treatment cost for

public water systems. Yet Tetra Tech has convincingly shown that any impact from reducing the criterion to 0.3 mg/L will be negligible on account of the unlikelihood of dissolved manganese reaching a potable water supply withdrawal. The most generous case involves a savings to the average household in the range of \$0.40 to \$1.00 per year by reducing the criterion. This minuscule amount does not justify the outsized burden placed on permitted dischargers and, by extension, their employees and their families and the vendors that depend on their business. Additional purported benefits put forth include specific ones that can be shown to be at odds with the most up-to-date science, such as protection of human health and aquatic life, and general ones, such as impacts to tourism and property values, that are speculative and included with no justification or evidence that the current criteria is harmful in those regards. The net result is a rulemaking that fails the cost-benefit analysis. (951)

Response: DEP disagrees that the proposed rulemaking provides no benefit to the residents and visitors of the Commonwealth and that the purpose of the criterion is to reduce costs for public water systems. DEP must satisfy federal and state laws when developing WQSSs. DEP has followed these requirements. The manganese WQ criterion has not been comprehensively reviewed or updated since 1979. Many scientific studies and data have become available since that time, which warranted a review of the current science. DEP's review of the available, peer-reviewed scientific literature and data resulted in the proposed human health criterion of 0.3 mg/L.

DEP does not agree that the Tetra Tech report has shown negligible impact to public water systems. As noted in the Drexel report (Hamilton et al., 2022), "Regardless if an existing potable water supply treatment plant is considered to employ 'conventional treatment,' in a survey conducted by Kohl and Medlar (2006), it was discovered that utilities that did not have specific treatment in place to control manganese were not able to handle variable or intermediate manganese loadings and therefore manganese would pass through the treatment system into the distribution system, with a ratio of maximum manganese to average manganese concentration greater than 7.5:1 resulting in manganese issues, suggesting the concern raised by the Pennsylvania American Water Company and the Reading Water Authority, is also a concern for other utilities in the state of Pennsylvania. These fluctuations in finished water quality typically result in customer complaints that are costly to manage. Case studies show that many consumers will experience episodic dissatisfaction with water quality even at the SMCL of 0.05 mg/L." See the response to Comment 147 for more discussion on the challenges that public water systems face with respect to manganese removal.

With respect to the commentator's statements on impacts to tourism and property values, the commentator states DEP did not provide evidence or justification that the current criterion is harmful. First, the existing WQ criteria were promulgated by rulemaking, which included public comment opportunities and reviews by Commonwealth and Federal agencies. With respect to this rulemaking, DEP did evaluate the impacts of moving the point of compliance for the manganese criterion to the point of downstream potable water supply withdrawal. DEP has addressed the costs/benefits associated with clean water. The RAF generally refers to several studies and sources that discuss how clean water translates to increased property values. The study, *The Effect of Water Quality on Rural Nonfarm Residential Property*

Values, (Epp and Al-Ani, American Journal of Agricultural Economics, Vol 61, No. 3 (Aug. 1979), pp. 529-534 (www.jstor.org/stable/1239441), used real estate prices to determine the value of improvements in WQ in small rivers and streams in Pennsylvania. WQ, whether measured in pH or by the owner's perception, has a significant effect on the price of adjacent property. The analysis showed a positive correlation between WQ and housing values. They concluded that buyers are aware of the environmental setting of a home and that differences in the quality of nearby waters affect the price paid for a residential property.

A 2010 report from the Delaware Riverkeeper Network (www.delawareriverkeeper.org/sites/default/files/River_Values_Report_0.pdf) discusses a case study from the Maine Agricultural and Forest Experiment Station which compared water-front property values based on whether the water that the homes faced was considered clean. Properties located near higher quality waters had higher market value than if the waterbody was lower in WQ. It was shown in some cases that a decline in WQ can completely abate the market value premium associated with a home being a waterfront property.

A 2006 study from the Great Lakes region estimated that property values were significantly depressed in two regions associated with toxic contaminants (polyaromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs) and heavy metals). The study showed that a portion of the Buffalo River region (approximately 6 miles long) had depressed property values of between \$83 million and \$118 million for single-family homes, and between \$57 million and \$80 million for multi-family homes as a result of toxic sediments. The same study estimated that a portion of the Sheboygan River (approximately 14 miles long) had depressed property values of between \$80 million and \$120 million as the result of toxics. “*Economic Benefits of Sediment Remediation in the Buffalo River AOC and Sheboygan River AOC: Final Project Report*,” (www.nemw.org/Econ). While this study related to the economic effect of contaminated sediment in other waters in the Great Lakes region, the idea that toxic pollution depresses property values applies in Pennsylvania. A reduction in toxic pollution in Pennsylvania’s waters has a substantial economic benefit to property values in close proximity to waterways.

Southwick Associates prepared a report for the Theodore Roosevelt Conservation Partnership that analyzed the economic contribution of outdoor recreation in Pennsylvania. This 2018 report, “The Power of Outdoor Recreation Spending in Pennsylvania: How hunting, fishing, and outdoor activities help support a healthy state economy” (www.trcp.org/wp-content/uploads/2018/12/TRCP-and-Southwick-PA-Economic-Analysis-12-6-18.pdf), states that during 2016 there were greater than 390,000 jobs supported by outdoor recreation activities in Pennsylvania, and for comparison, this is greater than the number of jobs in Pennsylvania that supported the production of durable goods. Outdoor recreation had an economic contribution in Pennsylvania of almost \$17 billion in salaries and wages paid to employees and over \$300 million in federal, state and local tax revenue.

154. Comment: The source of dissolved manganese in surface waters at potable water supply withdrawals is likely from upstream historic mining activities, but unrelated to NPDES discharge points from mining. Lewis (1978) studied the Susquehanna River basin and found manganese concentrations in basins with mining was significant. However, this manganese

was not from permitted mining sites where treatment removes manganese to established effluent limits but from past abandoned mine sites where the mine water is left untreated. Review of two recent watershed reports including the “Moshannon Creek Watershed TMDL” prepared by DEP (2009) and the “Acid Mine Drainage TMDLs for the Kiskimentas-Conemaugh River Watershed, Pennsylvania” prepared by the EPA (2010b) indicates the vast majority of mine drainage loading (and manganese) in these mining affected basins is from abandoned legacy sources. It is these abandoned untreated sources that have resulted in TMDL implementation and would be the sources affecting downstream potable water supply withdrawals and, not the regulated and treated NPDES mine water sources. Treatment of these legacy discharges would be needed to comply with the 0.3 mg/L WQS, and this would be at the burden of the state and the state taxpayers. Unfortunately, watershed restoration goals for nearly all of the legacy sites do not include manganese removal. There may be some manganese removal but it is typically very limited because of the additional costs to achieve this manganese removal that can double treatment costs, limited available funding, and the minimal benefit of manganese removal at achieving watershed restoration objectives that primarily focus on pH, iron, aluminum and acidity/alkalinity for aquatic life restoration and recreational benefits. **(618, 901)**

Response: DEP recognizes that acid mine discharges from legacy AML sites are significant contributors to many of the mining-related, surface water impairments and TMDLs. However, even if an active mine discharger is not the cause of an existing impairment, they may not contribute to the impairment.

When properly designed to remove manganese and with periodic maintenance, manganese removal through cost-effective passive treatment systems can be significant, and passive treatment systems are capable of removing manganese down to the proposed criterion or lower. The Glasgow AMD site contains passive treatment beds and is operated by DEP. The system was designed to treat a 40 gpm discharge containing high acidity, no alkalinity, high iron (~95 mg/L), high aluminum (~55 mg/L) and high manganese (~97 mg/L). This system effectively raises the pH from 3 to 7.5, adds alkalinity, reduces both iron and aluminum to <0.1 mg/L and reduces manganese from 97 mg/L to an average of 2.7 mg/L. Examination of the effluent data shows that the manganese levels in approximately 50% of the effluent samples are below 0.3 mg/L and 70% are below 1.0 mg/L. More information is provided on the Glasgow site in Comment 156.

155. Comment: Applying the federal technology-based 2.0 mg/l standard at the discharge, and the 1.0 mg/l Potable Water Supply use standard at the potable water supply withdrawal, would result in significant chemical cost savings to coal mining operations. Discharge flow rates vary based on a number of factors, including the type of operation, season, and precipitation. However, as a reasonable estimate, treating coal mine discharges to 2.0 mg/l costs approximately \$.00065 per gpm to treat manganese. If an average discharge rate is 200 gpm, the chemical cost savings for caustic addition at one discharge would be over \$68,000 annually. Considering there are hundreds of NPDES permits for coal mining operations in Pennsylvania, including facilities being operated by watershed associations and other non-profit organizations to treat acid mine drainage from legacy operations, the economic impact could be upwards of a million dollars. **(618)**

Response: DEP appreciates this information on the potential cost savings to the industry associated with moving the point of compliance.

Removing Manganese from Wastewater Including Treatment Technologies and the Technical Feasibility of Achieving the Proposed Manganese Criterion

156. Comment: The commentator provided information on the economics and treatability of manganese based on years of experience as a research ecologist with the U.S. Bureau of Mines (Department of Interior) and as the owner of an environmental consulting firm.

- Manganese oxidation occurs by two distinct chemical processes – homogeneous and heterogeneous reactions. Homogeneous reactions require a pH above 9, which is achieved through the addition of caustic chemicals. Most conventional manganese-removing treatment systems in PA promote this type of reaction using sodium hydroxide. Manganese oxidation also occurs by a heterogeneous process that involves the oxidation of manganese that has been adsorbed onto a solid. This reaction occurs at circumneutral pH and the solids produced are dense. The presence of manganese dioxide acts as a catalyst to speed up the reaction. This is a natural process that occurs widely in soils and streams. Many streambeds in mining-impacted areas of PA have black substrate due to the natural formation of manganese dioxide. It is suspected that microbes may contribute to the oxidation of manganese under these conditions.
- Passive mine water treatment systems utilize the heterogeneous process. Passive systems contain physical substrates that provide points of attachment for solids and microbes that subsequently catalyze the manganese removal process. The two most common substrates are wetlands and aggregate. The use of constructed wetlands for manganese removal was pioneered in the 1980's and 1990's. The approach is effective, but the results can be variable due to changing redox conditions and flow paths in the wetlands. Aggregate has proven to be a more reliable substrate. In PA, where mine water is often acidic, limestone aggregate is typically used. However, in areas where the water is alkaline and limestone is not available, non-calcareous aggregates have been used with similar manganese-removing success.
- Information was provided on four passive treatment systems. Three systems contain limestone beds that are open to atmosphere and are designed to promote oxic conditions. These three systems are located in Cambria, Tioga and Clinton Counties. The fourth bed is an open system in Phu Kham, Laos that contains granite aggregate.
 - Mitchell West Box, Tioga County - An experimental oxic limestone treatment bed was installed at the Anna S Mine in 2008 as part of DEP-funded research project. The system consists of limestone aggregate in a roll-off container that is plumbed to receive acid mine drainage from the Mitchell Mine. The passive system is still operating and is maintained by the Babb Creek Watershed Association. While the research was focused on treatment of acidity, aluminum and iron, sustainable removal of manganese has also been observed (graph below). Over the last four years of treatment, the effluent manganese concentrations have been <= 0.5 mg/L and three measurements have been less than 0.3 mg/L.

- Tangascootac #1 Passive System, Clinton County - The system was installed in 2010 at an abandoned surface mine site in Clinton County. The system includes an oxic limestone bed that treats acidic water contaminated with aluminum and manganese. It is operated by the Clinton County Conservation District. The system has decreased manganese to very low levels. The median effluent from the system has contained 0.3 mg/L manganese. The accumulation of solids in limestone bed requires periodic maintenance and it has been cleaned twice. Manganese removal, which had lessened prior to the second cleaning, was restored to < 0.5 mg/L manganese after cleaning. Four of the six samples collected since 2016 contained < 0.3 mg/L.
- Glasgow Passive System, Cambria County - The Glasgow passive system is a bond forfeiture system operated by the Cambria District Mining Office. The system receives water with high concentrations of acidity, iron, aluminum, and manganese. Treatment is by several passive units arranged in series and the last unit is an oxic limestone bed intended to remove manganese. The raw water manganese concentrations average between 70-150 mg/L. The median manganese concentration of the effluent leaving the final limestone bed is < 0.3 mg/L.
- Phu Kham, Laos - Copper mining at the Phu Kham mine in Laos created a discharge from a tailings facility that is alkaline with 3-8 mg/L manganese. The effluent limit is 0.5 mg/L. A passive system consisting of a large bed of granite aggregate was installed. After a six week start-up period, the system consistently produced a final effluent with < 0.5 mg/L manganese. Approximately 90% of the effluent samples have contained < 0.3 mg/L manganese.
- Data from a variety of sites indicate that passive treatment designs that promote the heterogeneous and microbial removal of manganese can reliably produce final effluents with less than 1.0 mg/L manganese and, in many cases, less than 0.3 mg/L manganese. Sustaining such treatment requires maintenance as the aggregate must be periodically stirred and cleaned. These efforts typically occur on a multi-year schedule and the costs are minor. It is likely that sustaining effluents with <0.3 mg/L manganese would require more frequent maintenance, but not to a degree that substantially erodes the attractive economics of the treatment approach.
- The ability of oxic aggregate beds to sustainably produce effluents with < 0.3 mg/L manganese is uncertain but, based on the information available from these four sites and many other passive systems in PA, it is achievable. Many effluent samples with < 0.3 mg/L manganese have been collected from these systems. If the Commonwealth implements the new manganese standard, it should also support research efforts to optimize passive manganese-removing treatment processes and develop best management practices for operation & maintenance of systems.
- Lastly, a common criticism of passive treatment is that the systems are too large and cannot be accommodated by available space. The passive treatment of manganese contained by large deep mine discharges (>1000 gpm) may require large aggregate beds that cannot be accommodated on the mine sites by gravity flow systems. In these cases, pumping of water to a suitable site will need to be considered. Pumping is never preferred, but the combination of pumping with highly effective passive

treatment is likely less expensive and more effective for manganese removal than standard chemical treatment alternatives. If the Commonwealth implements the new manganese standard, it should support research that determines the comparative costs and effectiveness of conventional chemical treatment, aggregate-based passive treatment, and aggregate-based passive treatment with pumping. (17)

Response: DEP appreciates the submission of this information on the operation of passive treatment systems. DEP supports continued research into the technologies and techniques, including emerging new technologies, available to remove manganese from mine drainage.

157. Comment: Regulation of manganese in surface waters initially followed EPA's 1972 and 1977 CWAs where resulting manganese concentrations were limited in the range of 2-4 mg/L. EPA's mid 1970s report of Coal Mining Effluent Guidelines indicated treating water to these limits also ensured other trace elements were controlled, as manganese acted as a surrogate for other elements. Manganese was selected because when manganese was present, other priority pollutants were also present, and when manganese was removed during conventional treatment, other priority pollutants were also removed. Conventional treatment typically involves adding alkalinity to raise pH, then precipitating the metals in a settling area. However, this technology may require the pH to be raised to over 10 standard units to precipitate manganese, followed by a chemical re-acidification of the water in order to discharge the water at a pH below 9. Manganese treatment involves a careful balance between chemical dosage to control pH, while carefully managing total suspended solids and aluminum levels to ensure a compliant discharge. (8, 922, 955)

Response: As is stated in EPA's 2008 Effluent Guidelines Program Plan, "EPA reviewed the Technical Development Documents supporting the Coal Mining effluent guidelines and did not identify any discussion regarding promulgating manganese effluent guidelines to ensure surrogate removal of other metals (*see DCN 06117*). EPA's review of these documents showed that EPA's rationale for requiring manganese control for a subset of coal mines was to address drinking water organoleptic effects."

DEP is aware of the complexities that can be encountered in removing manganese using conventional mining wastewater treatment (that is, active chemical addition and settling). Based on a report completed by PSU (Burgos, 2021) for DEP, other treatment options beyond chemical addition may be available for some types of discharges.

158. Comment: Several PA Chamber members have noted that meeting an in-stream standard of 0.3 mg/L will require a treatment approach that will produce finished water with pH and aluminum levels that are themselves unacceptable for discharge. (897)

Response: Any permitted discharge of pollutants into waters of the Commonwealth would be required to comply with the effluent limitations contained in the permit including those limitations based on achieving the WQ criteria for pH and aluminum.

159. Comment: There are several other aspects to a lower manganese effluent limit that should be part of any assessment and this relates to the additional pollution that will occur as a result of

promulgating the proposed 0.3 mg/L WQS. As indicated above, alkaline chemical addition will be expected to increase. Using lime as an example, the additional lime use will result in additional mining of limestone, production facilities to produce lime from the limestone, gas emissions (e.g., NOx, SOx, carbon dioxide, particulates) related to converting limestone to lime, and transportation (increased truck traffic) to deliver lime to each operating mine water treatment plant. Using lime as a basis the following is an assessment of the carbon dioxide emissions. The gas emissions from converting lime from limestone will include carbon dioxide, which is both evolved from the limestone and the energy used to heat the limestone in order to free the carbon dioxide from the limestone.

For each ton of lime produced about 0.6 tons of carbon dioxide will be released from the limestone. The energy to heat the limestone will result in the release of between 0.20 and 0.45 tons of carbon dioxide, depending on the heating fuel used (GGP 2020). Overall, the production of 1 ton of lime will result in about 1 ton of carbon dioxide emissions. In the above examples and based on a 1 MGD flow basis, carbon dioxide emissions just from the production of lime will be about 45,000 tons annually to meet the 0.3 mg/l WQS. The above analysis represents just the carbon dioxide emissions and as indicated above, there would be additional pollutants released to the environment for the mining industry to comply with the 0.3 mg/L WQS if applied at the discharge point. The carbon footprint of having a significant amount of additional treatment chemicals delivered flies in the face of DEP's approach regarding climate change. (618, 922)

Response: The commentator notes and the Department generally concurs that the use of additional treatment chemicals to achieve a WQ criterion of 0.3 mg/L near the point of discharge could result in additional environmental pollution through the generation of carbon dioxide. However, the same argument could be made for shifting the point of compliance to downstream potable water supply withdrawal. If the use of additional treatment chemicals results in increased pollution then moving the point of compliance would also be expected to result in additional pollution due to increased chemical usage by public water systems which would be required to remove additional manganese from their source water to achieve the SMCL of 0.05 mg/L in finished water as required under Chapter 109.

160. Comment: A unique challenge to our mining industry is that although we are a necessary industry to further the construction and infrastructure goals of the Commonwealth, mining is also pigeon-holed by local zoning regulations to minimal areas within each township, municipality or borough. Those short-sighted regulations also force the mining industry to maximize the use of available land. Additional area within mining facilities to create large treatment ponds for manganese removal just do not exist. (10)

Response: DEP appreciates the commentator's statement regarding local zoning restrictions, but DEP has no control over local zoning laws and regulations. It should not be assumed that large treatment ponds will be needed in all cases. Suitable treatment options will vary according to discharge flow and other characteristics, which must be evaluated on a site-specific basis. DEP recognizes that some situations could require the need for additional treatment and that land availability may be limited.

161. Comment: Treatment for manganese involves use of chemical materials to raise the pH to neutralize acidity and precipitate metals such as iron, aluminum and manganese. Contrary to public opinion, our industry strives for no violations of their permit limits. Consequently, to ensure a consistent pattern of no exceedances of a limit, the level of treatment will need to be below 0.3 mg/l, more likely near 0.15 mg/l. To lower the manganese levels, a neutralization process can be used, but it depends on a myriad of factors, which ultimately determines the dosage of the neutralizing product. There is a reason that manganese is not usually treated for, and it is due to the balancing act required between iron and aluminum precipitation and manganese precipitation, and the insignificant environmental and health benefit. It will require a closely monitored, pH-controlled process whereby the pH is increased to a level greater than a pH of 10 and where any iron and aluminum begins to dissolve. Unfortunately, this pH level is outside the WQ criteria limits of 6 – 9, and will subsequently require another pH adjustment to get the pH back in line with the 6 – 9 limits. While this may sound simple, and perhaps for a small discharge it is, it is significant undertaking for large discharges. (922, 955)

The Rushton AMD Treatment Plant uses neutralization in combination with large settling ponds to treat the pumped deep mine water to achieve effluent limits. This industry-wide and accepted treatment (Design Manual: Neutralization of Acid Mine Drainage – U.S. EPA: EPA-600/2-83-001) is the established BAT for coal mine discharge treatment.

The delicate operational balance is created by the conflicts in treatment of the lower manganese and lower aluminum effluent limits. The lower 1.0 mg/L manganese can usually be met but this requires increasing the neutralization pH from the upper 8's of historic operation to the mid- to upper 9's, thereby increasing the lime use, and sludge production. Sludge production is increased from precipitation of calcium and magnesium (a process known as cold water softening) and not manganese precipitation. This increase in neutralization pH for manganese removal conflicts with aluminum removal because aluminum is effectively removed between pH 7 and 8 but removal decreases, due to hydroxide solubility, as the pH is increased to greater than 9. As pH is increased to greater than 9, aluminum solubility increases to where 0.75 mg/L effluent limit for aluminum is approached and exceeded. The conflict between the two effluent limits becomes apparent and the plant is easily upset to a non-compliance condition with a shift in neutralization pH by as little as 0.1 units.

Lowering the effluent further to meet the proposed 0.3 mg/L manganese discharge standard would only exacerbate the pH neutralization conflict between manganese and aluminum. Neutralization pH would need to be increased to greater than 10 to consistently achieve the 0.3 mg/L manganese effluent limit. Lime for the neutralization would be expected to increase by between 50 and 100% and a corresponding increase in sludge volumes would occur, again from the precipitation of calcium and magnesium and not manganese. However, at this elevated pH the aluminum solubility would increase to well above the 0.75 mg/L effluent limit. In addition, the neutralization pH for manganese removal would necessitate post-neutralization pH adjustment to lower the pH to between 6 and 9, likely using costly sulfuric acid. While the pH adjustment would lower the solubility of aluminum, removal of the particulate aluminum would be an unlikely endeavor in the current treatment plant because

the aluminum solids would settle slowly, if at all, in any existing settling pond at the treatment plant. It becomes clear that new treatment facilities and operations would be needed to comply with the proposed manganese WQS at the discharge point, and may not even be reasonably available treatment technology for such a large mine water flow. (861)

Response: DEP understands that there can be many challenges associated with removing manganese from wastewater particularly when other metals, such as aluminum and magnesium, are present. In these cases, it is less likely that treatment for all pollutants can occur through use of a single stage treatment process and may require multi-stage treatment processes.

Impacts of the Proposed Manganese Criterion of 0.3 mg/L on NPDES Permitted Wastewater Facilities Including Treatment Costs

162. Comment: As our water pollution control plants discharge effluent with average manganese concentrations consistently below the proposed 0.3 mg/L ambient WQS and do so downstream of all regional drinking water utilities, manganese has not previously been incorporated into those plants' NPDES permits because the discharges do not pose an exceedance risk to the existing WQS of 1.0 mg/L manganese. Even with the application of a more stringent ambient WQS of 0.3 mg/L manganese at the nearest downstream potable water supply withdrawal, our water pollution control plants would not be impacted as there are no planned or existing potable water supply withdrawals downstream. However, applying the more stringent standard at all points of discharge and the subsequent incorporation of manganese into our water pollution control plant NPDES permits as a part of the next permit cycle may necessitate that we incorporate novel and expensive treatment technologies, as the plants are not currently designed to achieve such a stringent level of removal. Investing in such large-scale, physical updates that are inappropriate for our treatment systems would demand a significant cost that would ultimately need to be transferred to our customers in the form of rate increases. As the more stringent human health criterion would protect public health no better than the existing WQ criterion, our ratepayers would be forced to finance a debt that produces no discernible benefits. In its response within the required RAF submitted to the IRRC, DEP stated: "No costs will be imposed directly upon local governments by this regulation." As there is in fact potential for municipally-owned systems (which are a form of local government) to incur costs associated with this regulation, DEP appears to be understating to IRRC the potential cost implications of this rulemaking proposal. A more realistic cost analysis should be completed before the proposal is considered. (890)

Response: As indicated in responses to other comments, there is currently some misunderstanding regarding NPDES effluent limitations for manganese and the proposed manganese criterion. The manganese effluent limitations in public water systems' NPDES discharge permits reflect a BPJ-based TBEL of 1.0 mg/L, which is implemented as an end-of-pipe limit. The proposed manganese criterion of 0.3 mg/L is not equivalent to a TBEL. The criterion would be used by the NPDES permitting program to model WQBELs, which allows for inclusion of a compliance travel time (i.e., mixing zone). While some public water systems may receive more stringent limitations as a result of the criterion, many public water systems will see no change to their existing NPDES limitation for manganese, particularly where water systems discharge into large receiving waters (such as the Delaware River).

Question 20 of the RAF does recognize “certain municipally-owned water suppliers that treat surface water or municipally-owned wastewater treatment plants that discharge manganese to surface waters may be affected by this regulation.” DEP reviewed the non-mining permits with manganese effluent limitations and noted that the permits for most municipal sewage treatment plants contain only monitor and report requirements, which indicates that manganese is currently not present in the wastewater at levels of concern. A small handful of sewage treatment facilities have numeric manganese effluent limitations, and most are related to TMDLs. Most of the non-mining NPDES permits with numeric manganese effluent limitations are due to the BPJ-based TBEL for public water system facilities or a TMDL. DEP revised the RAF for the final-form regulation.

163. Comment: Imposing the proposed criterion on upstream dischargers (or all dischargers if the criterion applies to all surface waters) would increase the wastewater monitoring and treatment costs for many of those dischargers, including municipal wastewater treatment plants, industrial discharges, coal and non-coal mining dischargers, and earth disturbance activities. The proposed criterion is only 30% of the existing criterion, and is so low that many dischargers will trigger monitoring requirements and additional treatment would be required to meet a 0.3 mg/L effluent limit for manganese. Significantly, effluent treatment also may be required for public water system facilities, as the reject water and sludge handling from their water treatment systems may have total manganese in concentrations greater than 0.3 mg/L. (497)

Response: DEP recognizes that the final-form rulemaking has the potential to increase monitoring and treatment costs for certain permitted dischargers with manganese in their wastewater. Regarding the NPDES permits for public water systems, the final-form regulation is unlikely to affect the effluent limitations in many of these permits due to the fact that existing effluent limitations reflect technology-based limits that apply at the end-of-pipe. See the responses to Comments 134 and 147 for more discussion on the public water system technology-based effluent limitations. See the response to Comment 16 for discussion on impacts related to earth disturbance activities.

164. Comment: The proposed rule states that the economic impacts associated with a new WQ criterion of 0.3 mg/L and with applying the manganese criterion at the point of potable water supply withdrawal versus at the point of discharge depend upon the size of the discharges, specific treatment processes employed, the quality of the source water and many other factors; and therefore, concludes that it is not possible to precisely predict the actual change in costs. The proposed rule then fails to do any quantitative cost evaluation for the various economic impacts. Without such analysis it is impossible to determine whether the proposed rules are economically feasible or whether the economic impacts would be manageable or appropriate for the expect benefits versus the expected costs. Considering the treatment processes for manganese are well known for many industries, including the water treatment industry, an evaluation of the relative costs of various options should be performed using flow-based unit costs for capital and operating costs for treatment options to provide at least some basis for assessing economic impacts of the rulemaking options. (497)

Response: During the ANPR and public comment period for the proposed rulemaking, DEP and EQB received some information from public water systems and mining companies regarding the potential financial impacts of the proposed regulation. These cost estimates are tailored to each individual facility and reflect the site-specific factors that must be considered when evaluating potential impact for a given facility. DEP is not capable of conducting site-specific evaluations of every facility potentially affected by the proposed rulemaking, in part, due to the site-specific nature of each facility, but also because of the need to predict future business and operational changes that have not yet been decided or determined for the facility or facilities to be evaluated. Thus, DEP is only able to provide rough cost estimates on the potential impacts, and these cost estimates are based on many assumptions. DEP continues to discuss the rulemaking with knowledgeable individuals and groups and has updated the RAF as part of the final-form rulemaking to reflect additional economic evaluation information. See additional responses related to economic information in Comment 169 below.

As previously stated, DEP must develop and adopt WQ criteria that are protective of all water uses and users. Under the Federal Clean Water Act, DEP may not consider and use other factors, such as economic achievability and related considerations, to develop WQ criteria. See the response to Comment 165 for discussion on the consideration of economic factors in developing WQ criteria.

165. Comment: With these potential treatment challenges and significant cost implications at just one AMD treatment plant, it becomes evident that DEP has not thoroughly evaluated the overall cost implications of the proposed WQS for the coal mining sector and other industrial/municipal discharge sectors. DEP has not determined the implications of manganese treatment at coal mine discharges, or any other of industry/activity in the state, that includes treatment technologies and costs associated to achieve compliance concentrations. DEP has not conducted any treatment cost analysis for either the discharges or the public water systems to demonstrate the benefits versus the costs of the proposed WQS for manganese. (861)

Response: DEP did review implementation costs associated with this final-form rulemaking as required under the Commonwealth's Regulatory Review Act. However, the development of water quality criteria as mandated under the federal CWA does not include consideration of economic factors. When states develop water quality standards, they are required to designate protected uses of waters and the water quality criteria necessary to protect those uses. The federal CWA states "such standards shall be as to protect the public health or welfare, enhance the quality of the water and serve the purposes of this Chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value in navigation." 33 U.S.C.A. § 1313(c)(2)(A). Federal regulations further state that water quality criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 C.F.R. § 131.11. When EPA promulgated regulations for 40 C.F.R. Chapter 131 (relating to water quality standards) in 1998, it stated the following in its preamble to the proposed regulations: "Economic and technological factors (e.g., the ability of analytical techniques to detect the pollutant and treatment cost considerations) may

not be used to justify adoption of criteria that do not protect the designated use.” 63 Fed. Reg. 36742.

Throughout the rulemaking process, DEP has done its best to gather information and evaluate the costs and impacts to all entities potentially affected by the proposed regulation.

DEP received comments through the ANPR and on the proposed rulemaking from several public water systems regarding the economic impacts to public water systems as a result of moving the point of compliance to the nearest downstream potable water supply withdrawal.

One commentator indicated their water authority would require an alternative treatment process with construction costs of \$2.1 million and a 20-yr. operating cost of \$15.8 million annually plus \$540,000 per year in increased treatment chemical costs. In addition, annual monitoring costs would increase by \$6,530 after the initial start-up monitoring costs of \$13,000.

Another commentator owns and operates 68 permitted water treatment plants in PA. The commentator identified 16 plants that would be challenged if manganese levels increased, and eight of those plants would be impacted to a point of requiring treatment plant modifications. The total capacity of the eight plants is approximately 40 MGD. The estimated costs for plant upgrades ranged between \$1-\$1.5 million per MGD, equating to an overall one-time capital cost of \$40-\$60 million. This estimate does not include anticipated increased annual operations and maintenance costs of \$700,000-\$1.4 million. As stated in the analysis completed by Drexel University (Hamilton et al., 2022), Kohl and Medlar (2006) studied the capital cost of manganese removal water treatment and produced various estimates that ranged from \$750,000 per MGD to \$2 million per MGD for manganese control. The figure of \$1.5 million per MGD quoted above is within the range estimated by Kohl and Medlar (2006).

A third public water system did not provide specific cost values, but they did estimate that extra monitoring, including testing equipment, testing chemicals, and training for personnel, would cost tens of thousands of dollars. Estimated costs for new infrastructure, including piping, pumps, chemicals, safety training and protective gear, would be in the tens of millions of dollars. The public water system also anticipated paying millions of dollars in lost efficiency with respect to plant performance and increased membrane filter replacement. This public water system noted that their raw water intake levels of manganese typically range between 0.03 mg/L and 0.15 mg/L with a higher average of 0.35 mg/L observed during a period of heavy rain with high turbidity.

DEP also received comments through the ANPR and on the proposed rulemaking from the mining industry regarding the economic impacts to mining dischargers as result of maintaining the point of compliance at the point of discharge, and one comment was received describing potential savings to the industry if the point of compliance is moved to the point of downstream potable water supply withdrawal. See Comment 155 for information on the cost savings and Comment 169 for more specific cost estimates and other information on the potential economic impacts to the mining industry. In addition, DEP collaborated with PSU

to better understand different manganese removal treatment options and potential costs associated with removing manganese from coal mine drainage. PSU conducted a comprehensive evaluation of available treatment technologies, including emerging technologies, as well as the costs associated with manganese removal treatment and provided a summary report of the findings to DEP.

While the PSU report (Burgos, 2021) does generally corroborate the cost estimates found in the Tetra Tech report, the PSU report also highlights several limitations of the Tetra Tech analysis and provides a more robust analysis. The Tetra Tech analysis assumed that every NPDES discharge permit for mining operations would require installation of treatment systems and that the treatment system utilized by every facility would be chemical precipitation water softening, which is generally the most expensive treatment option. The PSU analysis takes a more balanced and comprehensive approach to the evaluation of costs based on different percentages of permits potentially affected (for example, 50% and 75% versus 100%) as well as consideration of the most cost-effective treatment options for different sizes of mining operations based on flow and other water quality characteristics. PSU noted that chemical precipitation water softening was never the most cost-effective treatment option for any category of discharge.

The more refined PSU analysis indicates that total costs to the mining industry if 75% of permits are affected are in the range of \$137-\$143 million in capital costs and \$33 - \$46 million in annual operating costs. The ranges decrease to \$91-\$95 million in capital costs and \$22-\$31 million in annual operating costs if only 50% of permits are affected. These costs estimates were generated by PSU using OSMRE's AMDTreat software, which is the same software used by Tetra Tech and the mining industry to estimate treatment costs. The different treatment systems evaluated by PSU included limestone manganese removal beds, oxidative precipitation using chemicals followed by either a limestone removal bed or sand filter, coprecipitation and sorption, and chemical precipitation water softening. The PSU report also noted that actual costs may be substantially lower than these refined costs estimates (i.e., below the low range of these costs estimates) if sites are able to utilize existing treatment infrastructure or if the relatively few deep mines with larger flows are able to remove dissolved manganese using the coprecipitation and sorption option.

Furthermore, the PSU analysis indicates that, on an equal flow basis, capital costs for both the drinking water industry and the coal industry would be similar and, on an equal manganese (II) load basis, annual operating costs for both industries would be similar. See the regulatory analysis form that accompanies this final-form rulemaking for more information.

166. Comment: According to DEP, if this proposed criterion is adopted “those holding or seeking permits to discharge manganese into surface waters of PA will benefit.” Has DEP done or is it planning to do a reasonable potential analysis of its proposed rule change? (15)

Response: The commentator did not include the entire quote in the comment above. The Preamble to the proposed rulemaking stated, “if the proposed rulemaking is adopted and the first point of compliance alternative is adopted, those entities holding or seeking permits to

discharge manganese into the surface waters of Pennsylvania will benefit.” Under this scenario, the manganese criterion would only be applicable at the point of the nearest downstream potable water supply withdrawal, if one exists, which is expected to provide financial relief to many dischargers of manganese, particularly the coal mining industry.

BCW did consult with BMP regarding potential impacts to permitted entities. BMP staff examined a small subset of mining permit renewal applications that are currently in-house to evaluate the potential impact of a proposed criterion of 0.3 mg/L applied at the point of discharge (that is, the second point of compliance alternative). This analysis included coal and several non-coal permits as well as a few ABS bond-forfeited sites. The treatment processes used at these facilities included both active and passive treatment systems. BMP staff also indicated that any current permit with WQ-based effluent limitations is likely to require reduced limits for manganese as a result of the proposed criterion of 0.3 mg/L being applied at the point of discharge.

167. Comment: The second alternative point of compliance keeps the burden of treatment and compliance on the mine operators and DEP acknowledges that using this basis of compliance to meet new effluent limitations costs to treat “may exceed that which is required under existing guidance.” Further with this acknowledgement, DEP provides absolutely zero analysis on the economic impact of implementing such a rule change. (15)

Response: DEP has evaluated and continues to evaluate the economic impact of the regulation on the regulated community. DEP worked with PSU to better understand different manganese removal treatment options and potential costs associated with removing manganese from coal mine drainage. See Comment 169 and the responses to Comments 164, 165 and 184 for more information relating to the economic impact of the proposed regulation on public water systems and the mining industry.

It is important to reaffirm that Section 101(a)(3) of the CWA declares the National policy that the discharge of toxic pollutants in toxic amounts be prohibited. See 33 U.S.C.A. § 1251(a)(3). The control of toxic pollutants to protect public health should keep pace with science. Since the mining industry and other permitted dischargers are responsible for the discharge of the manganese into surface waters of the Commonwealth, it is appropriate for improvement in treatment techniques and compliance to remain with these entities at the point of discharge.

It is also important to recognize that states must meet specific requirements in establishing protected water uses and adopting water quality criteria necessary to protect those water uses. The CWA provides that “Such standards shall be such as to protect the public health or welfare, enhance the quality of the water and serve the purposes of this Chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value in navigation.” 33 U.S.C.A. § 1313(c)(2)(A). In accordance with 40 C.F.R. § 131.11, water quality criteria “must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use.” In addition, when EPA promulgated regulations

for 40 CFR Chapter 131 (relating to water quality standards) in 1998, it stated the following in its preamble to the proposed regulations: “Economic and technological factors (e.g., the ability of analytical techniques to detect the pollutant and treatment cost considerations) may not be used to justify the adoption of criteria that do not protect the designated use.” 63 Fed. Reg. 36742

168. Comment: The Senate Environmental Resources and Energy Committee asks how will this proposed rulemaking increase costs for PennDOT and other state agencies? (953)

Response: DEP does not anticipate any increased costs for PennDOT as a result of the proposed rulemaking. A PennDOT representative sits on the EQB and did not voice any concerns about the proposed rulemaking to DEP prior to EQB’s adoption of the proposed rulemaking.

Following the close of the public comment period for the proposed rulemaking, DEP noted several comments regarding impacts to PennDOT projects. In response, DEP met with PennDOT to inquire if the agency had any concerns with the proposed rulemaking and to discuss any potential concerns. PennDOT indicated that they had no specific concerns related to the proposed rulemaking for manganese. PennDOT indicated that the agency has provided, and will continue to provide, the level of treatment required to address any environmental discharges of pollutants, including manganese, where such treatment has been determined to be necessary.

Significant financial impacts to NPDES dischargers with little environmental benefit; anticipated costs and permit examples

169. Comment: While the environmental benefits from the proposed criterion will be limited, the financial costs to numerous industries will be significant, especially if the proposed criterion of 0.3 mg/L is imposed at the discharge location under the second alternative of the proposed rule. The proposed rulemaking would limit new investment and cost Pennsylvania jobs. The manganese removal is complex, and costs are high due to challenges with space limitations, chemical dosing, sludge handling and additional personnel costs. The additional cost to meet the proposed limits can be more like doubling or tripling the cost, not just a small percent increase in cost. This is particularly the case where large discharges are being treated. Many existing systems are simply not capable of treating manganese to a level below 0.3 mg/L, and new treatment systems may be needed for other facilities that may not currently be treating for manganese.

The increase in costs would likely push already financially strapped mining companies into bankruptcy; thus causing the forfeiture of long-term trust fund sites. Operators of post-mining treatment sites that are currently spending private money to treat discharges would likely start to forfeit their treatment trust since it will become too expensive to treat to such low levels of manganese. The sites would then revert to DEP to carry out treatment. DEP already has issues with treating bond forfeiture sites and has not even begun treatment at some. Pennsylvania leads our nation in the number of AML sites without sufficient funds to address their attendant environmental problems. This would provide an extra burden to the

taxpayers and take funding resources away from treating the important parameters at abandoned mine discharges. In fact, manganese would likely be ignored by the DEP at these abandoned sites, which shows the importance of manganese mitigation as compared to other parameters like pH, iron and aluminum. (8, 10, 12, 15, 89, 728, 862, 897, 901, 922, 935, 951, 955)

- The commentator represents the 10 unique environmentally beneficial environmental reclamation energy facilities located in Pennsylvania that remediate AMLs by utilizing circulating fluidized bed (CFB) boiler technology to convert coal refuse into alternative energy and steam. The commentator anticipates significant capital costs would be required to expand the treatment footprint and install the necessary treatment equipment at many of the sites. The industry will also see additional operating costs at both plants and reclamation sites. It is possible we will need additional personnel to manage the additional treatment systems. The ELG limit for on-site fuel storage at the plants will lead to increased costs for fuel handling and storage. The industry is already struggling to recoup our environmental remediation costs due to low wholesale electricity prices and would not be able to recuperate these costs in today's depressed wholesale electric power market. Operators of mine land reclamation-to-energy facilities are currently spending private money to remediate AML sites that may become too expensive to treat to such low levels of manganese. If this industry is unable to continue reclamation on these and other sites, the responsibility and cost would revert to DEP to carry out this remediation work. DEP has already identified more than 220 million tons of coal refuse covering 8,300 acres of mining affected land for which the state receives insufficient resources through the federal AML fund to address. A 2019 study by Econsult Solutions found that the cost of the state to replicate the work performed by this industry would be as much as \$267 million per year. The labeling of manganese as a toxin may have other unintended consequences regarding AML remediation. DEP's latest biennial report lists 25,468 miles of Pennsylvania waters, 5,500 miles more than in its 2016 report, as being harmed by pollution. The report found that nearly 30 percent of Pennsylvania's rivers and streams do not meet WQS for water supply, aquatic life, recreation, or fish consumption. The top three major sources of WQS impairment identified in the 2020 report are: agricultural runoff, 5,765 miles; abandoned mine runoff, 5,559 miles; and stormwater, 3,206 miles. This proposed regulation would increase costs and make it more difficult for mine land reclamation-to-energy facilities, mining operators, and groups involved with AML site remediation to prevent the water pollution. (862)
- The commentator operates mine drainage treatment systems to comply with NPDES permit effluent limits imposed on seven postmining pollutational discharges that resulted from surface coal mines. Currently, two of the seven sites are required to meet manganese effluent limitations. With this rule all seven sites will be required to meet the new manganese limit. Due to the severe financial impact, significant issues with feasibility in adding manganese treatment to the existing passive treatment systems. The present-day capital cost for all seven systems is approximately \$650,000. Adding manganese limits on the five other discharges, an additional investment approximately equal to the current capital value of the existing treatment systems will be needed, effectively increasing the treatment costs by 100%. Related

costs including maintenance and recapitalization would also increase commensurately.

Manganese removal in passive treatment systems requires the iron concentration to be reduced to less than 1 mg/L, well below the standard effluent limit for mine discharges of 3.0 mg/L, prior to entering a component specifically designed to remove manganese. These additional treatment components require significant quantities of limestone and land area. Many treatment sites do not include viable construction area within the existing permit boundary. In the case of the commentator's water treatment sites, adding a restrictive manganese effluent limit at the point of mine site discharge will require significant redesign and expansion of most of the treatment systems. Area that is currently wooded and provides wildlife habitat would need to be sacrificed to accommodate additional rock-filled treatment ponds. Though the seven treatment systems operated by the commentator achieve permit compliance with passive technology, it is well known that active treatment systems that use chemicals to remove manganese are subject to similar cost increases. Watzlaf 1988 reported that manganese removal can increase the chemical reagent cost by 140 – 180%, at least doubling and almost tripling the cost for chemical treatment when compared to the cost needed to achieve a circumneutral pH with compliant iron concentrations. (**698**)

- Tetra Tech has estimated that the reduction in the criterion would result in reagent costs increasing \$0.10 to \$0.15 per 1,000 gallons treated for systems using lime and \$0.30 to \$0.45 per 1,000 gallons treated for systems using sodium hydroxide. The proposed reduction to the manganese criterion would increase annual conventional treatment costs for the coal industry by \$44 to \$88 million, which essentially doubles the chemical cost to treat water, creating a substantial compliance burden. Tetra Tech also estimated that treating for manganese and aluminum could cost the coal industry upwards of \$200 million. Commentator 951 has evaluated this impact across its water treatment sites and found that its water treatment costs would increase by 82% on the low end of the estimate and by 122% on the high end. Then there is the impact on costs to other areas affected by treating manganese to lower limits. Tetra Tech's report does a good job of detailing the impact to aluminum treatment and sludge disposal, two areas that are critical components of our water treatment systems. Lowering the criterion for manganese is not as simple as just adding more reagent. Rather, it would entail spending millions of dollars on labor, capital and operating costs to meet the need for expanded treatment and disposal facilities. Commentator 901 is presently working cooperatively with DEP to meet TMDL limits through an innovative passive treatment system that removes manganese by limestone pH adjustment and microbiological reduction in a reconstructed stream channel. This system can be a model for similar mine sites in PA, including abandoned sites where nonprofit watershed organizations or DEP's BAMR treat a discharge. However, changing the manganese criterion to 0.3 mg/L threatens the project and may prevent its implementation at our mine and elsewhere in the state. (**901, 951**)
- The commentator holds 51 NPDES permits across Pennsylvania. Eight permits currently contain conditions limiting the discharge of manganese. These eight

permitted discharges currently comply with the existing 1.0 mg/L manganese standard at cost of approximately \$150,000/year for all sites. Six of the eight discharges would not be able to achieve permit limits based on a standard of 0.3 mg/L without additional treatment. Many of the sites have low pH and high aluminum, which makes treatment more complex and expensive. The commentator anticipates capital costs of \$320,000 to expand existing treatment footprints and install new treatment equipment with additional combined operating costs of \$450,000/year. Costs include engineering, construction, treatment systems, sludge disposal, power systems and automation systems as necessary. Some sites have land availability issues that could limit expansion of treatment. Additional personnel may also be needed, and the commentator does not expect to be able to recuperate the costs by increasing prices in these locations. (7, 618, 922)

- The Rushton AMD Treatment Plant has successfully achieved a high-quality effluent from treatment of up to 5,000 gpd mine pool flow achieving low metals concentrations for decades. The facility has been in continuous compliance until recently when the combination of lower effluent limits for manganese (1.0 mg/L), iron (1.5 mg/L) and aluminum (0.75 mg/L) were imposed in renewed NPDES permits. While generally meeting these new and more stringent effluent limits, operation of the treatment plant and compliance with the effluent limits has become of a delicate balance, and at times during abnormally high precipitation periods, the treatment is easily upset resulting in exceedances of effluent limits for either manganese or aluminum. Overall, the treatment plant has added additional pre-aeration treatment and has had increased operational costs due to greater lime use, greater solids production and associated management, and increased operational labor to maintain these current effluent limits. While we have not developed designs for a new system, a conceptual approach would entail replacing the settling ponds with clarifiers to develop a first stage high pH neutralization treatment, followed by pH adjustment (decrease) to between 8 and 9 and filtration (micro to ultra) to capture fine aluminum particles. Estimates for the new clarifiers could exceed \$9 million and microfiltration for a 7 million gallon per day flow could likely exceed \$20 million. Overall capital expenditures to comply with the proposed manganese WQS, if applied at the discharge, could be approximately \$30 million. In addition, annual operating costs for chemicals, electricity, sludge disposal and manpower could be expected to double, with annual costs potentially exceeding \$2 million annually. At these potential increases in capital and operating costs continued treatment of the Rushton AMD Treatment Plant will be challenged to obtain the necessary funding for this operation, and which, as noted earlier, would have no measurable improvement to the WQ of the receiving stream nor any improvement to the quality of the intake water of the nearest downstream water supply, which is over 100 miles downstream on the Susquehanna River. (861)
- Tetra Tech provided real-world examples of titration curves related to lime dose, manganese removal, and endpoint pH. The first example (Figure 5-1) is for a mine discharge containing alkalinity, ferrous iron of about 40 mg/L, and an initial manganese concentration less than the 2.0 mg/L BAT-based effluent limit. The second example (Figure 5-2) is for an acidic mine discharge containing about 100

mg/L ferrous iron, 10 mg/L of aluminum, and about 8 mg/L of manganese. As shown, dissolved manganese decreases nonlinearly with pH and approaches 0 mg/L at pH approaching 11. However, alkaline chemical (e.g., lime) dose increases nonlinearly with pH, which is due to the effect of calcium and magnesium precipitation as pH increases. Both figures show the pH and chemical dose must be increased from the BAT limit of 2.0 mg/L lime dose by more than 100 mg/L to achieve a 1.0 mg/L effluent limit, and by more than 200 mg/L to achieve a 0.3 mg/L limit. Using the two examples, lime use costs would increase by between \$0.10 to \$0.15 per 1,000 gallons treated and sodium hydroxide use costs would increase by between \$0.30 to \$0.45 per 1,000 gallons treated. In general, lime is used at higher flow discharges (> 200 gpm) and sodium hydroxide is used at lower flow discharges. Evaluating this on a coal industry-wide basis for the approximately 700 NPDES permits, and assuming approximately 200 gpm of mine discharge per NPDES permit, the total industry increase alkaline chemical cost would be between \$15 and \$40 million annually, depending on the percent of discharges treated with lime or sodium hydroxide.

In addition to lime costs, there would be an increase in several other operating costs including sludge disposal from the increased calcium and magnesium precipitation that will increase sludge volumes at the higher pH needed to meet the lower proposed manganese criterion. Sludge handling costs are about \$0.05 to \$0.10 per 1,000 gallons treated, based on calculations provided in AMDTreat, an OSMRE software product. If sludge volumes are merely doubled from the higher pH required to achieve the low manganese concentrations, this increased sludge handling would amount to an additional \$5 to \$10 million in treatment costs.

Additional treatment will also be required to meet the effluent pH of between 6 and 9. This will require acid addition or post-treatment aeration to lower the pH to the required effluent range. Acid addition for pH adjustment will require storage tanks and chemical feed systems with operating costs associated with acids and manpower, which will be similar in capital costs for a sodium hydroxide system used to raise pH for manganese removal. The estimated capital costs per location using AMDTreat is between \$30,000 and \$40,000 per year. Using the number of permit locations this results in a total capital cost of \$20 to \$40 million. Expected sulfuric acid doses to lower pH would range between \$0.05 and \$0.10 per 1,000 gallons treated resulting in an expected operating cost between \$4 and \$8 million annually. There is one additional factor for some discharges that the alkaline chemical dose and pH for manganese removal does not capture. This is related to the conflict of effluent compliance with a proposed low manganese effluent limit of 0.3 mg/L with the Chapter 93 aluminum criterion of 0.75 mg/L, which is established for the protection of aquatic life. Aluminum that is normally precipitated in treated mine water from neutralization between pH 8 and 9 will be resolubilized at pH higher than 9. The aluminum solubility indicates an effluent limit of 0.75 mg/L (the Chapter 93 criterion) will be exceeded at pH greater than about 9.5. This is a result of the formation of an aluminum hydroxide complex (Al(OH)_{41-}) that will increase dissolved aluminum in the discharge as the pH is increased above 9.5, which would be required to meet the low manganese effluent limit. This situation would be

applicable to all mine discharges with elevated aluminum in the untreated mine water. Addressing the removal of this dissolved aluminum is not simple. The decreased pH adjustment to less than 9 using acid described following high pH manganese removal would precipitate the aluminum in response to the lower pH, but the suspended solids would be less 5 mg/L and would not settle effectively. Because of this, higher aluminum discharges could require installation of a completely new treatment plant, addition of treatment components of equal size (i.e., a second stage), or addition of filtration components to existing plants. Based on equivalent cost of current treatment at half of the existing NPDES permits to address aluminum there is potentially capital cost of \$175 million with between \$20 and \$30 million in additional operating costs annually.

Based on the above preliminary analysis based on the treatment in the general mining sector, the proposed 0.3 mg/L WQS if applied at the discharge point could increase treatment costs by between \$44 and \$88 million annually. The wide range is due to generalizations and more refined estimates would require better understanding of flow, chemistry and treatment at each NPDES permit location. In addition to the increase in capital costs there is a potential additional capital costs in order to meet the 0.3 mg/L WQS. The capital costs could exceed \$200 million. **(618, 954)**

- The Pennsylvania Coal Alliance contracted with TetraTech to assess compliance costs for both mine-water discharges and drinking water treatment facilities. Pursuant to the TetraTech report, “... active mine drainage treatment involves use of caustic chemicals (e.g. lime) to raise the pH to neutralize acidity and precipitate metals including iron, aluminum and manganese. Aeration may be provided to promote the oxidation of ferrous to ferric, and its resulting precipitation as an iron oxyhydroxide. Normally a neutralization pH of 8.0 ± 0.2 is adequate for the precipitation of iron and aluminum to effluent limits.” This statement is reflective of the treatment process at the [commentator’s] operation in Indiana County. TetraTech goes on to document how mine-water treatment would have to be modified to comply with the lowered standard. Treatment to reduce manganese to concentrations capable of meeting the proposed regulatory limit will increase exponentially as dissolved manganese decreases nonlinearly with increasing pH. In addition to lime costs, there would be an increase in several other operating costs including sludge disposal from the increased calcium and magnesium precipitation that will increase sludge volumes at the higher pH needed to meet the lower proposed manganese criterion. Additional treatment will also be required to meet the effluent pH of between 6 and 9. This will require acid addition or post-treatment aeration to lower the pH to the required effluent range. Acid addition for pH adjustment will require storage tanks and chemical feed systems with operating costs associated with acids and manpower, which will be similar in capital costs for a sodium hydroxide system used to raise pH for manganese removal. **(832)**

Response: DEP disagrees that the proposed regulation would provide limited benefits to the environment and residents or visitors of the Commonwealth. The current science and data continue to support the findings that manganese consumed in excess amounts is a

neurotoxicant and can negatively and irreversibly affect neurodevelopment in children. Furthermore, in addition to protecting human health, the proposed criterion provides for the protection of other statewide water uses including aquatic life, industrial water supply, livestock water supply, wildlife water supply, irrigation, and esthetics. The final-form rulemaking includes a manganese criterion of 0.3 mg/L to protect human health and other water uses.

DEP recognizes that manganese treatment is often complex, and the final-form rulemaking has the potential to increase treatment costs for dischargers.

The commentators have speculated that the rate of bond forfeitures will increase as a result of the proposed rulemaking, but no data or information has been provided to support this claim. DEP agrees that implementation of the final-form rulemaking will require additional treatment for many mining discharges, but DEP has received no information from the industry or other groups which demonstrates that a significant portion of mining companies operating in PA are likely to declare bankruptcy, shut down their companies or forfeit their bonds as a result of the proposed regulation.

The fact that PA leads the nation in AML sites is largely due to the significant amount of historical, unregulated mining that occurred in the Commonwealth prior to the establishment of current environmental laws including SMCRA. AML sites in PA are not the same as bond-forfeited sites, and they are managed somewhat differently. The reclamation of AML sites is primarily managed by BAMR. These sites include lands and waters that were affected by coal mining and were either abandoned or inadequately reclaimed prior to August 3, 1977. As authorized by SMCRA, States receive federal grant money through the Abandoned Mine Reclamation Fund to implement their AML programs and reclaim mine sites. This fund is supported by fees collected from coal mining operators based on coal production.

The bond-forfeited sites, including those that were bonded under the defunct ABS, are managed by BMP. It is important to note that there are many factors that can contribute to a bond-forfeiture. While manganese is often present in the discharges from these sites, it has not been identified as the sole cause of forfeiture in any of the existing cases. Nonetheless, DEP recognizes that treatment costs may increase as a result of this rulemaking and that bond forfeitures can occur when treatment costs exceed the funds that an operator has available. However, DEP has no reason to believe at this point that there will be a significant increase in the number of mining discharges that will be abandoned as a result of the rulemaking. Furthermore, the current full-cost bonding system for mining activity generally establishes sufficient funding to cover expected reclamation and treatment costs for each mine site. Bond amounts sufficient to cover expected reclamation and treatment costs may increase for some sites as a result of this rulemaking

It is also worthwhile to note that in 1998 DEP evaluated permitted sites for occurrences of post-mining discharges of pollutants and determined that only 17 of approximately 1700 permits issued since 1987 (less than 1%) resulted in discharges of pollutants. DEP also noted the discharges on the failed sites were much less severe in quantity and quality than historical AML discharges. Much like the AML sites managed by BAMR, SMCRA funding is used to

address ABS forfeited sites. In addition to SMCRA sources, funding for these sites also comes from per-acre reclamation fees, civil penalties, forfeited bonds and interest. The burden of financing these reclamation and treatment operation programs does not fall on the taxpayers.

Following the adoption of a final rulemaking, DEP will continue to administer the mining reclamation programs under BAMR and BMP in order of the priorities identified by SMCRA, which may or may not immediately address elevated levels of manganese in the discharges. States are directed to prioritize reclamation projects under a three-tier system:

- 1) Priority 1 projects involve reclamation of lands and waters to protect public health, safety, and property from extreme danger.
- 2) Priority 2 projects involve the reclamation of lands and waters to protect public health and safety from adverse effects of coal mining practices.
- 3) Priority 3 projects involve the reclamation of lands and waters previously degraded by adverse effects of coal mining practices for the conservation and development of soil, water, woodland, fish and wildlife, recreation resources and agricultural productivity.

DEP must use its limited funding to address high-priority sites before tackling less immediate dangers to public health and safety.

DEP agrees that remining and third-party AML remediation projects provide an environmental benefit to the Commonwealth, and DEP is working to ensure that these beneficial projects continue. At the present time, DEP does not anticipate a significant impact to remining efforts when permits for these activities are authorized under the existing remining regulations.

DEP disagrees that passive treatment of manganese requires prior removal of iron down to 1.0 mg/L followed by a separate treatment stage to remove the manganese. DEP is aware that metals removal in passive systems will occur in a specific chemical order. Iron is removed first, followed by aluminum and finally manganese. Thus, the treatment bed must be adequately designed and sized to allow for this sequential removal. However, treatment can and does occur in single limestone treatment beds and does not always require multiple, large treatment ponds. DEP understands that many existing passive systems were not specifically designed to remove manganese. In these cases, it may be necessary in the future to expand existing treatment beds or add new treatment beds to achieve the desired level of manganese removal.

DEP appreciates the treatment cost estimates provided by the commentators. Aside from Commentator 698, all of the treatment evaluations and cost estimates provided appear to be for active chemical addition and the use of clarifiers. Analyses of passive or emerging/alternative treatment technologies does not appear to have been thoroughly considered or evaluated by the mining industry. It is DEP's understanding through consultation with various experts that when passive treatment systems are properly designed and operated, they can successfully and consistently remove manganese to low levels and

often at a fraction of the cost of active treatment systems. New and emerging technologies are also showing promise in removing manganese and if determined to be scalable to handle larger volumes of discharge flow, may be able to significantly reduce the footprint needed for treatment beds (for example, EcoIslands LLC). See response to Comment 165 for additional information on treatment cost estimates.

170. Comment: Commentator does not believe that the DEP has fully vetted the economic impact of its proposed rulemaking to list manganese as a “toxic substance.”

- A. How does this impact the classification of streams as to whether or not a TMDL must be prepared?
- B. The proposed rule impacts mine drainage treatment facilities operated by the Commonwealth and could require them to upgrade the treatment levels to control manganese. This increase could be in terms of both operating and capital costs.
- C. What is the impact on Pennsylvania’s Coal Remining Program (Subchapter F of Chapter 87 and Subchapter G of Chapter 88)?
- D. There have been a large number of trust funds established to provide long-term treatment and funding. The proposed manganese rules could result in a significant increase in capital and operating costs and a resulting increase in the amount of money needed in the trust funds that puts these companies at financial risk.
- E. The DEP has not provided an economic analysis as to how this will impact existing industrial manufacturing facilities that have manganese in their discharges.

As such, the DEP needs to provide a comprehensive economic analysis of the changes going from the existing rule to the proposed rule (changing the criteria from drinking water protection to a toxic substance) and the impact based on where the Chapter 93 standard is applied (at the point of discharge or at the point of the downstream use as a potable water supply). (862)

Response: The final-form rulemaking does not impact the classification of streams. As to whether or not a TMDL will be required for a waterbody, DEP will follow its published assessment protocols to determine whether the designated uses and criteria for surface waters of the Commonwealth are being met. If a more stringent criterion for manganese is adopted, assessments utilizing the new criterion could identify additional waters as being impaired. If NPDES permits require manganese limits, based on reasonable potential analyses, permits will contain appropriate conditions to limit effluent. If, after NPDES permits are updated, the waterbody is impaired, the waterbody will be placed on the Clean Water Act § 303(d) list, for future TMDL development. In some instances, the adoption of a new WQ criterion may necessitate revisions to existing TMDLs to reflect the new goals for the waterbody. This final-form rulemaking has the potential to result in new TMDLs or modifications to existing TMDLs.

The final-form rulemaking has the potential to impact any permitted discharger of manganese. The characteristics of each effluent discharge and receiving waterbody are unique and require a site-specific evaluation. Generally speaking, generic technology or cost equations are not available for the purposes of comparing costs and/or savings for entities

that are responsible for discharges. Thus, DEP uses the best information available to determine who will be affected by this final-form regulation, how they will be affected and to what extent they will be affected. However, DEP does not currently anticipate a significant impact to the operation of bond-forfeited sites managed by BMP. In addition, DEP does not anticipate a significant impact to remining efforts when permits for these activities are authorized under the existing remining regulations (Subchapter F of Chapter 87 and Subchapter G of Chapter 88).

DEP recognizes that additional trust funding may be required to fully cover anticipated site reclamation and remediation costs. DEP has received no information from the industry or other groups which demonstrates that mining companies operating in PA are likely to declare bankruptcy, shut down their companies or forfeit their bonds as a result of the proposed regulation. See also the response to Comment 169.

Based on information in Comment 169 (economic impact information provided by the mining industry), DEP would anticipate similar estimated impacts to other industrial dischargers of manganese if the point of compliance is maintained at the point of discharge.

DEP did review implementation costs associated with this final-form rulemaking as required under the Commonwealth's Regulatory Review Act. However, the development of water quality criteria as mandated under the federal CWA does not include consideration of economic factors. When states develop water quality standards, they are required to designate protected uses of waters and the water quality criteria necessary to protect those uses. The federal CWA states "such standards shall be as to protect the public health or welfare, enhance the quality of the water and serve the purposes of this Chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value in navigation." 33 U.S.C.A. § 1313(c)(2)(A). Federal regulations further state that water quality criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 C.F.R. § 131.11. When EPA promulgated regulations for 40 C.F.R. Chapter 131 (relating to water quality standards) in 1998, it stated the following in its preamble to the proposed regulations: "Economic and technological factors (e.g., the ability of analytical techniques to detect the pollutant and treatment cost considerations) may not be used to justify adoption of criteria that do not protect the designated use." 63 Fed. Reg. 36742. See also the response to Comment 165.

171. Comment: DEP contends the lowered manganese standard would reduce costs incurred by water treatment facilities as they treat raw intake water to meet the SMCL currently in effect for manganese (0.05 mg/L). DEP further contends that should the first alternative point of compliance point be permitted (point of intake), water treatment facilities costs to treat raw intake water could increase. (832)

Response: DEP agrees with these statements.

172. Comment: The proposed rulemaking supporting documents lack sufficient explanation of how the revised criterion would be implemented in NPDES permits. The discussions on page 10 of the proposed rulemaking document are not clear as to whether or how assessments of intakes on water bodies downstream of the discharger's receiving stream would be evaluated in the context of WQBEL development. See excerpt below from the proposed rulemaking document regarding the alternative of applying the criterion only at the point of potable water supply withdrawal:

Under this alternative the proposed human health criterion for manganese will not apply unless a potable water supply withdrawal is located on the surface water. If a potable water supply is located on the stream, a discharger's point of compliance with the proposed manganese criterion will be modelled from the upstream point of discharge to the point of potable water supply withdrawal, allowing for attenuation of the effluent as it travels downstream. The discharger's effluent limitation would be determined based on achieving the proposed manganese criterion of 0.3 mg/L at the point of potable water supply intake.

The statement is not clear as to whether "the surface water" and "point of potable water supply withdrawal" means only the receiving stream of the permittee's discharge, or intakes on downstream water bodies as well. A more specific and clearer explanation is required for stakeholders to adequately assess the proposed revision. (880)

Response: This comment relates to the first point of compliance alternative, which would move the point of compliance to the nearest downstream potable water supply withdrawal. If this alternative would be adopted, DEP would model the discharge to the nearest potable water supply withdrawal assuming there exists a reasonable potential for impact. If reasonable potential exists, this modeling will occur whether the potable water supply withdrawal exists on the same stream as the discharge or the withdrawal is located on a larger downstream water that receives flow from a tributary containing the discharge. Each circumstance would need to be evaluated independently by the permit writer assigned to the permit to determine if modeling is needed. In some cases, modeling would not be needed even though a potable water supply withdrawal is located in the vicinity of a discharge. For example, if a drinking water intake is located almost directly across but slightly downstream from a discharger, the intake is less likely to be impacted by the discharge and may not require modeling. This could also be the case in situations where the intake is located on the opposite stream bank from the discharge and complete mixing with the receiving water does not occur until some distance downstream. Permit writers will follow the available NPDES permitting guidance and, as appropriate, will use their BPJ in determining the need for modeling. Generally speaking, under the proposed first alternative point of compliance, an effluent limitation would only be established in a permit if reasonable potential to exceed the manganese criterion at the downstream potable water supply withdrawal exists.

173. Comment: The Senate Environmental Resources and Energy Committee notes from an economic perspective, as testimony from our Senate hearing also revealed, the proposed rulemaking will impose significant compliance costs not only on the coal mining industry, but potentially on numerous other industries that may not currently be treating for

manganese. Did DEP consult with industry prior to presenting the proposed regulation to the EQB? (953)

Response: DEP developed the ANPR to provide an opportunity for all stakeholders to present information relating to the science of manganese and the costs associated with its treatment. Additionally, BCW works with WRAC, which includes industry representatives, during the development of WQSs. DEP initiated several WRAC meetings during the rulemaking development period. WRAC meetings are open to the public, and meeting information is published on DEP's website.

While DEP satisfied its obligations to visit its advisory committee (that is, WRAC) in developing the proposed rulemaking, DEP recognized the uniqueness of this rulemaking and expanded its public outreach efforts to include additional advisory committees and stakeholders. Prior to the EQB meeting, DEP was consulting with other state agencies and actively working to establish meetings with the mining industry and others. DEP met with mining groups shortly after EQB adopted the proposed rulemaking. In addition, the agency met multiple times with industry, additional Department advisory committees, other state agencies, and other entities potentially affected.

While an economic impact evaluation for each regulation is required to be provided in accordance with the RRA, it is important to understand that, under the Federal Clean Water Act, States may not consider non-WQ factors, such as economics or treatability, in setting the protection levels for surface waters. WQSs include designated water uses and the WQ criteria necessary to protect those uses. WQ criteria must be established using the best science and data available, and they must sufficiently protect all water uses and users. In other words, States may not establish less stringent criteria based on economic impact or treatability if the criteria would not be fully protective of the water uses.

**Impacts of the Proposed Manganese Criterion on Abandoned Mine Lands (AMLs),
Watershed Restoration and Remediation Activities in Watersheds Impacted by Legacy
Mining**

174. Comment: The commentator concludes that lowering the numeric manganese WQS will not necessarily improve source WQ in coalfield regions because manganese loads are dominated by unregulated, legacy discharges with no responsible party required to implement the proposed WQS. The commentator recommends that watersheds impacted by legacy mining activities be afforded incentives to facilitate restoration, even where restoration outcomes may plateau at levels below full aquatic life use attainment. Compliance with a strict manganese numeric WQS is likely to create technical and financial hurdles as well as impede stakeholder willingness to assume liability that focuses on restoration efforts on unregulated/legacy mine discharges. (925)

Response: DEP recognizes that WQ in streams located in the coalfield regions may continue to experience degradation following the adoption of a final regulation and that many of the impacts are due to unregulated mine discharges emanating from AMLs.

DEP is evaluating ways to ensure that watershed restoration and AMD remediation projects continue after a final regulation is adopted. DEP does not anticipate significant impacts to the incentives afforded through the remaining regulations.

175. Comment: The commentator encourages DEP to adopt tiered restoration goals for watersheds impacted by legacy mining activities to acknowledge that a strict manganese numeric WQS is likely to create technical and financial hurdles as well as impeded stakeholder willingness to assume liability focused on restoration efforts of unregulated/legacy mine discharges. The commentator also encourages DEP to detail implementation plans for the proposed WQS, including potential financial assistance, with specific emphasis on consequences for facilities that have assumed responsibility to treat acid mine drainage. (925)

Response: BCW is working closely with the Office of Active and Abandoned Mine Operations to ensure that beneficial remining and watershed restoration projects will continue.

DEP will implement the WQ criterion in accordance with existing regulations and guidance for the issuance of permits. Regarding financial assistance, DEP's Growing Greener Plus grants program manages the SMCRA grants and AMD set-aside grants. These grant funds are available to qualifying projects.

176. Comment: *The proposed rulemaking will negatively impact the Department's Subchapter F program and disincentivize remining of abandoned mine lands:*

- Pennsylvania contains more than three quarters of the mine-land reclamation energy facilities in the nation (i.e., 10 of 13 facilities). The majority of PA coal refuse-to-alternative energy plants were originally constructed as Qualifying Facilities (QFs), subject to size restrictions pursuant to the Public Utility Regulatory Policy Act of 1978 (PURPA). As a result, these facilities are relatively small in size, with all but one facility between 33 and 112 megawatts (MW) net operating capacity and a combined electric generation capacity just under 1,200 MW.

These plants play a critical role in environmental remediation in the coal regions where they are located by removing coal refuse piles, remediating and reclaiming mining affected lands and reducing or even eliminating surface and groundwater pollution by AMD from coal refuse piles. By converting coal refuse into alternative energy, these facilities are removing one of the principal sources of contamination to surface water and groundwater in coal mining regions of the United States. In addition, the plants work closely with state environmental agency officials, various local watershed groups, and environmental groups such as Earth Conservancy, the Western Pennsylvania Coalition for Abandoned Mine Reclamation (WPCAMR), and the Eastern Pennsylvania Coalition for Abandoned Mine Reclamation (EPCAMR), to reclaim abandoned mine lands and convert polluted streams into clean and usable waterways.

The environmental benefits of these facilities that remove coal refuse from the environment are widely recognized and documented. Particularly, they are responsible for helping to improve WQ for the more than 5,500 miles of AML impaired Pennsylvania streams. For example, see the DEP study, “Reclamation of Refuse Piles using Fluidized Bed Combustion Ash in the Blacklick Creek Watershed, Pennsylvania”:

<https://blacklickcreekwatershed2.files.wordpress.com/2018/11/reclamation-of-refuse-piles-using-fluidized-bed-combustion-ash.pdf>. Since its inception, the coal refuse to energy industry in Pennsylvania has removed and consumed as fuel more than 225 million tons of coal refuse, improved more than 1,200 miles of streams, and reclaimed more than 7,200 acres of previously polluted mining affected land. At full capacity, this industry can remove about 10 million tons of coal refuse from the environment and reclaim approximately 200 acres of mining affected land in Pennsylvania each year. When considering the limited federal dollars for reclamation and remediation of mining affected lands and the magnitude of coal mining’s legacy in the United States, through the operation of their facilities, our members remove, remediate, and reclaim coal refuse piles that will otherwise remain in communities and other areas throughout the coal regions. Those coal refuse sites produce acid mine discharges to surface waters and groundwater and in a number of locales uncontrolled air pollution caused by coal refuse pile fires.

At least 3,000 people are directly or indirectly employed by the coal refuse to energy industry, and live, along with their children, families, and extended families, in communities within close proximity of these alternative energy plants. The surrounding communities, lands, and streams have experienced vast environmental and economic improvements due mainly to the decades of hard work and dedication these workers and our industry have provided at no cost to taxpayers.

These facilities operate under the same rules and regulations as traditional surface coal mining operations despite the fact that they are involved in environmental remediation. As a precondition to removing coal refuse piles, the permitting requirements require companies to obtain a surface mining permit including development of abatement plans for discharges of surface and ground waters. Companies are required to take baseline measurements of water conditions and are liable for any worsening conditions, which creates an economic incentive for the improvement of local WQ and allows improvements to be scientifically quantified.

Our industry provides one of the only options for removing coal refuse piles from the environment without shifting the significant cost to public resources. Should that option become unavailable, the entire cost for removal and remediation would fall on taxpayers. The DEP has testified that such costs would reach billions of dollars and require over 500 years to accomplish. For these reasons, EPA, DEP, OSMRE, and other organizations have long recognized the environmental benefits of the combustion of coal refuse for energy and reclamation. **(862)**

- DEP's responses to the IRRC RAF for the WQS for manganese proposed rulemaking references 1315 NPDES permits that contain limits or monitoring requirements for manganese. While these include several industry categories, what they do not include is the hundreds of untreated abandoned coal mine legacy discharges—for which DEP itself is responsible to restore and treat—that (1) have no NPDES permits and (2) discharge levels of manganese that are considerably higher than the 1 mg/l manganese limit. Furthermore, Pennsylvania streams limited by TMDLs house the majority of manganese concentrations where the TMDLs are the result of legacy coal mine sites that are not currently treated by the Commonwealth nor are they the responsibility of current mine companies to do so. But they are the responsibility of DEP to reestablish and treat. Lowering manganese limits would put an additional financial burden on Pennsylvania as the state is already responsible for treating water from all previous bond-forfeited sites, regardless of whether those sites have NPDES permits. This will be a significant cost and DEP has not addressed this in the IRRC RAF and we request they do so to allow for an accurate cost of this regulation to just the Commonwealth alone. Also, the many watershed groups across the Commonwealth who take care of some of these abandoned mine discharges do not currently treat for manganese. We believe DEP puts itself at a significant legal and financial liability risk by not having considered this issue in the analysis of this rulemaking. **(922)**
- By being the first and only state in the nation to classify manganese as a toxin, DEP is creating a huge disincentive in both the anthracite and bituminous coal fields to re-mine and reclaim long abandoned coal mine lands. According to best DEP statistics available, since 1998, more than 43,000 acres of coal lands have been reclaimed as a result of re-mining in the Commonwealth of PA. Anthracite coal mine operators have re-mined and reclaimed more than 20,436 acres of surface AML features and 193 acres of underground AMLs. Additionally, bituminous coal mine operators have reclaimed 14,040 acres of abandoned surface mine lands and 8,739 acres of underground abandoned mine lands for a total of 22,779 acres. That is an average of over 2,500 acres annually. Based on current BAMR costs, the environmental benefits to the Commonwealth in the anthracite region over this period is an estimated \$900 million or about \$52 million annually since 1998. As a result of this rulemaking, thousands of acres of long abandoned strip pits will remain open and dangerous to human, animal and aquatic life in the anthracite region and to waters our area rivers and streams contribute to.

War time needs of the last century required that coal be mined as quickly and as cheaply as possible. As a result, U.S. law prior to 1977, discouraged the back filling and reclamation of surface coal mines. Many of those scarred pits still remain a hazard today discharging millions of gallons of pollution daily into the region's water system. This water eventually finds its way into the nation's major drainage systems, the Delaware and Susquehanna River basins. However, today nearly all mining being done in the anthracite region is the re-mining of coal left behind in previously mined areas. Anthracite mining operators are actually cleaning up mine drainage and the environment by mining from the surface and "day-lighting" old abandoned deep

mines and surface mines. When complete, they then reclaim the landscape by backfilling and reseeding the area for other uses. In the anthracite region, surface coal mining and environmental reclamation go hand-in-hand. One does not occur without the other.

Further, re-mining provides the added benefit of decreasing surface water flow into underground mine pool complexes and groundwater systems. When land reclamation occurs as a result of re-mining, there is a reduction of surface water runoff.

Infiltration is eliminated or significantly decreased preventing pathways and flow paths into the highly fractured bedrock and underground workings that tend to elevate mine pools which cause them to fluctuate. Left unimpeded, surface water runoff will eventually find its way into long abandoned mine works creating AMD discharges with varying flows. The re-mining of abandoned mine land in the anthracite and bituminous regions reclaims more land and provides more water improvement than BAMR at minimal costs associated with administering the program. In addition to the environmental benefits of remining, it is also important to note the significant economic benefits associated with remining.

Today nearly 1,000 persons are directly employed by companies engaged in remining activities in the anthracite region. The industry contributes a direct payroll of nearly \$100 million to the state's economy. The average remining employee earns a salary and benefits package of between \$60,000 and \$75,000 annually. In addition, remining contributes to the creation of hundreds more ancillary jobs adding more income to the region and state, local and federal taxing bodies.

The evidence is beyond conclusive that re-mining is having a positive impact on the region and state's environment. Classifying manganese as a toxin and creating more stringent 0.3 mg/L will do very little for the environment. In fact, it will needlessly propitiate dangerous abandoned highwalls and abandoned mine pollution by discouraging re-mining operators from permitting and re-mining those areas where the risk encountering treatment for manganese as toxin at a much more stringent level. (15)

- The proposed rulemaking could disincentivize mining operators from treating abandoned mine discharges because of the burdensome manganese effluent limits placed on the dischargers NPDES permits. A perfect example of this issue would be the St. Michael Treatment Plant. In 2012, the commentator constructed a \$20 million dollar AMD plant to treat a 4,000 gpm discharge from the abandoned Maryland No. 1 Mine. This discharge was depositing 2.2 million pounds of iron into the Conemaugh River every year. This discharge also contained some manganese at around 5.0 mg/l, but iron and pH were the main pollutant loading impairing the Conemaugh River. The plant was turned on in 2013 and now prevents 98% of that 2.2 million pounds of iron from entering the river every year. If the commentator had to achieve the 0.3 mg/l manganese level, instead of the current 1.0 mg/l effluent standard, that project would have never occurred.

Even when watershed groups, like BAMR or DEP treat an abandoned mine discharge, manganese is usually not treated, or at the very least no specific concentration of manganese is targeted. pH, iron, aluminum and acidity are usually the parameters that are treated for since they impact the aquatic life the most. Manganese tends to not be treated due to the difficulty in removal using passive treatment systems and the balancing act between iron/aluminum precipitation and manganese precipitation. To remove manganese, the pH must be increased to a level that iron and aluminum begin to dissolve. Thus creating a two phase treatment system. Since iron and aluminum have the most impact on aquatic life and manganese has little impact, treatment for manganese is typically ignored. DEP does not issue NPDES permits for abandoned mine sites, so changing the effluent discharge limit will have not impact the stream quality for abandoned mine sites. Even on bond forfeiture sites where DEP has a legal obligation to treat the water, NPDES limits for manganese are not applied. So basically, the regulated community will have to go from a 2.0 or 1.0 mg/l manganese limit to a 0.3 mg/l, and the adjacent abandoned mine discharge and bond forfeiture sites will continue to spew out high manganese levels with no potential treatment in sight.

The proposed rulemaking may have detrimental impacts to the DEP's subF program. This program incentivizes mine operators to re-mine abandoned surface mines that can improve abandoned mine discharges without having to take 100% ownership of the discharge, while still taking some risk that improvement may not occur. If manganese is labeled as a toxin, an operator would then be unwilling to take the risk and the abandoned surface mine and discharge would go on unmitigated. (728)

- The instream manganese concentration in Moshannon Creek upstream of Rushton AMD Treatment Plant (Plant) was found to be 3.0 mg/L and 3.4 mg/L on August 4, 2015 and August 25, 2015, respectively. At the time of this sampling, the Rushton AMD treatment Plant was discharging less than 1.0 mg/L of manganese. It is also unlikely the upstream concentrations of manganese have changed significantly since this sampling. As indicated in the 2009 TMDL there are a large number of coal mine water sources contributing to the impairment of Moshannon Creek for pH, iron, aluminum and manganese. These included:
 - Title IV AML surface and deep coal mines from the late 1800's through the 1960's located throughout the watershed and contributing AMD and high concentrations of manganese.
 - Regulated coal mine discharges through the NPDES program with TMDL maximum instantaneous effluent limits of 1.0 mg/L, that would also be required to neutralize acidity and remove iron and aluminum from the AMD.
 - Bankruptcy and bond forfeiture (legacy) coal mining discharges with minimal treatment.

Of the three types of coal mine discharge in Moshannon Creek the Title IV AML AMD are the largest source of manganese and are the cause of the manganese impairment and in the watershed. The Title IV AML sites and associated AMD fall

under the jurisdiction of BAMR. BAMR uses limited funding (public and coal tax) to reclaim AML sites and treat AMD from these areas. These efforts typically do not address manganese due to the high costs and minimal benefit on watershed restoration.

An additional source of coal mine discharges causing impairment to Moshannon Creek are the bankruptcy and bond forfeiture sites. The bankruptcy and bond forfeiture sites fall under the jurisdiction of BMP. Typically, funds are limited and treatment, where it does occur, is minimal and does not meet established TMDL limits due to high costs. While these are regulatory mine sites, BMP does not generally impose NPDES effluent limits at these discharges but only establishes treatment objectives. Treatment typically does not include manganese to TMDL effluent limits established for regulatory coal mine and other discharges.

Finally, the TMDL lists the publicly owned and operated Moshannon Joint Sewer Authority as a source of manganese to Moshannon Creek. It is likely this plant has levels of manganese in its raw water and discharge from source waters related to infiltration/inflow, industry, and dietary supplements. This municipal wastewater treatment plant could receive effluent limits that require additional treatment costs that would be placed on increases rates to the public. It is likely Moshannon Creek is representative of the majority of AMD impaired waters in Pennsylvania where the NPDES treated coal mine discharges achieve better WQ than the receiving stream and are not major contributors to the surface water manganese concentrations. It is more likely, if there are manganese issues, the elevated stream manganese concentrations are caused by Title IV AML AMD and bankruptcy/forfeiture (legacy) sources.

Based on the above, DEP has not adequately assessed the various sources of manganese within the Moshannon Creek or other mining impacted watersheds in Pennsylvania as part of this rulemaking. As conditions at the Moshannon Creek demonstrate there is little likelihood the largest sources of manganese from Title IV AMD sources will be addressed any time in the near future, indicating there is little likelihood this or any other mining-related surface water will achieve a “drinkable” condition, except directly in the discharge and outfall of the NPDES treated mine discharges. This demonstrates there will be no benefit to promulgating the proposed standard at the Rushton Plant or most other treated discharges. It also raises suspect whether there will be any benefit of the new WQS in improving drinking water supplies where there are upstream Title IV mine-related impacts.

There is also the issue of equitable application of the proposed manganese WQS across all regulatory coal mining discharges, specifically equal application at bond forfeiture and bankruptcy (legacy) discharges under the jurisdiction and responsibility of the BMP. While a number of these discharges are treated, none have NPDES permits nor is manganese considered in the treatment goals established by BMP for treatment. This demonstrates two aspects. First, the environmental regulations and NPDES requirements under the CWA are not equally and fairly applied in

Pennsylvania. Second, we understand that not all BMP managed sites treat for manganese likely due to the high cost of such treatment. So if these even lower manganese discharge standards are applied equitably to all former mine site discharges, the increased cost of treating these legacy site would be an extremely high burden to Pennsylvanian taxpayers. (861)

Response: DEP disagrees that categorizing manganese as a toxin and establishing protective criteria will do very little for the environment.

DEP evaluated the manganese criterion in association with moving the point of compliance. Given that the criterion had not been evaluated since the 1970's, that the Federal Clean Water Act requires states to review their water quality standards and that moving the point of compliance would potentially allow more manganese to be present in waters of the Commonwealth, it is appropriate that the criterion be updated to reflect newer science.

DEP disagrees that the proposed rulemaking would result in increased numbers of abandoned mine discharges due to bond-forfeitures and in additional financial burdens being placed on the Commonwealth's taxpayers. DEP presently manages AMLs and bond-forfeited sites using funding from a variety of sources. The majority of the funding comes from SMCRA grants, which were established through fees paid by coal companies. In addition to SMCRA grants, bond-forfeited sites also utilize other sources of non-public funding. See also the response to Comment 169.

Commentators raised concerns about other dischargers, such as municipal sewer authorities, being impacted. Commentator 861 specifically referenced the Moshannon Valley Joint Sewer Authority. While it is possible that some sewage treatment facilities could require additional treatment processes due to more stringent effluent limitations based on the proposed rulemaking, the number of facilities affected is expected to be limited, based on a review by DEP. Regarding the Moshannon Valley Joint Authority, their permit contains effluent limitations for manganese as a result of the Moshannon Creek TMDL. However, it is important to note that the manganese levels reported in the Authority's discharge are generally low, typically below 0.3 mg/L. DEP does not expect the proposed rulemaking to have a significant impact on sewage treatment plants.

However, DEP does agree with the commentators that the remining of AMLs is beneficial to the environment and the economy. DEP also agrees that watershed groups and volunteer organizations play an important role in the efforts to clean up AMLs. DEP's BCW is working closely with the Office of Active and Abandoned Mine Operations to ensure that beneficial remining and watershed restoration projects will continue.

177. Comment: The Senate Environmental Resources and Energy Committee asks when DEP addresses legacy acid mine drainage sites in PA, what level of manganese does DEP treat to? When DEP addresses bond forfeiture sites in PA, what level of manganese does DEP treat to? (953)

Response: DEP will continue to administer the mining reclamation programs under BAMR and BMP in order of the priorities identified by SMCRA, which may or may not immediately address elevated levels of manganese in the discharges. States are directed to prioritize reclamation projects under a three-tier system:

- 1) Priority 1 projects involve reclamation of lands and waters to protect public health, safety, and property from extreme danger.
- 2) Priority 2 projects involve the reclamation of lands and waters to protect public health and safety from adverse effects of coal mining practices.
- 3) Priority 3 projects involve the reclamation of lands and waters previously degraded by adverse effects of coal mining practices for the conservation and development of soil, water, woodland, fish and wildlife, recreation resources and agricultural productivity.

DEP must use its limited funding to address high priority sites (priority 1) before tackling lower priority sites. In addressing AMD degradation, DEP's primary goal has been to restore designated uses to as many impacted streams as possible. While manganese removal does occur at a number of sites across PA (some to very low levels), most of the treatment systems were not designed specifically to address manganese in the discharge due to limited funding availability.

BMP has continued to operate the AMD treatment processes that currently exist for the ABS bond-forfeited sites. See also the response to Comment 169.

The Proposed Manganese Criterion and Second Alternative are Consistent with the Federal Clean Water Act and the Pennsylvania Clean Streams Law; Act 40 is Not Consistent

178. Comment: *The CWA and CSL prohibit the discharge of toxic pollutants in toxic amounts:*

- The CWA and CSL recognize that the discharger must be responsible for limiting the pollution it dumps into Pennsylvania's waters. Additionally, requiring the new standard to be met at the discharge point protects not only human health, but all of the uses of our streams – from aquatic life and recreation to municipal, industrial, and agricultural uses. (931) Changing the long-standing point of compliance from the discharge point to the intake for public water systems would undermine critical protections of Pennsylvania's waterways that have been in place for decades. (93, 864, 918) ...and setting potentially illegal precedent. (930)
- Even absent the constitutional infirmities of Act 40, the act directs the EQB to promulgate a regulation that violates the fundamental precept of Pennsylvania law: the prevention, reduction and treatment if necessary, of pollution entering these waters *is the responsibility of the polluter* not the public or other downstream users. (936)

- The proposed rulemaking runs congruent with environmental statutes such as the CSL and the Pennsylvania SDWA. (596, 705) Additionally, DEP has the duty and authority to implement regulations that would prevent and eliminate water pollution, in this case, manganese. (500, 593-594, 620-639, 641-686, 688-697, 705, 710-721, 723-724, 726-727, 729-730, 813, 828, 845, 885, 933, 941, 943-944, 946, 948)
- [The second alternative point of compliance (that is, at the point of discharge)] is consistent with the statutory obligations of DEP and the EQB under the CSL, Pennsylvania's SDWA, and the CWA. (536)
- If a pollutant is toxic to human health or aquatic life, the CSL and Pennsylvania SDWA require development of appropriate WQ criteria. *See* 35 P.S. §§ 721.1—721.17; 35 P.S. § 691.4(1); 25 Pa. Code § 93.8a (the waters of this Commonwealth may not contain toxic substances attributable to point or nonpoint source waste discharges in concentrations or amounts that are inimical to the water uses to be protected.). Section 303(c) of the CWA and 40 CFR Part 131 (relating to water quality standards) requires DEP to develop WQSs that consist of designated uses, WQ criteria to protect those uses and antidegradation requirements. 33 U.S.C. § 1313(c). Those standards must “protect the public health or welfare and enhance the quality of water” and protect water uses including public water supplies, aquatic life, recreational and agricultural uses. Section 101(a)(3) of the Clean Water Act declares the National policy that the discharge of toxic pollutants in toxic amounts be prohibited 33 U.S.C.A. §1251(a)(3). (536, 929)
- It is Representative (now Senator) Comitta’s understanding, from the Pennsylvania Environmental Council, that the proposed reduction in manganese and maintenance of the point of compliance at discharge are consistent with the statutory obligations of the DEP and the EQB under the CSL, Pennsylvania’s SDWA, and the CWA. (920)

Response: DEP agrees that Pennsylvania’s WQSs regulations must comply with the CSL and CWA. Additionally, DEP must develop WQSs that support, and do not conflict, with obligations under other statutes, such as the SDWA. The final-form rulemaking includes a manganese criterion of 0.3 mg/L applicable at the point of discharge, which satisfies the requirements of these laws.

179. Comment: Changing the point of compliance from the point of discharge to the point of potable water supply withdrawals would result in significant degradation of Pennsylvania’s waterways and the endangerment of human health and aquatic life in violation of the CSL and CWA. Under the CWA, state WQSs must “protect the public health or welfare.” 33 U.S.C. § 1313(c)(2)(A). In setting a new WQS, the CWA also requires states to consider the standard’s “use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes . . .” *Id.* Similarly, an objective of the CSL is to prevent pollution and to restore presently polluted streams. 35 P.S. § 691.4(3). The CSL defines pollution to include contamination that renders waters “harmful, detrimental or injurious to public health, safety or welfare, or to domestic, municipal, commercial, industrial, agricultural, recreational, or other legitimate beneficial uses, or to

livestock, wild animals, birds, fish or other aquatic life" *Id.* § 691.1. The CSL also requires the consideration of present and possible future uses of waters in the adoption of rules and regulations. *Id.* § 691.5(a).

The proposed alternative would change the point of compliance from the point of discharge to the point of a potable water supply withdrawal, leaving the waters between those two points devoid of protections from the toxic effects of manganese. Failure to establish a WQS, which includes an appropriate point of compliance, that is protective of human health, aquatic life, and other beneficial uses such as recreation and agricultural violates the CSL and CWA. The central principle of our national and state water protection laws is to prevent the discharge of pollutants into our waterways. The regulation and elimination of the discharge of pollutants forms the foundation of the entire system of environmental laws that has sought to protect our WQ for decades. A national goal of the CWA is the elimination of the discharge of pollutants into navigable waters. 33 U.S.C. § 1251(a). A fundamental pillar of the CWA is its prohibition of the discharge of any pollutant from a point source into navigable waters without a permit. *See* 33 U.S.C. § 1311(a). The CSL similarly prohibits the unpermitted discharge of sewage, industrial wastes, and other pollutions, 35 P.S. §§ 691.201, .301, .401, and declares as policy the prevention and elimination of pollution, 35 P.S. § 691.4(4). The foundation of the CWA and CSL is the regulation and elimination of discharges of pollution.

Here, the proposed change in compliance point turns the entire system of water protections on its head by regulating pollution at the point of potable water supply withdrawal rather than regulating the discharge of pollution into the waters of the Commonwealth. This would remove the long-standing obligation the CSL and CWA place on dischargers to limit the pollution they release into waterways. This change will establish a dangerous precedent of allowing industry dischargers to circumvent their responsibilities to comply with environmental laws, to pollute our waterways without limits thereby endangering public health and the environment, and to burden water suppliers and the public with the cost of cleaning up the resulting pollution. A WQS that shifts the burden of pollution control from the discharger to the public runs counter to public policy and the central premise underpinning our water protection laws. The CWA was established to end the harmful idea that "dilution is the solution to pollution" and Pennsylvania cannot backslide its protections by changing the point of compliance from the discharge point. **(870)**

Response: DEP agrees that moving the point of compliance for a WQ criterion, such as manganese, without a comprehensive review of the criterion may result in inadequate WQ protections for some protected water uses and is inconsistent with current DEP regulations and policies concerning toxic substances. The final-form rulemaking reduces toxic pollutants and protects public health, aquatic life and other sensitive water uses by maintaining control of the pollutant at the point of discharge and reducing the manganese criterion.

180. Comment: Changing the compliance point for manganese, a toxic pollutant under the proposed rule, would be unprecedented in Pennsylvania. The criteria for all human health toxic pollutants currently listed in Table 5 of 25 Pa. Code § 93.8 must be met in all surface waters, meaning at the point of discharge, consistent with 25 Pa. Code § 96.3(c). In contrast,

the proposed alternative compliance point would list manganese as an exception in § 96.3(d), which only requires compliance at the point of potable water supply withdrawal. This exception has only been applied to certain Potable Water Supply use criteria that have not been identified as toxic. No toxic substances are currently identified as an exception under § 96.3(d).

The proposed alternative compliance point for manganese would carve out an exception allowing industry to discharge a toxic pollutant into Pennsylvania's waters with no WQ-based effluent limit if no potable water supply withdrawal exists. Even if there is an existing or proposed potable water supply withdrawal downstream, a discharger's effluent limitation would be determined based on achieving the 0.3 mg/L limit at that downstream point. The intervening surface waters between the discharge and the potable water supply withdrawal would be left with no protection from dangerous levels of toxic manganese pollution.

This runs counter to both the CSL and the CWA. The CSL regulations provide that “[t]he waters of this Commonwealth may not contain toxic substances attributable to point or nonpoint source waste discharges in concentrations or amounts inimical to the water uses to be protected.” 25 Pa. Code § 93.8a(a). Under the CWA, it is national policy to prohibit the discharge of toxic pollutants in toxic amounts. 33 U.S.C. § 1251(a)(3). Here, industry would be allowed to discharge toxic amounts of manganese into waterways as long as the discharge is able to meet the 0.3 mg/L criterion at the nearest downstream potable water supply withdrawal. Accordingly, the EQB would violate the CSL and CWA in approving the [first] alternative compliance point for the manganese WQS, and the EQB should maintain the compliance point at the point of discharge. **(870)**

Response: DEP concurs with the commentator's assessment.

The Proposed Manganese Criterion and Second Alternative are Not Consistent with the Federal Clean Water Act or the Regulatory Review Act (RRA)

181. Comment: The proposed manganese water quality criterion of 0.3 mg/L does not meet the requirements of the CWA:

- EPA cannot approve the proposed criterion because it is not based on sound scientific rationale. 40 CFR 131.5(a)(2). The report that Gradient Corporation prepared for the PA Coal Alliance confirms there is no conclusive evidence to suggest that exposure to manganese in drinking water at 2 mg/L will lead to adverse health effects.
- The proposed criterion of 0.3 mg/L is not based on EPA's Section 304(a) guidance as required by 40 CFR 131.11(b).
- EPA chose not to regulate manganese with a National Primary Drinking Water Regulation because manganese is generally not considered to be toxic and instead chose to regulate manganese as a secondary maximum contaminant level, which is not based on toxic effects. 68 Fed. Reg. 42898, 42903-04 (July 18, 2003). **(618, 901)**

Response: DEP disagrees with the commentator's statement that the manganese criterion recommendation does not meet the requirements of the CWA.

Regarding sound scientific rationale, DEP reviewed over 80 human health studies relating to the toxicological effects of manganese, including those studies provided by the mining industry (Song et al., 2018; Yoon et al., 2019). In addition, DEP followed all applicable laws, regulations, policies and guidelines required in the development of the human health WQ criterion for manganese. DEP also consulted with EPA toxicologists and WQS staff at EPA headquarters and Region 3 throughout the manganese criterion development and rulemaking processes. See also the responses to Comments 53-92 and DEP's criterion rationale document for more detailed discussions on the science and information used to develop the criterion recommendation.

It is important to note that EPA has not established Section 304(a) human health criteria recommendations for all toxic substances, including manganese. 40 CFR 131.11(b) states that “in establishing criteria, states should (1) establish numerical values based on: (i) 304(a) guidance; or (ii) 304(a) guidance modified to reflect site-specific conditions; or (iii) other scientifically defensible methods.” DEP’s development of the proposed criterion satisfies these requirements and uses “other scientifically defensible methods”. EPA approved Pennsylvania’s WQS regulations which state that “water quality criteria for toxic substances shall be established as described under Chapter 16.” Chapter 16, also approved by EPA, identifies that where no EPA 304(a) recommendation exists DEP 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). See § 16.32(c). Furthermore, § 16.32(d) identifies the sources that may be used by DEP to obtain risk assessment values, which include EPA’s IRIS database, maximum contaminant level goals (MCLGs), Section 304(a) criteria recommendations and other data that have been peer-reviewed. DEP used a verified RfD from IRIS in combination with an evaluation of the current peer-reviewed scientific data on manganese to develop the criterion recommendation.

See the response to Comment 60 for discussion relating to the comment on the lack of a drinking water MCL in the second bullet.

182. Comment: The commentator is aware of the requirements of Section 303(c)(1) of the CWA and 40 CFR 131.20 of the federal regulations requiring states to review their WQSs and modify them, as appropriate, at least once every three years. However, this regulation appears to be driven by more than the federal requirement. (922)

Response: While the current timeline for this regulation is related to Act 40’s directive to evaluate the point of compliance, DEP also evaluated and updated the manganese criterion in accordance with Section 303(c)(1) of the CWA and 40 CFR 131.20, which direct states to update their WQSs as appropriate. Act 40 directed the EQB to adopt a change in the implementation of the manganese criterion. Changes in how WQSs are implemented can affect the levels of surface water protections afforded to the protected water uses identified in § 93.3. Thus, any proposed change in criteria implementation necessitates a comprehensive review of the criterion and all protected water uses to ensure adequate WQ protections will continue to exist for all surface waters and uses once implementation changes are adopted. Furthermore, the manganese criterion for Potable Water Supply use

had not been comprehensively reviewed since it was adopted as a statewide criterion in 1979, and a significant amount of new information has been published on the neurotoxicological effects of manganese that was not available in 1979. Therefore, DEP is obligated to review and consider all current peer-reviewed scientific information in its modification of the manganese criterion and implementation.

183. Comment: The proposed rulemaking moves manganese into the toxic substance category, unlike the EPA and other states, who do not regulate manganese as a toxic substance. This was not the intent of the legislative action surrounding Act 40. Questions 11 and 12 of the IRRC RAF ask if this proposed rulemaking is more stringent than federal standards and how this proposed rulemaking compares to other states. DEP itself states in response to question 11 that “EPA does not currently have national recommendations concerning surface water quality criteria for manganese.” In their response to question 12, they fail to answer the question, and merely misdirect the answer to state “Other states are also required to maintain WQSs...”. DEP incorrectly answered Question 12 of the IRRC RAF. We direct the DEP to the states of West Virginia, Ohio, Kentucky, Illinois, and Indiana, all of whom base their manganese standard on the manganese concentration at the potable water supply withdrawal, with no adverse effects on the health of the general public. We also refer you to the testimony by Rosebud Mining given at the September 9, 2020 Senate Environmental, Resources and Energy Committee hearing. (922)

Response: Regarding the regulation of manganese as a toxic substance, see responses to Comments 56 and 60.

DEP is not recommending adoption of a regulation that is more stringent than federal standards and correctly answered question 12 of the RAF. DEP reviewed the WQS regulations for Ohio, Kentucky, Illinois, Indiana and West Virginia. All of these states currently base their WQS for the protection of Potable Water Supply use on the concentration at the potable water supply withdrawal. However, Ohio, Kentucky, and Indiana do not actually have WQ criteria for manganese to protect *any* water uses. Illinois and West Virginia are the only states listed in the comment with a Potable Water Supply use criterion for manganese. To the best of DEP’s knowledge, none of these states has evaluated the need for a human health criterion in at least the past decade. Furthermore, when states implement WQS, they are not required to collect health effects data from their residents and, therefore, it is not known if negative health effects have resulted from the point of compliance being located at the point of potable water supply withdrawal. See the response to Comment 133.

DEP is not aware of any efforts in Pennsylvania to identify or track negative developmental health outcomes in children that have been associated with exposures to elevated manganese through drinking water, including memory and behavioral issues. With that stated, a lack of study and examination in Pennsylvania does not imply that negative health effects are nonexistent. Recent studies have been conducted in other states, including Ohio (Haynes et al., 2015), and other countries to examine the effects of manganese exposure on neurodevelopment in children. The results of those studies support the link between excessive manganese and negative neurodevelopmental outcomes in children. For more

information on these studies, see DEP's criterion rationale document. See also the response to Comment 149.

184. Comment: DEP's answers to the questions on the IRRC RAF analysis regarding economic impact fail to adequately address economic impacts for industries, large and small, as well as the domino effect implementation would cause. In particular, the IRRC RAF did not adequately explain how the benefits of the regulation would outweigh the costs, nor provide any specific estimates and/or savings to the regulated community. The costs were identified as "Not Measurable". (922)

Response: DEP did review implementation costs associated with this final-form rulemaking as required under the Commonwealth's Regulatory Review Act. However, the development of water quality criteria as mandated under the federal CWA does not include consideration of economic factors. When states develop water quality standards, they are required to designate protected uses of waters and the water quality criteria necessary to protect those uses. The federal CWA states "such standards shall be as to protect the public health or welfare, enhance the quality of the water and serve the purposes of this Chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value in navigation." 33 U.S.C.A § 1313(c)(2)(A). Federal regulations further state that water quality criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." 40 C.F.R. § 131.11. When EPA promulgated regulations for 40 C.F.R. Chapter 131 (relating to water quality standards) in 1998, it stated the following in its preamble to the proposed regulations: "Economic and technological factors (e.g., the ability of analytical techniques to detect the pollutant and treatment cost considerations) may not be used to justify adoption of criteria that do not protect the designated use." 63 Fed. Reg. 36742.

DEP has made a substantial effort to identify the potential economic impacts of the proposed and final-form regulation. DEP requested information through the ANPR, which preceded the proposed rulemaking, and met with various entities that might be impacted both before and after publication of the proposed rulemaking. Data and information were also received during the public comment period for the proposed rulemaking. In addition, DEP met with WRAC, Public Water System TAC, MRAB, the Agricultural Advisory Board (AAB) and the Aggregate Advisory Board to discuss the proposed criterion and seek additional information on impacts. Aside from the facility-specific information received during these processes, it is difficult for DEP to accurately quantify the economic impact of a proposed change to WQSS on regulated entities since costs for monitoring, treatment and other components are often site-specific based on the waterbody and facility. Industry also noted as much in their comments and reports submitted on the proposed rulemaking. Commentator 618 stated "the wide range [in the estimated impact to the mining industry of \$44-\$88 million] is due to generalizations and more refined estimates would require better understanding of flow, chemistry and treatment at each NPDES permit location". DEP has updated the economic evaluation information in the RAF to include information obtained since the proposed rulemaking was published, including data submitted by the drinking

water and mining industries during the public comment period and a report completed by PSU (Burgos, 2021). See also Comment 169 and the response to Comment 165 for additional information on potential economic impacts of the final-form rulemaking.

185. Comment: The Senate Environmental Resources and Energy Committee felt this proposed rulemaking warranted further discussion and therefore held a hearing on September 9, 2020 at the State Capital. The rulemaking is the first we have seen that has more than one “alternative” in it, and one that may or may not be voted on at some point. How do we determine what the final regulation is going to be? During the hearing, it was asked of DEP whether this type of alternative rulemaking has been done in other regulatory settings and the Committee is still waiting on a reply. Usually regulations seem to be focused on a single issue or point.

The DEP has acknowledged that this particular instance is “unique”, and the final rulemaking will be one recommendation based on comments received from the draft regulation. That being said, will this proposed draft regulation need to go back through the whole regulatory process again? (953)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulations include language consistent with that mandate. Additionally, as detailed in the Preamble to the proposed rulemaking, the proposed regulations included alternative language based on other legal considerations, such as compliance with the Pennsylvania SDWA, the CSL, and the CWA. Each alternative was discussed in great detail in the Preamble to the proposed regulation and RAF to obtain public comments and inform the final-form rulemaking.

The EQB properly presented the proposed regulation with two alternatives. The Preamble, RAF and Annex A of the proposed rulemaking provided language reflecting both alternatives. The EQB requested public comment on both alternatives. The inclusion of language in the proposed Annex A that reflected both alternatives prevents enlargement of the scope of the proposed regulation, consistent with the Commonwealth Documents Law, if one or the other alternative is chosen for final regulation. See *Brocal Corp. v. PennDOT*, 528 A.2d 114 (Pa. 1987).

Because the Pennsylvania SDWA requires finished water to meet an SMCL of 0.05 mg/L for manganese, the EQB is obligated to propose regulations that allow public water systems to operate in a manner which will result in compliance with the law and the standard. Additionally, the EQB’s action must be consistent with the CSL and CWA.

Please also see the response to Comment 213.

186. Comment: The commentator also believes that the proposed regulation does not comply with the RRA for several reasons:

- EQB did not properly present the “second alternative point of compliance” in Annex A as a proposed regulation.
- The RAF does not analyze the full economic impact of the proposed rule on the private sector, political subdivisions, and the Commonwealth. 71 P.S. § 745.5(a)(4). It is especially concerning that the RAF stated it was impossible to estimate the costs to the private sector, when it is evident that the proposed rule will impose tremendous costs on the coal industry and specially on our operations. The proposed rule will impose significant costs on public water systems that have NPDES permits to discharge filter backwash water and on publicly-owned or other sewage treatment works in PA that have NPDES permits to discharge treated effluent.
- There is no need for the proposed rule. See 71 P.S. § 745.5(a)(3). DEP overestimated the health effects of manganese, the treatment costs for public water system operations, and the benefit to residents of PA and the environment. Revising the manganese criterion will harm the Commonwealth because it will likely force at least some coal companies and other companies to shut down, dramatically curtail operations or forego opportunities.
- EQB has not provided acceptable data to support the regulation, contrary to Section 5(a)(14) of the RRA, because it relied on scientific data which is over 17 years old to establish a proposed criterion of 0.3 mg/L.
- The “second alternative point of compliance” should not have been proposed because it is not the least burdensome alternative as required by the RRA. 71 P.S. § 745.5(a)(12). The first alternative is less burdensome based on the costs imposed on industry. **(618, 901)**

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation includes language that satisfies the EQB’s obligation under Act 40 by including language consistent with Act 40.

Subsection (j) of Act 40 states the following: “Within 90 days of the effective date of this subsection, the board shall promulgate proposed regulations.” DEP published an ANPR within 90 days of the effective date of Act 40. The purpose of the notice was to gather information necessary to satisfy the EQB’s rulemaking obligations under various laws including the Commonwealth Documents Law, the Commonwealth Attorneys Act, the RRA, and the Administrative Code. Additionally, the Pennsylvania Commonwealth Court confirmed DEP’s and the EQB’s compliance with the timeframe for proposing regulations under Act 40. *See Scarnati v. Department of Environmental Protection*, 220 A.3d 723, 729 n.9 (Pa. Cmwlth. 2019) (“...the statute itself does not indicate the 90-day timeframe is essential. Thus, the 90-day timeframe in Act 40 is directory only.”), *aff’d*, 240 A.3d 536 (2020) (per curiam).

The EQB properly presented the proposed regulation with two alternatives. The Preamble, RAF and Annex A of the proposed rulemaking provided language reflecting both alternatives. The EQB requested public comment on both alternatives. The inclusion of language in Annex A that reflected both alternatives prevents enlargement of the scope of the proposed regulation, consistent with the Commonwealth Documents Law, if one or the

other alternative is chosen for final regulation. See *Brocal Corp. v. PennDOT*, 528 A.2d 114 (Pa. 1987).

DEP has updated the RAF to include economic information that was received from public water systems and the mining industry during the public comment period for the proposed rulemaking. See the response to Comment 184. DEP disagrees with the statement that costs to public water systems were overestimated. See the response to Comment 165 for more detailed information on the anticipated costs to public water systems. DEP does not anticipate a change to the NPDES permit limits for many public water systems. See also the responses to Comments 109, 127, 134, and 147.

DEP also disagrees with the statements that health effects and benefits to residents and the environment were overestimated. DEP reviewed the most current peer-reviewed scientific literature and data available on the toxic effects of manganese with respect to human health, which continues to identify the central nervous system as a critical end point for toxic effects, particularly regarding neurodevelopment. In fact, several other states, countries and health organizations are already using the same science to establish health-based drinking water guidelines that range between 0.08 mg/L and 0.12 mg/L, which are more stringent than the proposed WQ criterion of 0.3 mg/L. For this final-form rulemaking, DEP evaluated numerous studies published during the period spanning EPA's most recent toxicological review of manganese in 2003 through 2021, including a handful of PBPK model studies referenced by the mining industry. See the responses to Comments 53-92 for more detailed discussions on DEP's evaluation and use of the scientific literature.

The final manganese criterion is consistent with the Federal CWA. Section 303(c) of the Federal CWA (33 U.S.C.A. § 1313(c)) requires states to review applicable WQSs from time to time, but at least once every three years. The current manganese criterion for the Potable Water Supply use had not been comprehensively reviewed since 1979, and it was not established to protect human health. WQ criteria must be based on sound scientific rationale and must be sufficient to protect the water uses defined in § 93.3 and all water users including humans, animals, plants and aquatic life in accordance with § 93.6. For surface waters with multiple use designations, the criteria must support the most sensitive, or critical, use identified by DEP. 40 CFR § 131.11. In Pennsylvania, the Potable Water Supply use was previously identified as the most sensitive use requiring protection from manganese, which is designated for surface waters statewide. DEP's reevaluation of the available peer-reviewed science and data indicates that manganese consumed in water can act as a developmental neurotoxin and negatively impact human health. Human health WQ criteria are not equivalent to Potable Water Supply use criteria. Human health criteria are developed to protect any designated uses related to ingestion of water, ingestion of aquatic organisms, or other waterborne exposure from surface waters. Such designated uses include protection of sources of drinking water (that is, the Potable Water Supply use). See EPA's *Water Quality Standards Handbook*. EPA's recommended approach for deriving these criteria is *The Methodology for Deriving Ambient Water Quality for the Protection of Human Health* (2000), which provides states with scientifically sound options for developing their own human health criteria in the absence of CWA Section 304(a) criteria recommendations established by EPA. Furthermore, Section 101(a)(3) of the CWA

declares the National policy that the discharge of toxic pollutants in toxic amounts be prohibited 33 U.S.C.A. §1251(a)(3). The final manganese standard was developed in accordance with the CWA and EPA's regulations and guidance.

Based on the Department's comprehensive review of the manganese water quality criterion in accordance with all applicable laws and statutes, the final-form rulemaking maintains the point of compliance for the human health manganese criterion in all surface waters in accordance with § 96.3(c). Section 5(a)(12) of the RRA requires an agency to include in the RAF a "description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome *acceptable* alternative has been selected." 71 P.S. § 745.5(a)(12). This point of compliance represents the least burdensome option for public water systems and other downstream water users, who are not responsible for the pollution caused by manganese but who are responsible for treating the source water to meet stringent regulatory limits for the safe delivery of drinking water to consumers or other such standards required for agricultural, industrial, or other protected water supply uses. The point of compliance also represents the least burdensome *acceptable* alternative as it ensures the EQB's action is consistent with the Pennsylvania SDWA, the CSL and the CWA.

187. Comment: Section 2(a), Legislative Intent, of the RRA states:

"It is the intent of this act to establish a method for ongoing and effective legislative review and oversight in order to foster executive branch accountability; to provide for primary review by a commission with sufficient authority, expertise, independence and time to perform that function; ..."

Section 5(a)(14) states, "*A description of any data upon which a regulation is based with a detailed explanation of how the data was obtained and why the data is acceptable data. An agency advocating that any data is acceptable data shall have the burden of proving that the data is acceptable.*"

In order to set a WQS, the following information should be collected: biological integrity data, chemical data, physical data, habitat assessment, and toxicity testing. It is our belief that DEP failed to develop a complete, acceptable data package to propose the manganese rulemaking and shortcut the regulatory analysis process by using unacceptable, outdated data in the form of a literature review. Current scientific data should be the basis for a regulation, and promulgating agencies are required to provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by Section 5(a)(14) of the RRA. (922)

Response: WQSSs are comprised of protected water uses and the criteria necessary to protect those uses. Different protected water uses require consideration of different types of data. For example, habitat and biota assessments would be important in the development of aquatic life use protections, but they are less important if they are not the most sensitive use. DEP conducted a review of data available for all water use protections and determined that human health was the most sensitive endpoint. WQ criteria must be developed to protect the most

sensitive, or critical, use or user of the water. After this review, DEP conducted a thorough and complete evaluation of the available peer-reviewed science and data with respect to the toxic effects of manganese on human health. For this final-form rulemaking, DEP evaluated numerous studies published during the period spanning EPA's most recent toxicological review of manganese in 2003 through 2021, including a handful of PBPK model studies referenced by the mining industry. See responses to Comments 53-92 for more detailed discussions on DEP's evaluation of the scientific literature. DEP also sought additional scientific data and information through the publication of an ANPR and consulted with experts at EPA throughout the criterion development and rulemaking processes.

The Second Alternative is Consistent with the Pennsylvania Constitution Article 1, Section 27

188. Comment: The proposed change in the WQS for manganese (that is, compliance at the point of potable water supply withdrawal) is contrary to Article I, Section 27 of the Constitution of Pennsylvania. Be advised that should this proposal be enacted, it would be unconstitutional and subject to immediate challenge. (73)

Response: DEP acknowledges the commentator's concern regarding Article 1, Section 27 of the Pennsylvania Constitution.

189. Comment: Maintaining the discharge point as the point of compliance protects all water uses between the point of discharge and the point of a downstream potable water supply withdrawal. The CSL, the SDWA, the CWA and Article I, Section 27 require nothing less. (936)

Response: DEP agrees the application of the criterion at the point of discharge is protective of all water uses between the point of discharge and the point of the nearest downstream potable water supply withdrawal. This final-form rulemaking, which identifies the point of compliance at the point of discharge and the criterion of 0.3 mg/L, is consistent with the requirements of the CSL, SDWA, CWA, and Article 1, Section 27 of the Pennsylvania Constitution.

190. Comment: The commentator strongly supports the second alternative point of compliance which maintains the current point of compliance for manganese in all surface waters. The second alternative point of compliance is in line with the Environmental Rights Amendments of the Pennsylvania Constitution. Article 1, Section 27 of the Pennsylvania Constitution promises that: "*The People have a right to clean air, pure water, and to the preservation of the natural, scenic, historic and aesthetic values of the environment. Pennsylvania's public natural resources are the common property of all the people, including generations yet to come. As trustee of these resources, the Commonwealth shall conserve and maintain them for the benefit of all the people.*" (103, 931)

Response: DEP acknowledges the comments. This final-form rulemaking, which identifies the point of compliance at the point of discharge and the criterion of 0.3 mg/L, is consistent with Article 1, Section 27 of the Pennsylvania Constitution.

191. Comment: The fundamental goal and purpose of the CSL and DEP's water protection regulations are to protect and maintain stream uses. Moreover, the DEP and the EQB have independent constitutional obligations to conserve and maintain the public natural resources of the Commonwealth. *See Pa. Envtl. Def. Found. v. Commonwealth*, 161 A.3d 911, 931 (Pa. 2017) ("PDEF"). Compliance with the statutes and regulations does not automatically mean that DEP (or the EQB) has met its obligation under Article 1, Section 27. *See Center for Coalfield Justice v. DEP*, 2017 EHB at 860; *Friends of Lackawanna v. DEP*, 2017 EHB at 1161 (recognizing that the Pennsylvania Supreme Court and the EQB had expressly rejected the argument that the constitutional duties under the Environmental Rights Amendment were coextensive with statutory and regulatory compliance.). The private trust principals underlying DEP's obligation pursuant to Section 27 require that DEP and the EQB act as a trustee, rather than a proprietor, and must measure its successes by the benefits it provides for all citizens in their use of public natural resources. Here, the EQB and DEP cannot elevate the interest of the coal and other industries above the interests of beneficiaries. Maintaining the point of compliance at the point of discharge is consistent with DEP's and the EQB's statutory obligations under the CSL, SDWA and the CWA, and the obligations imposed by Article I, Section 27. (929)

Response: DEP acknowledges the comment. This final-form rulemaking, which identifies the point of compliance at the point of discharge and the criterion of 0.3 mg/L, is consistent with the requirements of the CSL, SDWA, CWA and Article 1, Section 27 of the Pennsylvania Constitution.

Act 40 is Not Consistent with Current Laws and Regulations Governing Legislative Procedure and the Environment

192. Comment: The provision in Act 40 which directs the EQB to promulgate regulations moving the point of compliance for manganese WQ criteria to the point of potable water supply withdrawal under 25 Pa. Code § 96.3(d) violates Article III of the Pennsylvania Constitution. Article III, Section 3 of the Pennsylvania Constitution, commonly referred to as the single subject rule, provides that "No bill shall be passed containing more than one subject, which shall be clearly expressed in its title, except a general appropriation bill or a bill codifying or compiling the law or a part thereof." Pa. Const. art. III, § 3. To comply with Section 3, a final bill enacted by the General Assembly must meet two criteria: (1) the title of the bill must clearly express the substance of the proposed law; and (2) the differing topics within the bill must be germane to each other. The single subject rule requires that the provisions within the bill are germane to a single unifying subject and that there must be a common nexus among the provisions. Act 40 has no such single unifying subject or common nexus. (870, 936)

The clear expression of title requirement is violated where the title of the act fails to put a reasonable person on notice as to the act's contents. (936)

Act 40 also violates the Constitution's original purpose provision. Article III, Section 1 of the Pennsylvania Constitution provides: "No law shall be passed except by bill, and no bill shall be so altered or amended, on its passage through either House, as to change its original purpose." The original version of what became Act 40, HB 118 (PN 244), was a two page

bill to amend the Health Care Facilities Act by adding an “Emergency Drug and Alcohol Detoxification Program” to provide for detoxification in licensed health care facilities and to establish detoxification facilities. By the time HB 118 finally passed both houses and was enacted as Act 40, its purpose had changed to alleged amendments to the Administrative Code of 1929, which somehow also included the directive to amend the regulation of manganese on 25 Pa. Code Chapters 93 and 96. The original health care provisions were nowhere to be found. Here, comparing the original purpose of Act 40 to the final purpose establishes that there was an alteration or amendment that changed the original purpose. (936)

Article III, Section 32 of our Constitution provides that the General Assembly shall pass no local or special law in any case which has been or can be provided for by general law and specifically the General Assembly shall not pass any local or special law that regulates labor, trade, mining or manufacturing. Act 40 directs and enables the preferential treatment of the mining industry to the detriment of the Commonwealth’s citizens and their environment by allowing increased pollution of the waters of the Commonwealth, abatement of which will be borne by those citizens, rather than the polluters. This result is contrary to Article III, Section 32. The commentator submits that where the statute underlying the directive to promulgate a regulation is constitutionally infirm, the resulting regulation should not be approved and cannot stand. (936)

Response: *Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in 25 Pa. Code § 96.3(d) (relating to water quality protection requirements). The proposed regulation included language that satisfies the EQB’s obligation under Act 40.*

The constitutionality of a statute is a matter for the judiciary. According to the rules of statutory construction, when ascertaining the intention of the General Assembly, there is a presumption that the General Assembly does not intend to violate the Constitution of the Commonwealth, including the manner in which a law is passed. *See 1 Pa.C.S. § 1922(3) and Pennsylvanians Against Gambling Expansion Fund, Inc. v. Commonwealth, 583 Pa. 275, 877 A.2d 383, 393 (2005).*

193. Comment: The EQB should reject any change in the point of compliance as it stems from a constitutionally infirm statute. (78)

Response: See the response to Comment 192.

194. Comment: Act 40 puts a significant cost burden on public water systems as it transfers the treatment costs associated with manganese removal from the mining entities that discharge the manganese to the downstream public water systems, which have regulatory limits for manganese that must be achieved in the finished water they deliver to their customers. This is a significant shift which relocates the point of compliance for the discharge of a pollutant from the point of discharge to the potable water supply withdrawal. Dischargers must continue to be responsible for eliminating or mitigating the pollutants in their discharges.

Public water systems rely on protection of the raw source water to provide safe and adequate drinking water to their customers. (13, 14, 74, 595, 615, 867, 917, 936, 938)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). In accordance with the RRA, DEP must examine the cost burden of the proposed regulation on all potentially affected individuals, including public water systems. The RAF for this rulemaking describes those costs. See also the response to Comment 165 for more detailed information on the potential costs to public water systems.

Moving the point of compliance for manganese to a potable water supply withdrawal may be beneficial to some wastewater facilities that have permitted discharges of manganese in their wastewater, and it may be a burden to public water systems and other downstream water users that may have to treat that water before it is of appropriate quality for use. The proposed regulations take into consideration the responsibility of public water systems to meet their SDWA requirements for manganese. The second alternative point of compliance does not shift the treatment costs associated with manganese removal from the permitted dischargers to the public water systems.

Under the first alternative point of compliance, as the levels of manganese change in the surface water, many public water systems using surface waters as their source water will need to increase source water monitoring and may require facility upgrades or additional chemical usage to continue achieving the SMCL for manganese of 0.05 mg/L in the finished water, which is required under the Pennsylvania SDWA. *See* 35 P.S. §§ 721.3 and 721.5 and regulations at 25 Pa. Code § 109.202(b) (relating to state MCLs, MRDLs and treatment technique requirements). The SMCL is based on the Federal standard found at 40 CFR § 143.3. Also, see the preamble language for the proposed regulations (under First Alternative Point of Compliance) that describes more specifically additional requirements that public water systems may need to meet if a contaminant is present in the water supply and may cause a potential health hazard.

195. Comment: Public water systems in Pennsylvania must meet EPA's and DEP's SMCL for manganese. The 1 mg/L standard prescribed by Act 40 is 20 times the SMCL value that can be in the finished water. The SMCL values prevent taste, color, and odor issues. (13, 74, 595, 615, 917)

Response: The 1.0 mg/L Potable Water Supply criterion in Chapter 93 is not “prescribed by Act 40.” Act 40 is silent regarding the magnitude of the WQ criterion for manganese. Public water systems must achieve the SMCL for manganese of 0.05 mg/L in finished water based on the Federal standard found at 40 CFR 143.3. *Also see* 35 P.S. §§ 721.3 and 721.5 and regulations at 25 Pa. Code § 109.202(b).

196. Comment: Act 40 will have a significant environmental impact on Pennsylvania's waterways. (867) Aquatic life and recreating members of the public throughout the state would suffer the consequences of such a broad deregulation. (4, 890)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). DEP examined the environmental impacts associated with two alternative points of compliance and the proposed numeric criterion for manganese. These impacts are described in the Preamble to the proposed and final regulations.

197. Comment: Act 40 sets an alarming precedent for environmental rulemaking. Act 40 was hastily tacked on to an entirely unrelated administrative bill by Pennsylvania's elected officials. Future rulemakings should continue to be initiated in a way that allows adequate time for scientific review by both external stakeholders and DEP. (4, 890)

Response: DEP agrees that adequate time for scientific review is an important factor in the development of regulations.

198. Comment: Act 40 prescribed a change without any scientific basis. DEP has an obligation to review and update WQSSs to reflect current scientific knowledge and understanding. Any change to the laws and subsequent regulatory requirements (such as, changing the point of compliance as prescribed by Act 40), should consider and comply with the latest available toxicological data and science when promulgating regulations (that is, WQ criteria). (4, 867, 890, 938)

Response: DEP agrees that WQSSs should reflect current scientific information.

199. Comment: Act 40 is a step backwards in the environmental progress that the commentator has collectively made with their partner organizations. Recognizing that impacts to water quality even far upstream of Philadelphia inevitably affect the city's source waters at its points of intake, the commentator has embraced a comprehensive watershed protection approach to honor our commitment of providing safe, high-quality drinking water to the City of Philadelphia. As the response letter to the ANPR indicates, the commentator is extremely concerned with Act 40's directive to essentially deregulate manganese discharges. As a utility we have been dedicated to supporting abandoned mine drainage cleanup efforts in the upper region of our source watershed for nearly 20 years to reduce metals pollution and this rule change would be a step backwards in the environmental progress we have collectively made with our extensive network of partner organizations. (4, 890)

Response: DEP appreciates the information submitted to inform this rulemaking with respect to the appropriate point of compliance for a manganese criterion.

The Proposed Rulemaking Does Not Comply with Act 40

200. Comment: The House Environmental Resources and Energy Committee and a commentator state Act 40 provided clear and explicit direction to DEP and the proposed regulations contradict the simple instructions contained in Act 40. This regulation would have been a straightforward change resulting in moving the point of compliance to an existing or planned downstream potable water supply withdrawal. Proposing two different alternatives within the same regulatory package is not the process that the RRA envisions or authorizes. Doing so

makes it difficult for the interested public and industry to track, comment, and analyze the impact of the proposed regulation. No federal or state laws would have been violated by complying with Act 40 and promulgating the required regulations. (901, 952)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation included language consistent with that mandate and that satisfies the EQB's obligation under Act 40. Additionally, the proposed regulations include alternative language based on other legal considerations, such as compliance with the Pennsylvania SDWA. Each alternative was discussed in great detail in the Preamble to the proposed regulation and RAF to obtain public comments and inform the final-form rulemaking.

The statutory mandate to develop this rulemaking did not provide the EQB with an analysis of potential impacts to water users or other information necessary to satisfy the requirements of the RRA. Therefore, the collection of requisite information on two alternatives was necessary so the EQB would be in a position to choose, on final rulemaking, the one alternative that satisfies the EQB's obligations and does not conflict with statutory and regulatory requirements relating to manganese.

The Preamble, Annex A and the RAF developed for the proposed regulations clearly described what was intended by the two alternatives and the EQB is adopting a final-form regulation that includes one of the two alternatives. A proposed rulemaking may not mandate an outcome. Under Pennsylvania's Commonwealth Documents Law, a proposed rulemaking provides notice to the public of an agency's intention to promulgate a regulation. The Commonwealth Documents Law and the RRA require agencies to review and consider public comments and hold public hearings as appropriate. The Commonwealth Documents Law allows for changes between the proposed regulations and final adoption as long as the modifications to the proposed text do not enlarge its original purpose. *See* 45 P.S. §§ 1201 and 1202. The presentation of two alternative points of compliance in the proposed regulation provided the public the opportunity to comment on both, and for one alternative to be chosen for the final-form rulemaking; thus, the modification to adopt one alternative does not enlarge the original purpose of the proposed text.

Because the Pennsylvania SDWA requires finished water to meet an SMCL of 0.05 mg/L for manganese, the EQB is obligated to propose regulations that allow public water systems to operate in a manner which will result in compliance with the law and the standard. Additionally, the EQB's action must be consistent with the CSL and CWA.

Based on public comments received on both options, the choices are clear and the regulation satisfies the EQB's obligation under Act 40.

201. Comment: The proposed rulemaking does not comply with Section 1920-A of the Administrative Code of 1929 ("Act 40" – 71 P.S. § 510-20(j) (2017), which required EQB to promulgate within 90 days regulations that move the point of compliance for manganese from the point of discharge to the point of any existing or planned downstream potable

water supply withdrawal. (618, 901, 935, 954) Therefore, the proposed rulemaking to water quality criteria for manganese is not justified or valid. (935)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation includes language that satisfies the EQB's obligation under Act 40 by including language consistent with Act 40.

Subsection (j) of Act 40 states the following: "Within 90 days of the effective date of this subsection, the board shall promulgate proposed regulations." DEP published an ANPR within 90 days of the effective date of Act 40. The purpose of the notice was to gather information necessary to satisfy the EQB's rulemaking obligations under various laws including the Commonwealth Documents Law, the Commonwealth Attorneys Act, the RRA, and The Administrative Code of 1929. Additionally, the Pennsylvania Commonwealth Court confirmed DEP's and the EQB's compliance with the timeframe for proposing regulations under Act 40. *See Scarnati v. Department of Environmental Protection*, 220 A.3d 723, 729 n.9 (Pa. Cmwlth. 2019) ("...the statute itself does not indicate the 90-day timeframe is essential. Thus, the 90-day timeframe in Act 40 is directory only."), aff'd, 240 A.3d 536 (2020) (per curiam).

202. Comment: *Act 40 does not authorize or direct EQB to propose a second alternative point of compliance for the manganese criterion or re-evaluate manganese as a toxic substance:*

- Act 40 does not authorize or direct EQB to propose a "Second Alternative Point of Compliance" for the manganese criterion at the point of discharge. Act 40 requires the point of compliance be at the potable water supply withdrawal. Pennsylvania law makes clear that agencies do not have the authority to disregard an unambiguous statutory directive. *See A.S. v. Pennsylvania State Police*, 143 A.3d 896, 903 (Pa. 2016) ("The statute's plain language generally provides the best indication of legislative intent."); *Lancaster Cnty. v. Pa. Labor Relations Bd.*, 94 A.3d 979, 986 (Pa. 2014) ("[W]hen an administrative agency's interpretation is inconsistent with the statute itself, or when the statute is unambiguous, such administrative interpretation carries little weight."). Because there is no authority to propose a regulation that contradicts the plain language of Act 40, EQB should strike the "Second Alternative Point of Compliance" from the proposed rulemaking and consider only those comments in response to the proposed "First Alternative Point of Compliance." (618)
- The House Environmental Resources and Energy Committee and other commentators state the General Assembly unmistakably intended to place the Potable Water Supply compliance point for manganese at the same location as that for total dissolved solids, nitrite-nitrogen, phenolics, chloride, sulfate, and fluoride under 25 Pa. Code §96.3(d). Thus, the proposed rulemaking disregards the plain language and does not conform to the intent of Act 40. Act 40 does not authorize or direct EQB to propose a "Second Alternative Point of Compliance" for the manganese criterion at the point of discharge. Act 40 requires the point of compliance be at the potable water supply

withdrawal. Pennsylvania law makes clear that agencies do not have the authority to disregard an unambiguous statutory directive. **(618, 901, 935, 952)**

- Act 40 does not direct or authorize EQB to re-evaluate the current manganese criterion or propose a new criterion of 0.3 mg/L for manganese as a toxic substance. The statute simply directs EQB to change the point of compliance for the existing Potable Water Supply manganese criterion of 1 mg/L. EQB “cannot look beyond the language of an unambiguous statute” and propose a regulation that changes the manganese criterion itself. *First Union Nat'l Bank v. Commonwealth*, 867 A.2d 711, 715 (Pa. Commw. Ct. 2005); *see also* Section 1921 of the Statutory Construction Act of 1972, 1 Pa.C.S. § 1921(a) (“The object of all interpretation and construction of statutes is to ascertain and effectuate the intention of the General Assembly.”). By proposing to remove the Potable Water Supply 1 mg/L criterion and create a new toxic substance criterion, EQB disregards legislative intent of Act 40. Any review of the manganese water quality criterion itself should be done as part of DEP’s regular triennial review, not as part of implementing a simple, direct legislative requirement. **(618)**
- The Senate Environmental Resources and Energy Committee comments Act 40 directed the DEP to present to the EQB regulations listing manganese as an exception in 25 Pa. Code § 96.3(d), with the intent to move the water quality criteria found in Chapter 93 (currently 1 mg/L) to the water intake instead of the facility’s point of discharge. DEP has resisted compliance with Act 40 and instead proposes to classify manganese as a toxic substance. **(953)**
- Act 40 did not authorize EQB to either re-evaluate the current manganese criterion or to propose a new criterion for manganese as a toxic substance. **(901)**
- Any water quality criterion review should be done as part of the regular triennial review and should not be included when implementing a direct legislative requirement. **(935)**

Response: For discussion on how the rulemaking satisfies the EQB’s obligations relative to Act 40, see the response to Comment 200.

Chapter 93, which implements the CSL, defines the “potable water supply” use in a manner that ensures present and future public water systems will receive raw water at their intake structures that can achieve compliance with SDW standards in 25 Pa. Code Chapter 109, utilizing only conventional treatment. The manganese criterion is currently met at the point of discharge because manganese is difficult to treat and generally may not be met relying solely on conventional treatment. Even if the water quality criterion for manganese was not identified as a toxic substance, the complexities associated with moving the point of compliance would likely trigger source water monitoring to determine what treatment modifications would be necessary. The statewide Potable Water Supply use would not be protected if modifications beyond conventional treatment are needed for a public water

supply. The alternatives proposed for the point of compliance are intended to inform these complexities.

Because the Pennsylvania SDWA requires finished water to meet an SMCL of 0.05 mg/L for manganese, the EQB is obligated to propose regulations that allow public water systems to operate in a manner which will result in compliance with the law and the standard. Due to the complexities associated with proposing a regulation that must take into consideration an enforceable SDWA SMCL, it was necessary to gather public comment on more than one alternative to prevent creating new burdens on public water systems. The second alternative point of compliance takes into consideration the transfer of the manganese treatment burden from dischargers to public water systems. This alternative is included in Annex A.

For discussion on how the manganese criterion is consistent with the CWA and protective of the most sensitive protection use, see the response to Comment 186.

203. Comment: In response to Act 40, the EQB directed the DEP to provide regulatory language which brings the rules for manganese into line with the Federal guidelines. DEP submitted two separate alternatives, but neither of them complies with the spirit or intent of Act 40. The first alternative changes the point of compliance for manganese to the point of potable water supply withdrawal. While the proposed language complies with the letter of the law, it completely ignores the spirit and intent of the legislature's direction by exceeding Federal guidelines by classifying manganese as a toxin. The second alternative requires that a discharge criterion of 0.3 mg/L be met at the point of discharge putting a further burden on the mining industry. Option two totally ignores the legal standard established by Act 40 and appears to be the personal preference of unelected staff members within the DEP BCW. Option two totally ignores both the spirit and intent of Act 40 and it completely disregards the will of the citizens of the Commonwealth through their elected leaders. (15, 922)

Response: Act 40 is silent with respect to the WQS for manganese, found in Chapter 93. Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation includes language that satisfies the EQB's obligation under Act 40. See the response to Comment 56 for additional discussion on the reevaluation of manganese.

204. Comment: *Proposed rulemaking would not move the point of compliance:*

- The proposed rulemaking notice states that “the purpose and goals of this proposed rulemaking are: to comply with Act 40 of 2017” in addition to other changes to Chapter 93 standards and policy goals, and the notice further reads that “Act 40 directed the board to propose a regulation that moves the point of compliance for manganese from the point of discharge to any downstream public water intake.” However, the proposed rulemaking, which would establish an in-stream WQS of 0.3 mg/L statewide, would not in fact accomplish such a move of the point of compliance. (897)

- Act 40 directed the EQB to propose a regulation that moves the point of compliance for manganese from the point of discharge to any downstream public water supply intake as per § 96.3(d). **(860, 922)** The proposed rulemaking includes consideration of a recommendation for a secondary alternative point of compliance (i.e., maintain point of compliance at point of discharge). There should be no discussion of a secondary alternative point of compliance as this is not consistent with Act 40. **(901, 935)** The proposed second alternative would not accomplish the move of the point of compliance. **(860)** DEP is proposing two different points of compliance, one that complies with Act 40 and one that completely ignores Act 40. **(728, 862)**

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation included language that satisfies the EQB's obligation under Act 40. By providing a secondary, alternative point of compliance, the EQB invited all water users to consider their legal obligations and technical capabilities associated with meeting manganese limits, and to share their concerns with the EQB.

See also the response to Comment 200 for further discussion on how the rulemaking satisfies EQB's obligations relative to Act 40.

205. Comment: The House Environmental Resources and Energy Committee comments Act 40 requires that the point of compliance for manganese be moved from the point of discharge and be applied at the potable water supply withdrawal point. DEP entirely ignores this statutory directive in one of its alternatives and proposes that the point of compliance be the point of discharge. Other coal mining states utilize the potable water supply withdrawal point as the point of compliance for their manganese regulations. No evidence has been produced that residents of these states have had any negative health consequences as a result. Accordingly, DEP has no excuse for violating the law by proposing an alternative that contains the point of compliance as the point of discharge and this alternative should not be considered and must be withdrawn. This proposed regulation is unacceptable and if implemented would have serious negative effects on industry within our state. **(952)**

Response: For discussion on how the rulemaking satisfies the EQB's obligations relative to Act 40, see the response to Comment 200. Also see the response to Comment 212 for further details regarding consistency with the law. See also the responses to Comments 133 and 183 regarding other coal mining states' WQSs and no evidence of negative health effects in residents of those states.

206. Comment: Act 40 required the EQB to make a simple revision that would provide clarity on the point of compliance for the manganese effluent standard. The insertion of manganese into the list of other water quality criteria found in Chapter 96.3(d) would fulfill the intent of Act 40. Instead of this simple change, DEP is taking a far more complex approach. **(9, 728, 862)** The proposed rulemaking that DEP provided to the EQB relies on outdated science to label manganese as toxic, piles on an overly conservative 3 modifying factor, thereby proposing a 0.3 mg/L health and human criteria standard. In essence, DEP is trying to treat

manganese, a nutrient vital for human health, as if it were a toxic metal like cyanide, arsenic, or mercury. (728)

Response: For discussion about how the rulemaking satisfies the EQB's obligations relative to Act 40, see the response to Comment 200. Also see the response to Comment 212 for further details regarding consistency with the law.

For discussion regarding the impetus for this rulemaking and the obligations DEP has in the development of WQSs, see the response to Comment 182.

For this final-form rulemaking, DEP evaluated numerous studies published during the period spanning EPA's most recent toxicological review of manganese in 2003 through 2021, including a handful of PBPK model studies referenced by the mining industry. DEP also sought additional scientific data and information through the publication of an ANPR and consulted with experts at EPA throughout the criterion development and rulemaking processes. See the responses to Comments 53-92 for more detailed discussions on DEP's evaluation and use of the scientific literature.

207. Comment: The commentator has never seen DEP or any government agency present a menu of rulemaking options to the public for comment and the EQB to choose from. The commentator wonders if this is a one-time approach or part of a new trend on the part of BCW and DEP. Presenting the public and the EQB with two different options is not consistent with the laws governing the rulemaking process and should be abandoned. For that reason, option two should not even be considered by the EQB because it fails to meet the statutory language set forth under Act 40. (15)

Response: Moving the point of compliance for manganese to a potable water supply withdrawal may be beneficial to some wastewater facilities that have permitted discharges of manganese in their wastewater, and it may be a burden to public water systems. The proposed regulations take into consideration the responsibility of public water systems to meet their SDWA requirements for manganese. The second alternative point of compliance does not shift the treatment costs for wastewater discharges that contain high levels of manganese to the public water systems.

Under the first alternative point of compliance, as the levels of manganese change in the surface water, many public water systems using surface waters as their source water will need to increase source water monitoring and may require facility upgrades or additional chemical usage to continue achieving the SMCL for manganese of 0.05 mg/L in the finished water, which is required under the Pennsylvania SDWA. *See* 35 P.S. §§ 721.3 and 721.5 and regulations at 25 Pa. Code § 109.202(b). The SMCL is based on the Federal standard found at 40 CFR § 143.3. Also, see the Preamble language for the proposed regulations (under First Alternative Point of Compliance) that describe more specifically additional requirements that public water systems may need to meet if a contaminant is present in the potable water supply and may cause a potential health hazard.

Due to the complexities associated with proposing a regulation that must take into consideration an enforceable SDWA SMCL, it was necessary to gather public comment on more than one alternative to prevent creating new burdens on public water systems.

It should not be assumed that a proposed regulation will remain the same when a final-form regulation is considered by the EQB. See the response to Comment 200 for discussion about two alternative points of compliance in the proposed rulemaking and for discussion about how the rulemaking satisfies the EQB's obligations relative to Act 40. Also see the response to Comment 212 for further details regarding consistency with the law.

208. Comment: The House Environmental Resources and Energy Committee and commentators state the proposed rulemaking did not follow timeline dictated by Act 40. Act 40 states that within ninety days of the effective date (Act 40 was signed on October 30, 2017) of this subsection, the EQB shall promulgate proposed regulations. (**618, 901, 922, 935, 952**)

Response: Subsection (j) of Act 40 states the following: "Within 90 days of the effective date of this subsection, the board shall promulgate proposed regulations." The EQB published an ANPR within 90 days of the effective date of Act 40. The purpose of the notice was to gather information necessary to fulfill the EQB's rulemaking obligations under various laws including the Commonwealth Documents Law, the Commonwealth Attorneys Act, the Regulatory Review Act, and the Administrative Code of 1929. Additionally, the Pennsylvania Commonwealth Court confirmed the EQB's compliance with the timeframe for proposing regulations under Act 40. *See Scarnati v. Department of Environmental Protection*, 220 A.3d 723, 729 n.9 (Pa. Cmwlth. 2019) ("...the statute itself does not indicate the 90-day timeframe is essential. Thus, the 90-day timeframe in Act 40 is directory only."), *aff'd*, 240 A.3d 536 (2020) (per curiam).

209. Comment: The House Environmental Resources and Energy Committee comments that DEP's excuses about why the delay was necessary to fully analyze their obligations under various laws and the health implications of manganese are utter nonsense as the extensive review that DEP claims to have conducted was not required. If DEP had complied with Act 40, no federal or state laws would have been violated. The only law being violated is Act 40 itself by DEP. Why did Governor Wolf sign Act 40 into law if he intended for DEP to completely violate these provisions? (**952**)

Response: Act 40 obligated the EQB to propose regulations that move the point of compliance for manganese, consistent with the exceptions in § 96.3(d). The proposed regulation includes language that satisfies the EQB's obligation under Act 40 by including language consistent with Act 40.

Subsection (j) of Act 40 states the following: "Within 90 days of the effective date of this subsection, the board shall promulgate proposed regulations." The EQB published an ANPR within 90 days of the effective date of Act 40. The purpose of the notice was to gather information necessary to fulfill the EQB's rulemaking obligations under various laws including the Commonwealth Documents Law, the Commonwealth Attorneys Act, the Regulatory Review Act, and the Administrative Code. Additionally, the Pennsylvania

Commonwealth Court confirmed the EQB's compliance with the timeframe for proposing regulations under Act 40. *See Scarnati v. Department of Environmental Protection*, 220 A.3d 723, 729 n.9 (Pa. Cmwlth. 2019) ("...the statute itself does not indicate the 90-day timeframe is essential. Thus, the 90-day timeframe in Act 40 is directory only."), *aff'd*, 240 A.3d 536 (2020) (per curiam).

See the responses to Comments 153, 178, 182, 186, and 206 for discussion on DEP's obligations with respect to the development and adoption of WQSSs.

210. Comment: The House Environmental Resources and Energy Committee comments that agencies must follow the law, particularly when the law is clear and unambiguous, as Act 40 is. To permit or endorse DEP's blatant refusal to comply with the statute would set an extremely dangerous precedent. The Committee therefore asks IRRC to disapprove this regulation in its proposed form since the provisions of the regulation run contrary to the language and intent of the Act on which they are based and patently unreasonable. The Committee urges the EQB and DEP to withdraw this proposed regulation. (952)

Response: For discussion about how the rulemaking satisfies the EQB's obligations relative to Act 40, see the response to Comment 200. Also see the response to Comment 212 for further details regarding consistency with the law.

211. Comment: The Senate Environmental Resources and Energy Committee and others comment Act 40 directed the EQB to promulgate a regulation that would require the WQ criterion for manganese to be met consistent with its critical use in order to eliminate an apparent contradiction in the existing regulations. Specifically, since the critical use for manganese is the protection of permitted public water systems as outlined in Chapter 93, the point of compliance stipulated in Chapter 96 must be at the point of potable water supply withdrawal. This was not clear in the regulations prior to Act 40 as manganese was not listed in Chapter 96.3(d). Act 40 was intended to clarify that manganese should be listed in Chapter 96.3(d) along with other WQ criteria established for Potable Water Supply use protection. However, rather than following the clear intent of Act 40, the proposed rulemaking attempts to circumvent Act 40 by changing the critical use of manganese. The Committee objects to this obvious attempt to disregard the law as it was written and urges the EQB to reject the proposed rulemaking for having failed to achieve compliance with Act 40. (728, 905, 935, 951, 953)

Response: For discussion about how the rulemaking satisfies the EQB's obligations relative to Act 40, see the response to Comment 200. Also see the response to Comment 212 for further details regarding consistency with the law.

In Chapter 93, Table 1, Potable Water Supply use (which is a statewide use under § 93.4) is defined as a supply used by the public or by other uses that require a permit under the federal and state SDWA, *after conventional treatment*, for drinking and other purposes. Protection of the Potable Water Supply use means that the Commonwealth's waters are protected for present and future use as drinking water supplies by preventing pollution that would require more than conventional treatment. Prior to this final-form rulemaking, the Potable Water

Supply use criteria in § 93.7 included manganese, TDS, bacteria (Bac_2), color, phenolics, iron (Fe_2), fluoride, chloride, sulfate and nitrite plus nitrate. Most of these substances are regulated in drinking water and surface waters primarily because they cause organoleptic and aesthetic issues at low levels. At the levels necessary to avoid these issues, these substances are generally known to be non-toxic to humans. Each of the Potable Water Supply use criteria required to be met at the point of potable water supply withdrawal under § 96.3(d), except for phenolics, are based on drinking water MCLs or SMCLs. It is important to note that the Potable Water Supply use criterion for phenolics does not include those specific phenolic compounds that have been identified by EPA as priority pollutants (that is, toxic substances). Criteria for those specific phenolic compounds are found in § 93.8c, Table 5 (relating to human health and aquatic life criteria for toxic substances), and those criteria currently must be met in all surface waters in accordance with § 96.3(c). It is also important to note that not all Potable Water Supply use criteria are applied at the point of withdrawal. Presently, there are four Potable Water Supply use parameters that must be met in all surface waters including manganese, color, coliform bacteria (Bac_2) and dissolved iron (Fe_2).

Since DEP's review of the current science on manganese indicates that manganese ingestion can lead to neurotoxic effects, its characteristics no longer align with those of the other Potable Water Supply use criteria as non-toxic substances. All 122 of the human health criteria for toxic substances contained in § 93.8c, Table 5 are currently required to be met in all surface waters in accordance with § 96.3(c). This policy and expectation for compliance with toxic substances has been a long-standing policy of the EQB and DEP.

For discussion on how the manganese criterion is consistent with the CWA and protective of the most sensitive protection use, see the response to Comment 186.

IRRC Comments

212. Comment: This proposed rulemaking deletes manganese and the existing criterion of 1.0 mg/L from Table 3 of Section 93.7 and adds manganese and the criterion of 0.3 mg/L to Table 5 of Section 93.8c. Table 3 identifies a specific water use and was established for the protection of Potable Water Supply use. Table 5 identifies organisms to be protected by the criterion, such as human health and aquatic life.

The rulemaking also proposes two alternatives for point of compliance for the manganese WQS. The first alternative, as required by Act 40 of 2017 (Act 40), moves the point of compliance to the point of all existing or planned surface potable water supply withdrawals. The specific language of Act 40 that forms the basis for part of this rulemaking reads as follows:

The board shall promulgate regulations under the act of June 22, 1937 (P.L. 1987, No. 394) known as the "Clean Streams Law (CSL)," or other laws of this Commonwealth that require that the water quality criteria for manganese established under 25 Pa. Code Chapter 93 (relating to water quality standards) shall be met, consistent with the exception in 25 Pa. Code Section 96.3 (d) (relating to water quality protection requirements). Within ninety days of the effective date of this

subsection, the board shall promulgate proposed regulations. (See Section 1920-A (j) of the Administrative Code of 1929 (71 P.S. Section 510-20(j)).

The second alternative is to maintain the existing point of compliance in all surface waters, which is the point of discharge. In addition to Act 40, the EQB has cited the other environmental laws as part of its statutory authority for this proposed rulemaking. These laws include the CSL (35 P.S. § 691.1et seq.), the Pennsylvania SDWA (35 P.S. § 721.1 et seq.) and the CWA (33 U.S.C.A. § 1251 et seq.). The EQB states that these statutes, and the regulations promulgated under those statutes, require DEP to protect the waterways of the Commonwealth.

The EQB is seeking comment on both alternatives.

The House Environmental Resources and Energy Committee (House Committee) submitted a letter stating that the proposed regulation and the inclusion of two possible points of compliance for manganese is contrary to Act 40 and the intention of the General Assembly. According to the Committee, the intent of Act 40 was to move the point of compliance for manganese from the point of discharge to the point of potable water supply withdrawal. Commentators from the industrial and mining sectors have expressed the same concern. Other commentators, including public water system companies and environmental organizations are opposed to Act 40 and moving the point of compliance for manganese downstream.

While a goal of the RRA is the reaching of consensus among interested parties, this Commission must first and foremost determine whether the agency has the statutory authority to promulgate a specific regulation and whether the regulation conforms to the intention of the General Assembly in the enactment of the statute upon which the regulation is based. In making that determination, the RRA directs this Commission to consider, among other things, written comments submitted by a committee.

We recognize that the other environmental laws cited above require DEP to protect the waterways of the Commonwealth and also the health, safety and welfare of its citizens. Commentators have argued that the requirement of Act 40 and this proposal conflict with the other environmental laws. However, the mandate of Act 40 is clear and does not provide discretion to the EQB. Given the language of Act 40, the comments submitted by the Committee, and the requirements of the RRA, we ask the EQB to explain why this rulemaking and the inclusion of two possible points of compliance is consistent with the intent of the Act 40 and the General Assembly. (957)

Response: For discussion about how the rulemaking satisfies the EQB's obligations relative to Act 40, see the response to Comment 200. The proposed regulations include alternative language based on other statutory considerations, such as compliance with the Pennsylvania Safe Drinking Water Act, which requires that a public water supplier's finished water must meet a secondary maximum contaminant level (SMCL) of 0.05 mg/L for manganese. Although the SMCL for manganese in Pennsylvania is based on a non-mandatory Federal standard found at 40 CFR 143.3, the General Assembly intended the standard to be

mandatory in Pennsylvania. The EQB is obligated to propose regulations that take into consideration the ability of public water suppliers to operate in a manner which will result in compliance with the law and the standard. *See* 35 P.S. §§ 721.3 and 721.5 and regulations at 25 Pa. Code § 109.202(b) (relating to state MCLs, MRDLs and treatment technique requirements).

In addition to these regulatory requirements, the point of compliance for the manganese water quality criterion has implications for water suppliers based on other drinking water requirements. EPA developed one-day, 10-day and lifetime HALs for manganese, pursuant to the Federal SDWA (42 U.S.C.A. §§ 300f—300j-26). The lifetime HAL of 0.3 mg/L protects against potential neurological effects. The one-day and 10-day HALs of 1 mg/L are for acute exposure and EPA advises that for infants younger than 6 months, the lifetime HAL of 0.3 mg/L be used even for an acute exposure of 10 days, because of the concerns for differences in manganese content in human milk and formula and the possibility of higher absorption and lower excretion in young infants. Because EPA developed HALs for manganese, public water systems may be subject to additional monitoring and public notification requirements if the HALs are exceeded in the finished water.

In accordance with Pennsylvania's current water quality standards regulations found at 25 Pa. Code Chapter 93, the Potable Water Supply use water quality criteria are designed to ensure that public water systems receive raw water at their intake structures that can achieve compliance with SDW standards in 25 Pa. Code Chapter 109, utilizing only conventional treatment. If a water supplier or DEP indicates a contaminant is present in the potable water supply and may cause a potential health hazard, additional monitoring by the water supplier may be required under 25 Pa. Code § 109.302(b) (relating to special monitoring), which may then trigger additional treatment requirements pursuant to § 109.4 (relating to general requirements). If source water for public water system operations is received with manganese concentrations at or above 0.3 mg/L, sequestration of manganese is no longer an option and modifications to operations and/or additional treatment technologies for removal of manganese would be required. Sequestration does not remove the manganese, so manganese is still present and bioavailable after sequestration and, as such, can act as a neurotoxin. Finally, under § 109.407(a)(9) (relating to general public notification requirements) and § 109.408(a)(11) (relating to Tier 1 public notice—categories, timing and delivery of notice), Tier 1 public notice requirements may be triggered if exceedance of the HALs has the “potential to have serious adverse effects on human health as a result of short-term exposure.” For further discussion about protection of the statewide Potable Water Supply use defined in Chapter 93, see the response to Comment 202.

Although moving the point of compliance for the manganese water quality criterion to the point of existing or planned potable water supply surface withdrawal may be beneficial to some facilities that have permitted discharges of manganese in their wastewater, this could create an added burden to others, such as some public water systems. It could also burden facilities with surface water intakes that require a certain level of water quality for use in food and beverage production or preparation, paper and textile manufacturing, aquaculture, and irrigation. Moving the point of compliance for the manganese water quality criterion from the point of discharge to the point of withdrawal will likely require additional

monitoring by all of these facilities to determine the effects of increased source water manganese levels on their operations. As the levels of manganese change in the surface water, all public water systems using surface waters as their source water will need to monitor and may require facility upgrades or additional chemical usage to continue achieving the SMCL for manganese of 0.05 mg/L in the finished water, which is required under the Pennsylvania SDWA.

In addition to statutory requirements of the Pennsylvania SDWA, this rulemaking also had to consider relevant statutory requirements of the CSL and the CWA. Section 4(1) of the CSL (35 P.S. § 691.4(1)) declares that clean, unpolluted streams are absolutely essential if this Commonwealth is to attract new manufacturing industries and to develop the Commonwealth's full share of the tourist industry. Similarly, section 4(3) declares that an objective of the CSL is to prevent pollution and restore streams that are presently polluted (35 P.S. § 691.4(1)). Sections 4(4) and 5(b)(1) of the CSL (35 P.S. §§ 691.4(4) and 691.5(b)(1)) state that the Department has the duty to formulate regulations that prevent and eliminate water pollution. Section 1 of the CSL (35 P.S. § 691.1) defines "pollution" as "contamination of any waters of the Commonwealth such as . . . to render such waters harmful, detrimental or injurious to public health. . . , or to domestic, municipal, commercial, industrial, agricultural, recreational, or other legitimate beneficial uses, or to livestock, wild animals, birds, fish or other aquatic life. . . ."

In adopting rules and regulations under section 5(a) of the CSL (35 P.S. § 691.5(a)) to carry out the purposes of the act, the Department needs to consider, where applicable, the following: (1) water quality management and pollution control in the watershed as a whole; (2) the present and possible future uses of particular waters; (3) the feasibility of combined or joint treatment facilities; (4) the state of scientific and technological knowledge; and (5) the immediate and long-range economic impact upon the Commonwealth and its citizens.

Where a pollutant found in discharges to surface waters is toxic to human health or aquatic life, the Commonwealth's regulations require development of appropriate water quality criteria to control pollution. Section 93.8a (relating to toxic substances) specifically requires that "[t]he waters of this Commonwealth may not contain toxic substances attributable to point or nonpoint source waste discharges in concentrations or amounts that are inimical to the water uses to be protected."

Section 303(c) of the CWA and 40 CFR Part 131 (relating to water quality standards) require states to develop water quality standards that consist of designated uses, water quality criteria to protect those uses and antidegradation requirements. Such standards must "protect the public health or welfare and enhance the quality of water" (33 U.S.C.A. § 1313(c)). In addition, such standards must take into consideration water uses including public water supplies, propagation of fish and wildlife, recreational purposes, agricultural purposes and industrial purposes. Section 101(a)(3) of the CWA declares the National policy that the discharge of toxic pollutants in toxic amounts be prohibited (33 U.S.C.A. § 1251(a)(3)).

The EQB properly presented the proposed regulation with two alternatives. It was necessary to propose both alternatives, and receive public comments on both, to fully inform the EQB's

decisionmaking regarding the legal and technical impacts associated with a change to the current regulation. The Preamble, RAF and Annex A prepared for the proposed rulemaking provided language reflecting both alternatives, and the EQB requested public comment on both alternatives. The inclusion of language in Annex A that reflects both alternatives prevents enlargement of the scope of the proposed regulation, consistent with the Commonwealth Documents Law, if one or the other alternative is chosen for final regulation. See *Brocal Corp. v. PennDOT*, 528 A.2d 114 (Pa. 1987).

213. Comment: The House Committee, Senate Environmental Resources and Energy Committee (Senate Committee) and some commentators representing the industrial sector believe it is inappropriate for a proposed regulation to offer two alternatives for the regulation of manganese. The House Committee states, in part, “. . . proposing two different alternatives within the same regulatory package is not the process that the RRA envisions or authorizes.” They contend this approach does not provide the interested parties with a clear picture of what the final regulation will require of the regulated community, and therefore, it is not possible to provide appropriate comments.

In the Preamble to the final-form regulation, we ask the EQB to explain why it included two alternative points of compliance in a single regulatory package. We also ask the EQB to explain why this approach is in compliance with the RRA and the regulations of IRRC. Specifically, the EQB should explain why this proposal meets the RRA definition of a “proposed regulation” which reads as follows:

A document intended for promulgation as a regulation which an agency submits to the commission and the committees and for which the agency gives notice of proposed rulemaking and holds a public comment period pursuant to the act of July 31, 1968 (P.L. 769, No. 240), referred to as the Commonwealth Documents Law.

(957)

Response: No specific language in the RRA precludes the presentation of more than one proposed regulatory option, as long as the public has clear notice of the agency’s intentions.

Under the Commonwealth Documents Law, a proposed rulemaking provides notice to the public of an agency’s intention to promulgate a regulation. The Commonwealth Documents Law and the RRA require agencies to review and consider public comments and hold public hearings as appropriate. Section 1201(4) of the Commonwealth Documents Law requires agencies to include “a request for written comments by any interested person concerning the proposed administrative regulation or change therein.” Additionally, section 1202 states: “Before taking action upon any administrative regulation or change therein the agency shall review and consider any written comments submitted....” The Commonwealth Documents Law clearly includes an opportunity for the public to weigh in on proposed regulations. The proposed regulation included language for movement of the point of compliance to any existing or planned downstream potable water supply withdrawal (consistent with Act 40) and language that presented the option to retain the existing point of compliance (consistent with the CSL and other statutory and regulatory requirements), and this proposal invited public comments on the appropriate point of compliance. Based on public comments

received on both options, the public understands their opportunity to comment on both alternatives and there does not appear to be any confusion about the subject of the rulemaking. The choices are clear and the regulation satisfies the EQB's obligation under Act 40.

See also the responses to Comments 200 and 212 for more detailed discussion on the inclusion of two alternatives in the proposed rulemaking.

Additionally, under the RRA, § 745.5(a)(12) directs agencies to describe "any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected." Section 745.5b directs the IRRC to consider "the impact on the public interest of exempting or setting lesser standards of compliance." 71 P.S. § 745.5(a)(12) and 745.5b(b)(1)(v). Because the Department and the EQB did not initiate the development of this rulemaking, it was necessary to propose alternatives and gather information from various industry sectors to respond to this question in IRRC's RAF.

The explanation for why two alternative points of compliance were included in the proposed rulemaking is provided in Section F of the Preamble, under the heading "Statutory authority including the CSL, CWA, RRA and Act 40."

214. Comment: The proposed lowering of the manganese standard from 1.0 mg/L to 0.3 mg/L has generated significant comment from the regulated community. The House and Senate Committees also commented on this issue. Commentators that support the lower standard believe it is appropriate and backed by the science cited and reviewed by the EQB in support of the rulemaking. Commentators opposed to the lower standard do not believe the regulation of manganese at this level is needed to protect human health and is not backed by the most recent scientific data.

We ask the EQB to review and consider the scientific data and studies provided by the commentators that are opposed to the lower standard. In the Preamble to the final-form regulation, the EQB should clearly state and justify why the lower standard is needed and why the science on which the rulemaking is ultimately based is the most appropriate for the Commonwealth.

We also ask the EQB to explain why it is reasonable to impose a manganese standard that is lower than other states and why it is reasonable to regulate manganese in a manner different than the EPA.

Finally, we acknowledge the process used by the EQB to promulgate this rulemaking. This process included the issuance of an ANPR, consultation with the DEP's Water Resources Advisory Committee, the AAB, and the Public Water System TAC Advisory Board. The EQB also held three public hearings to solicit additional input. We believe other advisory boards of DEP could provide valuable input on this rulemaking. Since the representatives of the coal and aggregate industry have submitted comments questioning the science, need and

cost associated with this proposal, we suggest that the final-form regulation be presented to the MRAB and the Aggregate Advisory Board for input. We believe these Boards could provide valuable input that could lead to a final regulation that is in the best interest of all citizens of the Commonwealth. (957)

Response: DEP did review and consider several PBPK model studies in its evaluation of and recommendation for the proposed manganese criterion of 0.3 mg/L (Schroeter et al., 2011; Schroeter et al., 2012; Yoon et al., 2011), and DEP also reviewed the more recent studies conducted by Song et al. (2019) and Yoon et al. (2019) following the December 2019 EQB meeting and in response to comments received on the proposed rulemaking. See the responses to Comments 53-92 for detailed discussions on the data and literature used by DEP to develop the human health criterion for manganese. As discussed in the response to Comment 65, DEP's review of the PBPK studies did not change its criterion recommendation. The explanation for why a lower manganese standard is needed is provided in Section F of the Preamble, under the heading "Toxic effects of manganese of human health." Section D of the Preamble explains the statutory and regulatory requirements DEP must follow when reviewing a water quality standard and that the result from that process was the 0.3 mg/L manganese criterion.

While manganese has not been widely categorized as a toxic substance to date, EPA, States, and other health-focused groups, such as WHO and Health Canada, are currently reevaluating the science and data on manganese due to the number of studies that have emerged which support a link between manganese in drinking water and neurotoxicity.

Several states have reviewed the more recent toxicological data available on manganese and have adopted health-based guidance values for drinking water. In 2012, MDH adopted an HBGV for manganese of 0.1 mg/L to protect bottle-fed infants from neurological impacts. MDH relied on the Kern et al. (2010) study to develop the reference dose used in establishing the HBGV. In 2018, MDH reevaluated and readopted the 2012 HBGV. MDH recently published a paper about the development of the HBGV in *Environmental Health Perspectives* (Scher et al., 2021), which is available online. In addition to MDH, the Kern et al. (2010) study has also been used by WHO and Health Canada to develop their recommendations. New Hampshire is also currently evaluating the need for manganese drinking water standards to protect infants, and developed an updated RfD based on the current oral RfD published in EPA's IRIS database. The updated RfD uses an adjusted point of departure based on the 2015 EPA updates to exposure factors including body weight assumptions. Other assessment inputs include the application of the EPA-recommended MF of 3, an RSC of 0.5, and body-weight adjusted water intake rates for infants. The New Hampshire recommendation for manganese is also 0.1 mg/L.

WHO had previously withdrawn its recommendation of 0.4 mg/L for manganese from the WHO GDWQ in 2011 on the presumption that the "health based value [0.4 mg/L] is well above concentrations of manganese normally found in drinking water". However, drinking water levels above this value can be found in many countries, including the U.S. In December 2020, following a more recent review of the published scientific literature, WHO published a draft document, titled "Manganese in Drinking Water", for public review and

comment. Comments were due to WHO by February 8, 2021. The draft document recommended a value of 0.08 mg/L to protect bottle-fed infants, which is significantly lower than the organization's previous recommendation of 0.4 mg/L. On December 22, 2021, WHO published an update to its 4th edition of the GDWQ containing the recommendation that manganese in drinking water not exceed 0.08 mg/L to protect bottle-fed infants.

Health Canada (2019) also recently evaluated manganese and determined that a value of 0.12 mg/L for drinking water was warranted to protect infants based on the emerging science and data. Additional discussion on the Health Canada evaluation can be found in the responses to Comments 69, 83, 86, 87 and 91.

While EPA may not have chosen to regulate manganese in drinking water with a primary MCL in 2003, it is important to note that EPA OW published a Drinking Water Health Advisory for Manganese with a Lifetime Health Advisory value of 0.3 mg/L and a footnote that states "The lifetime health advisory includes a 3-fold modifying factor to account for increased bioavailability from drinking water." It is also important to note that EPA's Safe Drinking Water program identified manganese as a pollutant of potential concern and recently collected data on manganese in drinking water as part of the UCMR4, which was published in the *Federal Register* on December 20, 2016 (81 FR 92666). See responses to Comments 56 and 60.

Under the CWA, every state must evaluate and adopt WQSs to protect surface waters from pollution. For example, manganese is present in discharges to Pennsylvania surface waters, and the CWA requires states to develop WQSs for the purpose of establishing effluent limitations in wastewater discharges. For example, not every state has a mining industry that actively discharges manganese to surface waters. While every state must follow the requirements of the CWA and evaluate wastewater discharges for WQSs development, individual states may have adopted WQSs for pollutants that are not present in wastewater discharges in Pennsylvania. In addition, the timeline on which individual states evaluate and adopt or revise their WQSs, including any evaluations of specific WQ criteria, can vary significantly from state to state.

In response to this comment, DEP met with the two mining advisory committees to present the draft proposed and draft final regulations and to seek additional information. On January 21, 2021 and May 5, 2021, respectively, DEP met with the MRAB and the Aggregate Advisory Board to solicit additional information on the potential economic impacts associated with maintenance of the point of compliance at the point of discharge. DEP returned to present the draft final-form rulemaking recommendation to the MRAB on January 20, 2022 and to the Aggregate Advisory Board on February 2, 2022. As many of the members had already submitted comments during the public comment period for the proposed rulemaking, DEP received no additional information or data from either of these boards or from the industry in response to these meetings.

215. Comment: The RAF and the Preamble submitted with this proposal do not provide specific estimates of the costs or savings that may be experienced by the regulated community, local governments and state government. Potential cost of the rulemaking is an issue raised by

commentators. For example, some believe that moving the point of compliance will shift costs from dischargers to public water systems and those costs would be passed on to consumers. Others believe that the lower standard for manganese will be impossible for some dischargers, including those involved in remining and abandoned mine reclamation projects, to meet because of increased cost.

The Senate Committee also raised the issue of cost. They question how the lower standard will affect the remediation of legacy acid mine drainage sites, bond forfeiture sites and note the potential increased costs for state and local agencies related to public highway construction.

The EQB's response regarding cost does not provide this Commission with sufficient information to determine if the regulation is in the public interest. After the language of the rulemaking is finalized, the EQB should work with the regulated community and the advisory boards noted above to determine actual costs or savings that could be realized and this information should be included in the RAF and Preamble. (957)

Response: With respect to this regulation, the compliance and treatment costs for NPDES-permitted wastewater dischargers may increase based on discharge-specific and site-specific considerations. These considerations include, but are not limited to, the size, flow, chemical, biological, and other physical properties of both the receiving water and the effluent discharge. Additionally, some dischargers must comply with technology-based effluent limitations or other best available technology limits developed for their industry. All of these factors necessitate site-specific analyses to assess compliance and treatment costs. Considering that there are approximately 1,322 NPDES permits that currently contain manganese monitoring and report requirements or manganese effluent limits, specific estimates of treatment costs or savings for every potentially affected discharger of manganese are difficult to determine because estimating those costs or savings with any reasonable precision would require a site-specific analysis of each activity affected by this regulation.

DEP received estimated economic impact information from public water systems and the mining industry during the public comment period on the proposed rulemaking and has incorporated this information, as appropriate, into the RAF and final Preamble. Pennsylvania Coal Alliance, based on an evaluation completed by Tetra Tech, indicated the overall costs to achieve compliance with the 0.3 mg/L criterion at the point of discharge could range between \$44—\$88 million in annual costs (that is, for active treatment systems using chemical addition for manganese removal) and upwards of \$200 million in capital costs.

With respect to moving the point of compliance to the point of potable water supply withdrawal and increasing source water concentrations of manganese, the Pennsylvania American Water Company estimated the costs to their facilities would range between \$40-\$60 million in capital costs with an increase in annual operations costs of between \$700,000 and \$1.4 million. The total capacity of the eight plants that would likely need upgrades is approximately 40 MGD. The estimated costs for plant upgrades ranged between \$1-\$1.5 million per MGD, equating to an overall one-time capital cost of \$40-\$60 million. The City of Reading estimated capital costs at \$2.1 million with a 20-year operating cost of \$15.8

million. As stated in the analysis completed by Drexel University (Hamilton et al., 2022), Kohl and Medlar (2006) studied the capital cost of manganese removal treatment for public water systems and produced various estimates that ranged from \$750,000 per MGD to \$2 million per MGD for manganese control. The figure of \$1.5 million per MGD quoted above is within the range estimated by Kohl and Medlar (2006).

DEP consulted and collaborated with Drexel University to better understand manganese removal treatment options and the challenges associated with manganese removal for public water systems. An analysis completed by Drexel University (Hamilton et al., 2022) identified challenges for public water systems regarding the treatment and removal of dissolved manganese from surface waters that conflict with some of the statements made by Tetra Tech. The Tetra Tech report states that chlorine will oxidize inorganics, such as sulfurs, iron and manganese. The Tetra Tech report further states that chlorine is frequently used for the oxidation of dissolved manganese prior to greensand filters and the same principle would also apply to conventional treatment systems. Tetra Tech writes, “At most, any slight increase in dissolved (or reduced) manganese in intake water would require a modest increase in chemical (chlorine) use as part of pre-chlorination.” Drexel indicated that manganese is not readily oxidized by chlorine at pH values typical of water treatment. As stated in the Drexel report, “Tobiason et al. (2016) report that oxidation of manganese by chlorine is not effective until pH 9, which is well above the range in which most water supply treatment plants operate. Thus, the equation given on page 15 of the Tetra Tech report, which shows the oxidation of manganese by chlorine, while not incorrect, would not occur to a substantial degree under typical water treatment conditions per Tobiason et al.” Drexel also noted Tetra Tech’s comments about the difficulties of removing manganese from coal mine drainage when aluminum is present may be applicable to drinking water treatment. The Drexel report states, “Difficulties with simultaneous removal of aluminum and manganese from coal mine drainage are noted in Tetra Tech’s comments and clearly warranted careful consideration with respect to conventional drinking water treatment processes. Aluminum salts are widely used as a water treatment additive [i.e., coagulant] and at favorable pHs can precipitate readily.”

It is important to recognize that the Pennsylvania Coal Alliance noted similar challenges as DEP in estimating the economic impact of the proposed rulemaking on the mining industry stating “the wide range [\$44-\$88 million] is due to generalizations and more refined estimates would require better understanding of flow, chemistry and treatment at each NPDES permit location”. It is also important to note there are additional factors that may be considered by DEP which may result in the modification of effluent limitations or the deadline by which compliance with the limitations must be achieved. Cost and/or savings may be affected by the remedial measures leading to compliance with the effluent limitations. Based on site-specific evaluations, effluent limitations developed based on new water quality criteria may be modified, or more time for compliance may be granted under applicable regulations.

In response to comments about costs to the mining industry, DEP collaborated with PSU to better understand different manganese removal treatment options and potential costs associated with removing manganese from coal mine drainage. PSU conducted a

comprehensive evaluation of available treatment technologies, including emerging technologies, as well as the costs associated with manganese removal treatment and provided a summary report of the findings to DEP.

While the PSU report (Burgos, 2021) does generally corroborate the cost estimates found in the Tetra Tech report cited by the Pennsylvania Coal Alliance, the PSU report also highlights several limitations of the Tetra Tech analysis and provides a more robust analysis. The Tetra Tech analysis assumed that every NPDES discharge permit for mining operations would require installation of treatment systems and that the treatment system utilized by every facility would be chemical precipitation water softening, which is generally the most expensive treatment option. The PSU analysis takes a more balanced and comprehensive approach to the evaluation of costs based on different percentages of permits potentially affected (for example, 50% and 75% versus 100%) as well as consideration of the most cost-effective treatment options for different sizes of mining operations based on flow and other water quality characteristics. PSU noted that chemical precipitation water softening was never the most cost-effective treatment option for any category of discharge.

The more refined PSU analysis indicates that total costs to the mining industry if 75% of permits are affected are in the range of \$137-\$143 million in capital costs and \$33 - \$46 million in annual operating costs. The ranges decrease to \$91-\$95 million in capital costs and \$22-\$31 million in annual operating costs if only 50% of permits are affected. These costs estimates were generated by PSU using OSMRE's AMDTreat software, which is the same software used by Tetra Tech and the mining industry to estimate treatment costs. The different treatment systems evaluated by PSU included limestone manganese removal beds, oxidative precipitation using chemicals followed by either a limestone removal bed or sand filter, coprecipitation and sorption, and chemical precipitation water softening. The PSU report also noted that actual costs may be substantially lower than these refined costs estimates (that is, below the low range of these costs estimates) if sites are able to utilize existing treatment infrastructure or if the relatively few deep mines with larger flows are able to remove dissolved manganese using the coprecipitation and sorption option.

Furthermore, the PSU analysis indicates that, on an equal flow basis, capital costs for both the drinking water industry and the coal industry would be similar and, on an equal manganese (II) load basis, annual operating costs for both industries would be similar. See the RAF that accompanies this final-form rulemaking for more information.

DEP's BCW is also working with the mining industry and with DEP's Office of Active and Abandoned Mine Operations to minimize any adverse impacts of the regulation on remining and AML cleanup projects. DEP does not expect the rulemaking to lead to an increase in AML sites as a result of bond forfeiture. Some commentators claimed that the costs associated with manganese treatment will increase the number of bond forfeitures, but no commentators provided data or information to DEP to support claims that bond forfeiture rates will increase as a result of this regulation. See the response to Comment 51 for more discussion.

It is also worthwhile to note that in 1998 DEP evaluated permit sites for occurrences of post-mining discharges of pollutants and determined that only 17 of approximately 1700 permits issued since 1987 (less than 1%) resulted in discharges of pollutants. DEP also noted the discharges on the failed sites were much less severe in quantity and quality than historical AML discharges. Much like the AML sites managed by BAMR, SMCRA funding is used to address ABS forfeited sites. In addition to SMCRA sources, funding for these sites also comes from per-acre reclamation fees, civil penalties, forfeited bonds and interest.

Regarding stormwater-related permits, DEP WQS staff have met internally with staff in the NPDES Division and externally with PennDOT. PennDOT did not identify or express any potential concerns with the proposed rulemaking, including the discharge point of compliance option. The final-form rulemaking is not expected to impact DEP's current implementation practices for stormwater permitting or otherwise affect DEP's existing stormwater management programs. Stormwater discharges that contain problematic levels of manganese are currently, and would continue to be, addressed by DEP on a case-by-case basis rather than through policy changes made to the entire stormwater management program.

216. Comment: In response to Question #29 of the RAF, the EQB indicates that the effective date of the final-form regulation will be upon publication in the *Pennsylvania Bulletin* for CSL permit and approval actions, or as approved by EPA for purposes of CWA permits. A commentator does not believe the lower manganese standard will be approved by EPA because it is not based on sound science and it is not consistent with the manner in which EPA regulates manganese. If EPA does not approve the lower standard, how will DEP proceed with the implementation of this rulemaking? We ask EQB to explain this in the Preamble to the final-form rulemaking. (957)

Response: DEP disagrees with the commentators' statements regarding the science used to inform the rulemaking as generally discussed in the responses to Comments 53-92. DEP followed all applicable laws, regulations, policies and guidelines required in the development of the human health WQ criterion for manganese, including those established by EPA. DEP also consulted with EPA toxicologists and WQS staff at EPA headquarters and Region 3 throughout the manganese criterion development and rulemaking processes.

WQS must be approved by EPA before they can be used to implement the CWA. If EPA does not approve the lower standard, it will remain applicable for state-only permits. However, EPA Region 3 has indicated support for DEP's effort to develop a manganese WQ criterion for the protection of human health (see Comment 4).

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APPENDIX A



BUREAU OF CLEAN WATER

ANALYSIS OF MANGANESE IN PENNSYLVANIA SURFACE WATERS

January 2019

EXECITIVE SUMMARY

Act 40 of 2017 directed the Environmental Quality Board (EQB) to propose a regulation that would move the point of compliance for manganese from the point of discharge to any existing or planned potable water supply withdrawal. Where a pollutant found in discharges to surface waters is toxic to human health or aquatic life, the Commonwealth's regulations require development of appropriate water quality (WQ) criteria to control pollution. Manganese, which is found in discharges in the Commonwealth, has not been comprehensively reviewed since the Potable Water Supply use criterion was adopted in 1979. As such, the Department of Environmental Protection (DEP) has initiated the process of reviewing the manganese criterion to ensure that statewide protected water uses and all water users continue to receive adequate protection from toxic substances. As part of this review, DEP compiled and analyzed its manganese WQ data collected between 2008-2018 from surface waters of the Commonwealth.

More than 21,000 statewide water quality (SWQ) samples were collected by DEP from surface waters throughout Pennsylvania between 2008 and 2018, including at Water Quality Network (WQN) stations, continuous instream monitoring (CIM) sites and other monitoring sites, such as public water supply systems. In response to DEP's advance notice of proposed rulemaking (ANPR), DEP received additional data collected by a public water system (SUEZ) in Pennsylvania. From these datasets, yearly mean total manganese (TMn_{Avg}) concentrations were determined for each monitoring location that had sufficient data.

Results were used to determine the percentages of calculated TMn_{Avg} concentrations that were above three existing or proposed total manganese (TMn) limitations: 1.0 mg/L, 0.3 mg/L, and 0.05 mg/L. These three concentrations were selected because 1.0 mg/L is the current WQ criterion for manganese as found in § 93.7, Table 3 (maximum 1.0 mg/L manganese as total recoverable); 0.3 mg/L is the proposed human health WQ criterion calculated by DEP using the Environmental Protection Agency's (EPA's) methods for calculating human health criteria (note that 0.3 mg/L is also EPA's safe drinking water lifetime health advisory (HA) for children and adults); and 0.05 mg/L is the Federal and Pennsylvania Safe Drinking Water Act (SDWA) secondary maximum contaminant level (SMCL) for manganese, which is enforceable under Pennsylvania's SDWA.

Analysis of the SWQ data (2008-2018) indicated that 5% of the calculated TMn_{Avg} concentrations were above 1.0 mg/L, 16% of the calculated TMn_{Avg} concentrations were above 0.3 mg/L, and 60% of the calculated TMn_{Avg} concentrations were above 0.05 mg/L (see Figure 1 and Table 3).

ANALYSES OF THE WATER QUALITY DATA FOR MANGANESE

As part of the WQ criterion review process, DEP analyzed manganese data collected from surface waters throughout the Commonwealth. These analyses do not constitute an assessment of the surface waters for either their attainment of the protected water uses listed in § 93.3 (relating to protected water uses) or for compliance purposes, but rather, they were conducted to better understand manganese concentrations in surface waters throughout the Commonwealth,

including in targeted mining areas near public water systems which may likely be impacted by acid mine drainage (AMD).

Data used in the SWQ and WQI analyses were collected by DEP from surface waters throughout Pennsylvania between 2008 and 2018 at WQN stations, CIM sites and other monitoring sites, including surface waters used for potable water supply. Pennsylvania's WQN is a statewide, fixed station WQ sampling system operated by DEP, which provides data to characterize water quality conditions in Pennsylvania's surface waters. The public water system data is different and represents targeted monitoring efforts associated with assessing the Potable Water Supply use for surface waters with existing potable water supply withdrawals. DEP also reviewed and analyzed additional data provided by SUEZ, a company that owns and operates public water systems in Pennsylvania. The SUEZ dataset is specific to an individual public water system location. The potable water supply data for both the public water system and SUEZ datasets were collected between 2014 and 2018.

DEP evaluated and analyzed these three unique datasets - SWQ, public water system and SUEZ. The following sections summarize the calculated TMn_{Avg} concentration results for each dataset and provide comparisons of the datasets to specific existing and proposed regulatory limitations as well as an evaluation of the effect of anthropogenic stressors, such as land disturbance (LandDist), on TMn_{Avg} concentrations using DEP's Water Quality Index (WQI) tool. WQI scores and TMn_{Avg} concentrations for the SWQ dataset were analyzed to distinguish those TMn_{Avg} concentrations representative of natural background concentrations of manganese from TMn_{Avg} concentrations associated with impacts from anthropogenic activities.

SWQ TMn_{Avg}

The SWQ data collected by DEP throughout the Commonwealth between 2008 and 2018 were analyzed for manganese. It is important to note the 2018 data was incomplete at the time of analysis. In addition, since more than 1 sample result in any given year is necessary to calculate a yearly mean total concentration, locations containing only a single manganese sample result were excluded from the SWQ dataset. Some locations were sampled multiple times per year over a span of multiple years. Thus, TMn_{Avg} concentrations could be calculated multiple times for those locations. The number of calculated TMn_{Avg} concentrations in this dataset includes locations that were sampled multiple times across multiple years.

Upon review of the >21,000 SWQ sample results, sufficient manganese data was found to be available for the calculation of 641 TMn_{Avg} concentrations and included 2,811 samples. The results of DEP's analysis of the SWQ data indicated that 5% of the calculated TMn_{Avg} concentrations were above 1.0 mg/L, which is the current WQ criterion for manganese; 16% of the calculated TMn_{Avg} concentrations were above 0.3 mg/L, the proposed human health WQ criterion; and 60% of the calculated TMn_{Avg} concentrations were above 0.05 mg/L, which is the Federal SDWA SMCL.

The map in Figure 1 provides a statewide visual of the TMn_{Avg} concentrations calculated from the SWQ dataset. Surface waters with low concentrations of manganese (<0.3 mg/L) are characterized by the dark and light green dots on the map and include areas containing limited anthropogenic impacts on WQ. In contrast, surface waters with higher TMn_{Avg} concentrations

(>0.3 mg/L) are characterized by the orange and red dots and include areas containing moderate to significant anthropogenic impacts on WQ. As can be seen in Figures 6 and 7, these higher TMn_{Avg} concentrations most frequently occur in the bituminous and anthracite coalfield regions of the Commonwealth.

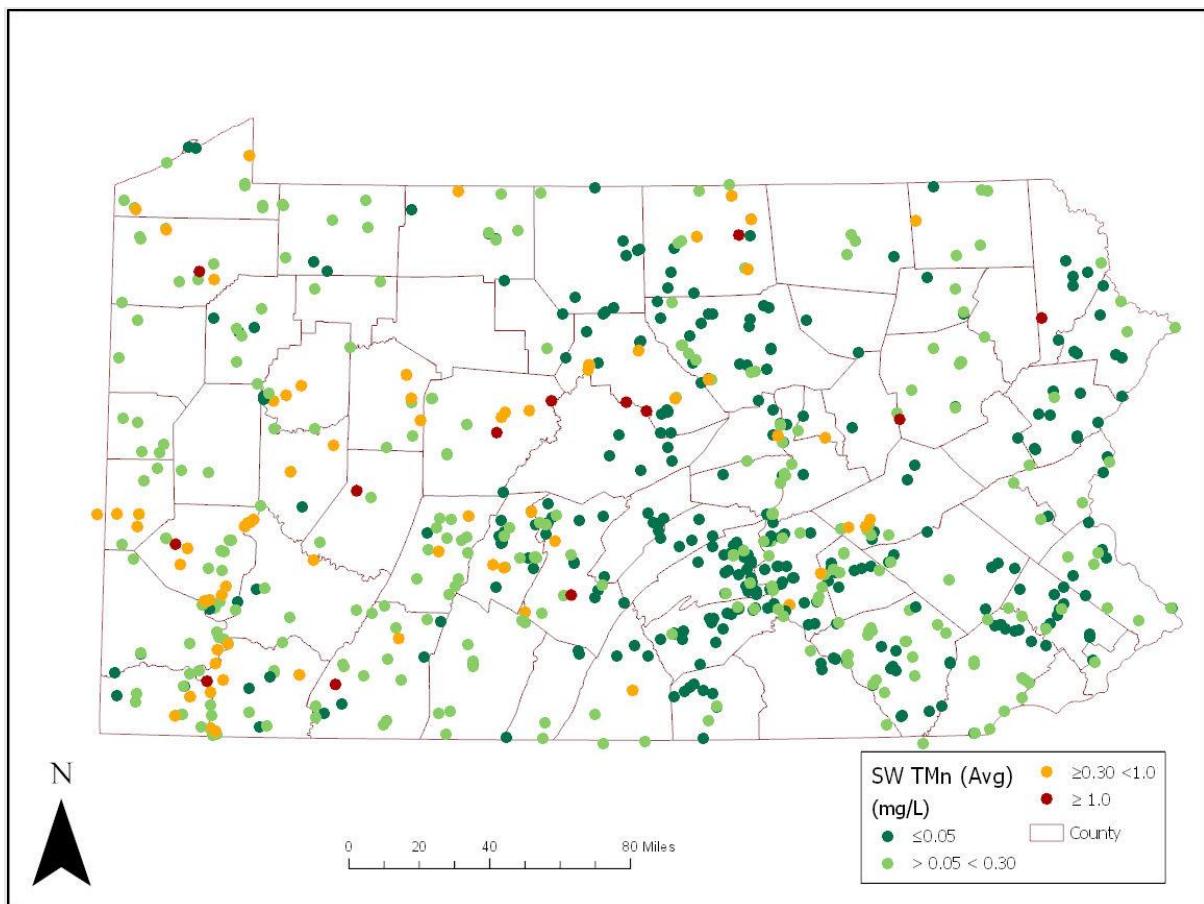


Figure 1. TMn_{Avg} (mg/L) concentrations in surface waters across Pennsylvania between 2008 and 2018, as analyzed from the SWQ data.

Public Water System TMn_{Avg}

DEP collected public water system data between 2014 and 2018 from surface waters at or near the location of potable water supply withdrawals (public water system dataset). The public water system dataset consists of 711 samples and 77 calculated TMn_{Avg} concentrations. Note that this dataset represents a subset of targeted public water systems and does not include samples from all public water systems operating surface water withdrawals in the Commonwealth. Available samples were analyzed for manganese, and TMn_{Avg} concentrations were calculated for locations with sufficient data. The results of DEP's analysis indicated that 3% of the calculated TMn_{Avg} concentrations were above 1.0 mg/L; 26% of the calculated TMn_{Avg} concentrations were above 0.3 mg/L; and 91% of the calculated TMn_{Avg} concentrations were above 0.05 mg/L.

Additional public water system data were received by DEP in 2019 from SUEZ. Surface water samples from a single location near one of their public water system withdrawals were collected

and analyzed for manganese. As with the public water system dataset, the SUEZ dataset spans the five year period of 2014 to 2018. DEP's analysis of the SUEZ samples resulted in calculated TMn_{Avg} concentrations which did not exceed the 1.0 mg/L or the 0.3 mg/L TMn comparison concentrations but did exceed 0.05 mg/L TMn concentration in all five years of sampling.

The map in Figure 2 provides a statewide visual of the TMn_{Avg} concentrations calculated from the public water system dataset and the SUEZ dataset. As was depicted in Figure 1, surface waters with low concentrations of manganese (<0.3 mg/L) are characterized by the dark and light green dots on the map. In contrast, surface waters with higher TMn_{Avg} concentrations (>0.3 mg/L) are characterized by the orange and red dots. As can be seen in Figures 6 and 7, these higher TMn_{Avg} concentrations most frequently occur in the bituminous and anthracite coalfield regions of the Commonwealth.

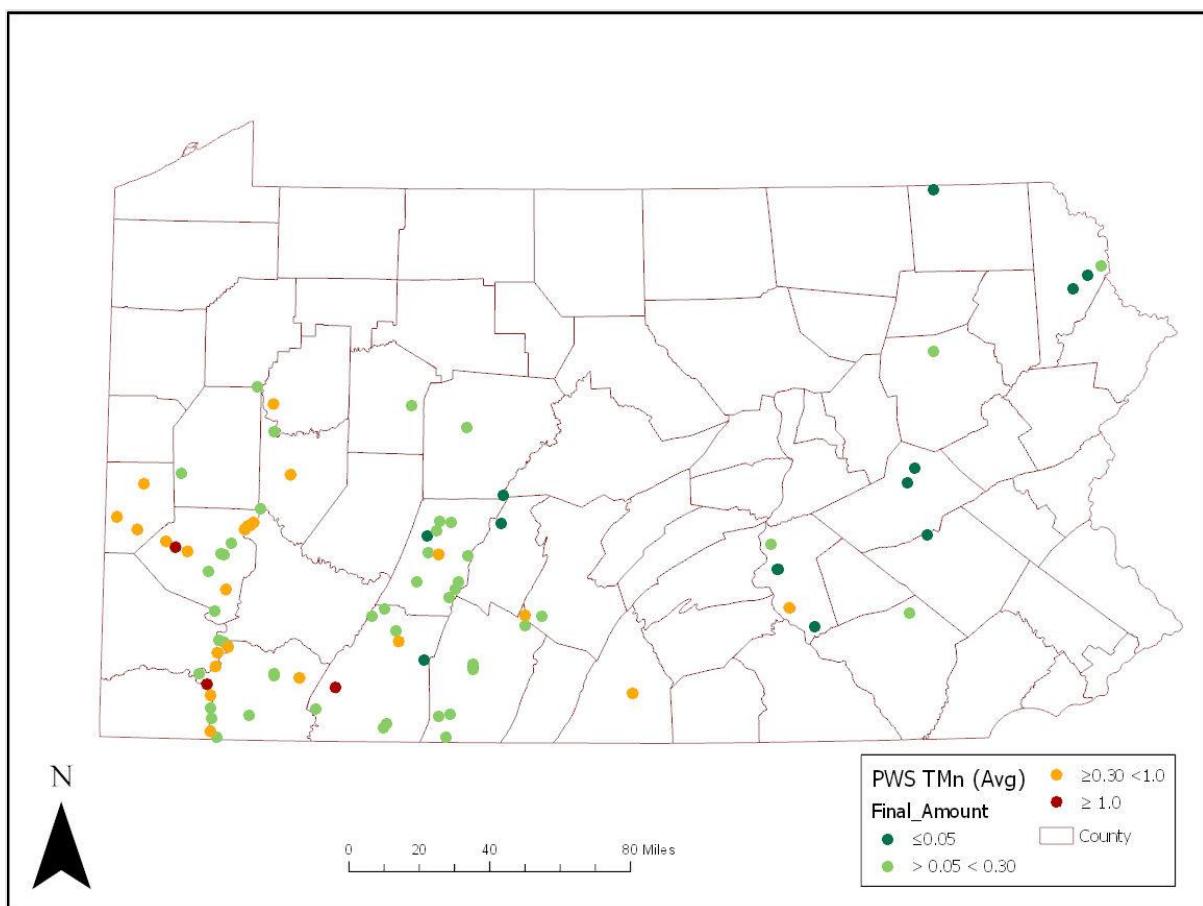


Figure 2. Calculated TMn_{Avg} (mg/L) concentrations at targeted public water system locations between 2014 and 2018, and at one withdrawal location for the SUEZ public water system.

Comparison of TMn_{Avg} concentrations between the SWQ, Public Water System, and SUEZ datasets

Upon completion of its analyses, DEP examined and compared the results of the datasets. The results of DEP's analysis of the SWQ data indicated that 5% of the calculated TMn_{Avg} concentrations were above 1.0 mg/L, which is the current WQ criterion for manganese; 16% of

the calculated TMn_{Avg} concentrations were above 0.3 mg/L, the proposed human health WQ criterion; and 60% of the calculated TMn_{Avg} concentrations were above 0.05 mg/L, which is the Federal SDWA SMCL. The results of DEP's analysis of the public water system dataset indicated that 3% of the calculated TMn_{Avg} concentrations were above 1.0 mg/L, 26% of the calculated TMn_{Avg} concentrations were above 0.3 mg/L, and 91% of the calculated TMn_{Avg} concentrations were above 0.05 mg/L. At the single SUEZ location, the TMn_{Avg} concentrations did not exceed the 1.0 mg/L or 0.3 mg/L TMn comparison concentrations (0%), but all values did exceed the 0.05 mg/L TMn concentration (100%).

Table 1 summarizes these results. The table describes the total number of samples collected (n), the number and percentages of concentrations where TMn_{Avg} was higher than three existing or proposed TMn limitations (that is, 1.0 mg/L, 0.3 mg/L, and 0.05 mg/L), and the number of concentrations calculated between 2008-2018 for the SWQ dataset and between 2014-2018 for the public water system and SUEZ datasets. As previously noted, locations containing only a single manganese sample result were excluded from the datasets since mean values could not be calculated. However, some locations were sampled multiple times per year over a span of multiple years. Thus, TMn_{Avg} concentrations could be calculated multiple times for those locations. The number of calculated TMn_{Avg} concentrations in the SWQ and public water system datasets include locations that were sampled multiple times across multiple years. The SUEZ dataset contains data from a single sample location.

Table 1. SWQ, Public Water System (PWS), and SUEZ data statistics.

	No. of calculated TMn _{Avg} concentrations:	No. of samples (n):	Comparison TMn Concentrations (mg/L):	No. of calculated concentrations where TMn _{Avg} > Comparison Concentrations:	Percent of calculated concentrations where TMn _{Avg} > Comparison Concentrations:
SWQ	641	2,811	1.0	32	5%
			0.3	103	16%
			0.05	383	60%
PWS	77	711	1.0	2	3%
			0.3	20	26%
			0.05	70	91%
SUEZ	5	533	1.0	0	0%
			0.3	0	0%
			0.05	5	100%

Figure 3 provides a graphical summary of the results and comparisons for the three manganese datasets (that is, SWQ, PWS, and SUEZ). Overall, the results demonstrate that TMn_{Avg} concentrations in many surface waters across the Commonwealth are below the current

manganese criterion of 1.0 mg/L and the draft proposed criterion of 0.3 mg/L. Approximately 80% of the TMn_{Avg} concentrations calculated from the SWQ dataset were at or below the proposed manganese criterion of 0.3 mg/L.

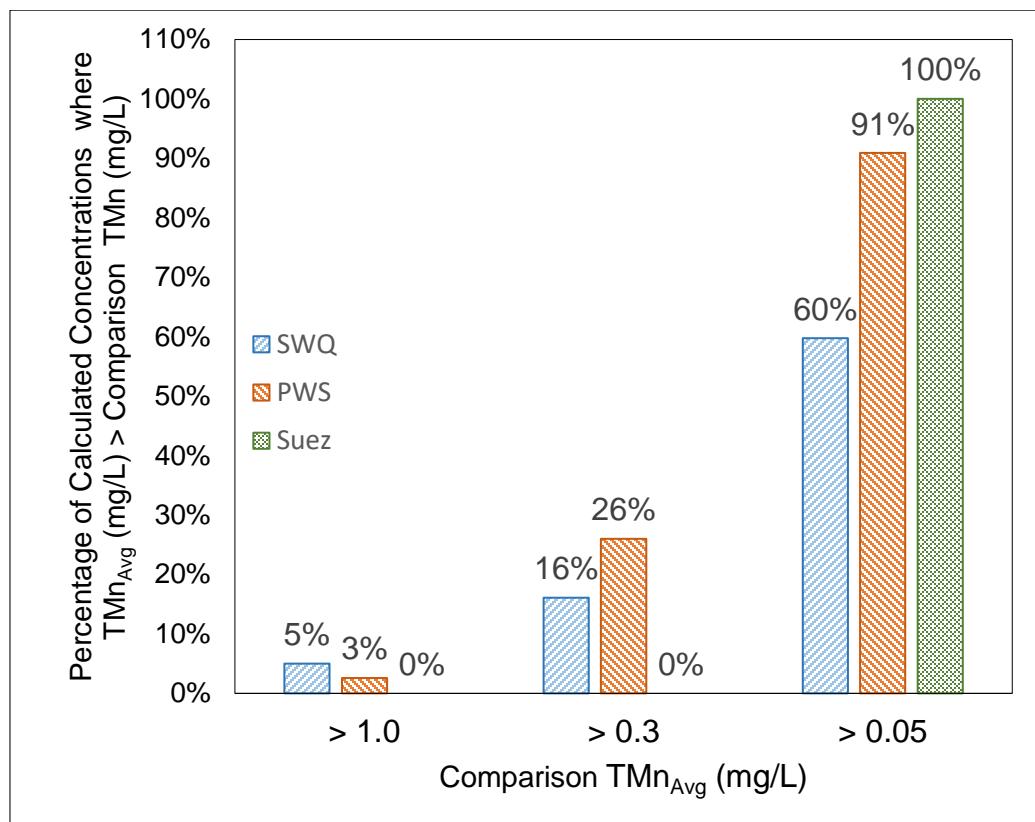


Figure 3. Percentage (%) of calculated concentrations for which the TMn_{Avg} (mg/L) concentration was above three manganese limitations. SWQ data included surface water samples collected between 2008 and 2018, and both the public water system (PWS) data and the SUEZ data included samples collected between 2014 and 2018.

Comparison of Statewide Background TMn_{Avg} Concentrations to Areas with High LandDist

DEP's WQI tool allowed for the identification of background concentrations of TMn_{Avg} throughout Pennsylvania as well as TMn_{Avg} concentrations in areas of high LandDist, such as mining regions. WQI and LandDist scores were determined for waters with calculated TMn_{Avg} concentrations in the SWQ dataset collected between 2008 and 2018. The TMn_{Avg} concentrations were then evaluated and categorized based on the WQI and LandDist scores corresponding to surface waters to identify TMn_{Avg} concentrations that were likely due to natural conditions versus those due to anthropogenic impacts.

From a 2008-2017 dataset, WQI scores and Sub-WQI (SWQI) scores were calculated for each location with a corresponding TMn_{Avg} concentration following methods outlined by Wertz and Shank (2019). This process began by calculating four SWQI scores based on similarity to WQ

from areas influenced by Forest, Urban, Agriculture (Ag) or LandDist. The lowest of the four SWQI scores indicates the primary influence on WQ and is used as the overall WQI score. The WQI scores rank WQ on a 1-100 scale, poor to good respectively, based on 21 WQ parameters from each sample.

Due to the geogenic nature of manganese in the environment, WQI scores driven by the SWQI LandDist were chosen for comparison against areas with minimal anthropogenic influences on WQ. Samples with WQI scores driven by SWQI LandDist that were <40 were considered “Poor”. Samples with WQI scores >79 were considered “Good”. For additional context, WQI scores ranging from 40 to 59 and 60 to 79 were considered “Fair” and “Average”, respectively. It was noted that an undetermined, and likely minimal, amount of circularity existed in this comparison as manganese was included in the original 21 parameter calculation. For more information about DEP’s WQI tool, refer to the publication found in the Literature Cited by Wertz and Shank, 2019.

The spatial distribution of WQI scores and TMn_{Avg} concentrations were analyzed to evaluate the impact of anthropogenic activities on manganese concentrations and characterize natural background levels of manganese. For TMn_{Avg} concentration locations that had a corresponding WQI score of “Good”, the overall calculated TMn_{Avg} concentration was 0.037 mg/L. This represents an estimate of background manganese concentrations in waters with relatively low anthropogenic impact. For TMn_{Avg} concentration locations that had a corresponding WQI score of “Poor”, the calculated TMn_{Avg} concentration was 0.807 mg/L. These statistics are summarized in Table 2.

Table 2. Statistics of the SWQ TMn_{Avg} (mg/L) measurements collected throughout Pennsylvania between 2008 and 2018 in areas with “Good” WQI scores and areas with “Poor” WQI scores due to high land disturbance, such as mining regions.

	Yearly Mean of Total Manganese (TMn _{Avg} (mg/L))						Correlation (R ²)
	Mean	Median	Max	Min	25th Percentile	75th Percentile	
Background (WQI Score = Good)	0.037	0.026	0.48	0.002	0.013	0.460	-0.71 (very strong)
High Land Disturbance (LandDist Score = Poor)	0.807	0.926	2.153	0.039	0.272	1.218	

A comparison of TMn_{Avg} concentrations to WQI scores and LandDist scores identified a strong negative correlation of TMn_{Avg} to LandDist ($R^2 = -0.71$). The strong negative correlation between TMn_{Avg} and LandDist is also evident in Figure 4, which shows TMn_{Avg} concentrations in surface waters were higher at the more disturbed sites (Poor and Fair scores) than at less disturbed sites (Average and Good scores).

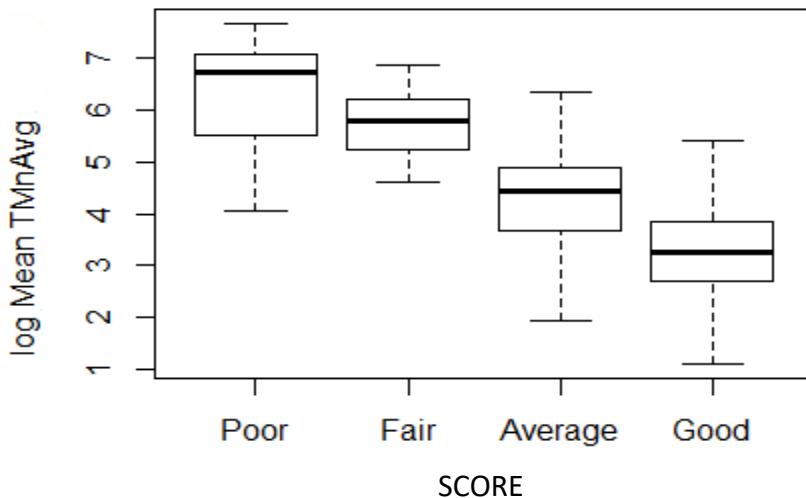


Figure 4. From the SWQ data collected between 2008 and 2018, a comparison of the WQI scores and the TMn_{Avg} (mg/L), excludes outliers and results where only one sample per year was measured ($n=1$).

Finally, the calculated TMn_{Avg} concentrations were mapped based on WQI scores (Figure 5), for which scores were ranked along a color gradient showing the range of sites from WQI “Poor” to WQI “Good” (red to green, respectively). The TMn_{Avg} concentrations in surface waters across Pennsylvania were then visually compared with both the WQI rank and Pennsylvania’s coalfields (Figure 6). The TMn_{Avg} concentrations ≥ 0.3 mg/L were also overlayed with Pennsylvania coalfields (Figure 7). It is important to note that there is significant overlap between surface waters with potable water supply withdrawals, Pennsylvania’s coalfield areas, and surface water impairments due to elevated concentrations of metals, including manganese.

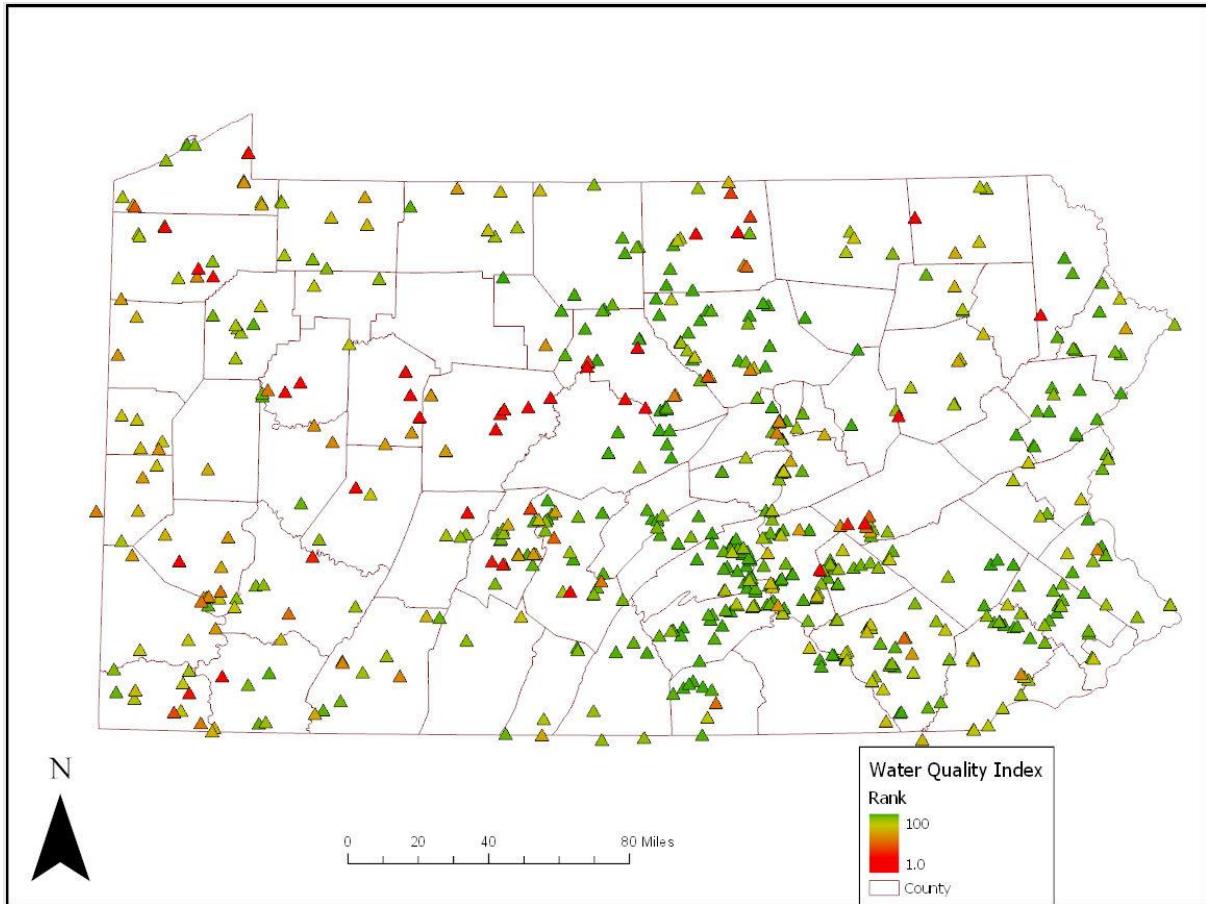


Figure 5. WQI rank of surface waters at locations with calculated TMn_{Avg} (mg/L) concentrations across Pennsylvania between 2008 and 2018, as analyzed from the SWQ data.

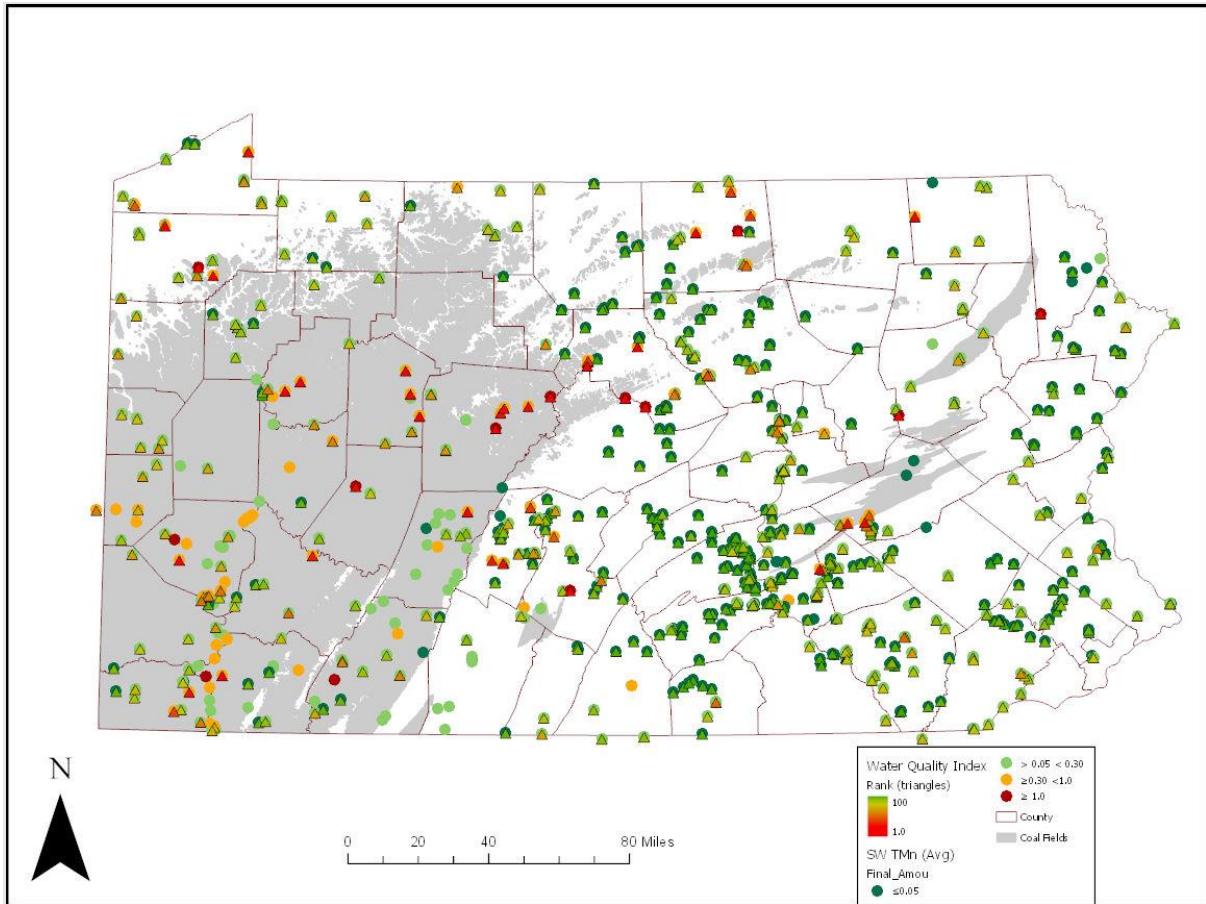


Figure 6. Calculated TMn_{Avg} (mg/L) concentrations in surface waters (circles) sampled between 2008 and 2018, WQI rank of surface waters (triangles) at locations with calculated TMn_{Avg} (mg/L) concentrations, and Pennsylvania coalfields (gray shaded areas).

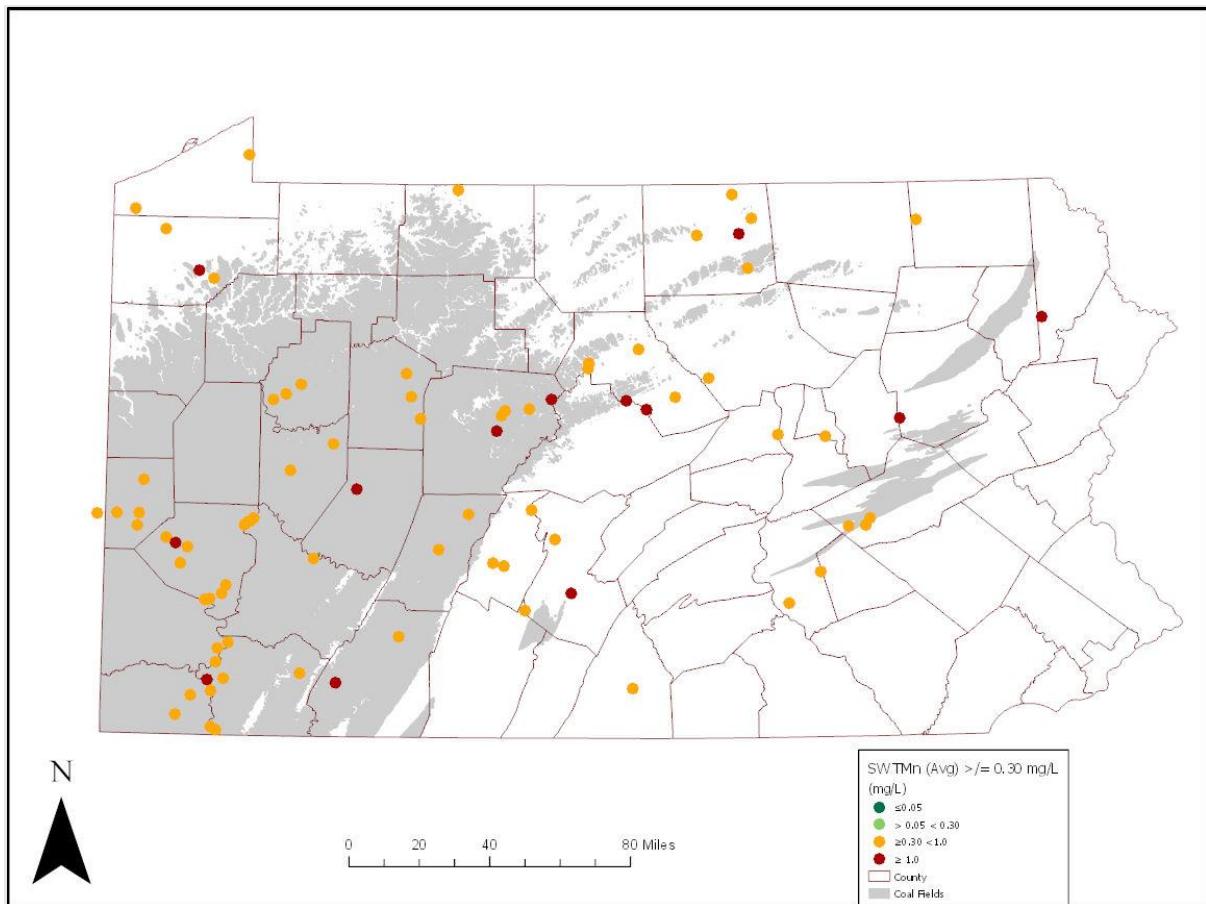


Figure 7. Pennsylvania coalfields overlaid by calculated TMn_{Avg} (mg/L) concentrations ≥ 0.3 mg/L in surface waters statewide.

DISCUSSION

The current manganese criterion of 1.0 mg/L was established as a statewide criterion in 1979 for the protection of the Potable Water Supply use, which is a statewide protected water use. This manganese criterion must currently be met in all surface waters (that is, at the point of discharge) in accordance with § 96.3(c). Act 40 directed the EQB to propose regulations that would move the point of compliance for the manganese criterion from all surface waters to the point of any existing or planned potable water supply withdrawal consistent with § 96.3(d). These analyses of TMn_{Avg} in surface waters throughout Pennsylvania and in targeted public water system source waters allowed DEP to characterize the natural background level of manganese in surface waters of the Commonwealth and to compare waters with natural background concentrations of manganese with those waters impacted by anthropogenic activities.

The results of these analyses indicated 5% of surface waters across the Commonwealth and 3% of targeted public water system source surface waters have the potential to exceed the current 1.0 mg/L criterion.

The results further indicated that, if the proposed manganese criterion of 0.3 mg/L is promulgated, only 16% of surface waters across the Commonwealth and 26% of targeted public water system source surface waters would likely exceed the WQ criterion. These percentages include waters impacted by anthropogenic activity. When impacted waters are removed from the dataset, the level of manganese that is representative of natural background WQ in waters across the Commonwealth is significantly less than 0.3 mg/L. However, even with the inclusion of data from impacted waters, it is important to note that over 80% of the surface waters across the Commonwealth would be expected to have WQ at or below 0.3 mg/L.

If the current SMCL of 0.05 mg/L would be considered for promulgation as the WQ criterion for manganese, the results indicated 60% of surface waters across the Commonwealth and 91% of targeted public water system source surface waters would likely exceed the WQ criterion.

DEP follows the CWA, CSL, and all relevant Commonwealth regulations when revising WQ criteria. While the results of these analyses cannot be used to determine the appropriate WQ criterion magnitude for manganese, the results provide DEP with a better understanding of the natural background levels of manganese in surface waters across the Commonwealth and the potential impacts that may result from the promulgation of a more stringent WQ criterion for manganese.

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