Testimony of Dr. Lisa A. Bailey:
PA Senate Environmental Resources & Energy Committee Meeting on September 9, 2020
Regarding the Proposed Rulemaking for the "Water Quality Criterion for Manganese and Implementation" (PADEP July 25, 2020 Bulletin)

- Hello – and thank you chairman Yaw for the opportunity to provide testimony today on Pennsylvania DEP's Proposed Rulemaking for the water quality criterion for manganese. My name is Dr. Lisa Bailey. I am a principal scientist employed by Gradient, an environmental consulting firm in Boston, Massachusetts. I have more than 20 years experience in the field of human health risk assessment and toxicology, and have extensive experience evaluating potential human health risks from exposure to manganese in air, water, and soil.
- At the request of the Pennsylvania Coal Alliance, I and my Gradient colleagues have reviewed the derivation of the Pennsylvania DEP proposed water quality criterion for manganese of 0.3 mg/L, and whether that criterion is necessary to protect human health.
- **Based on our analysis, we conclude that the proposed criterion is overly conservative and is not consistent with the current state of the science for manganese and human health effects. As I will describe further, the current 1 mg/L manganese water quality criterion is protective for human consumption.**
- In addition, it is very important to keep in mind that it is highly unlikely that someone would use untreated surface water as their main source of drinking water. The drinking water that most PA citizens consume will be after the water is treated to meet the manganese secondary maximum contaminant drinking water level of 0.05 mg/L (which is based on odor and staining and not on adverse health effects, and is well below the 0.3 mg/L proposed surface water criterion).
- **Therefore, not only is the proposed criterion overly protective regardless of where in the surface water body it is applied, the proposed criterion is based on a hypothetical scenario that will almost never occur, providing support that application of the criterion at the point of intake is health protective. In fact, as I will discuss further, application of the criterion at the point of intake is also health protective for more typical surface water uses, such as swimming and fishing.**
- Before describing the results of our analysis, I want to first provide a bit of background on Mn essentiality and health effects. It is important to understand that manganese is an essential nutrient needed for normal functioning of the human body. However, at high exposure concentrations, mostly observed from high occupational exposures *via* inhalation, manganese can cause adverse neurological effects. As for oral exposures, there are no studies currently available that provide reliable evidence of an oral manganese dose in humans that leads to adverse effects.
- Therefore, unlike other substances for which EPA has derived oral reference doses based on studies of adverse health effects, the manganese reference dose 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 an upper tolerable dietary intake level of manganese that is considered safe. The Pennsylvania DEP proposed manganese water quality criterion relies on this reference dose, and on a modifying factor of three applied to that reference dose 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 Mn 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 reference dose.
    - EPA also described a key study that found no significant differences in the bioavailability of Mn from food and water. Although EPA discussed possible increased uptake of Mn in fasted individuals as an additional basis for the MF of 3, there are no published studies that provide support for this concern.
- Since EPA's last review of its evaluation for manganese in 2002, more data have become available that provide support for removal of the modifying factor of three. In particular, recent application of a physiologically-based pharmacokinetic (PBPK) model for Mn published in two studies by Song *et al*. (2018) and Yoon *et al*. (2019) provides further evidence that:
    1. Manganese is not more bioavailable in drinking water compared to food;
    2. Manganese is not more readily absorbed in formula-fed infants compared to breastfed infants, or compared to children and adults; and
    3. Manganese drinking water concentrations of 1 mg/L did not alter Mn brain concentrations beyond normal levels for all age groups evaluated.
- Although PADEP did not discuss the PBPK studies, in its Rationale for development of the Mn water quality criterion, PADEP discusses several community studies that have been conducted since 2002 that reported possible associations between Mn in drinking water and intellectual impairment in children. However, as described recently by the Agency for Toxic Substances and Disease Registry (ATSDR) (2012) and Health Canada (2019), these studies have many limitations that make it impossible to attribute the reported effects to Mn, including:
    - 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).
- Therefore, we conclude, based on the most current and scientifically robust information available, that a MF of 3 is not needed for human health risk evaluation of Mn in drinking water, and that the proposed criterion of 0.3 mg/L is not necessary for the protection of human health.
- Removal of the modifying factor of three results in the current 1 mg/L criterion – that was originally developed on the basis of taste, odor, and treatability – but that is also protective for human consumption.
- In addition, since the Mn water quality criterion is a surface water criterion, and it is highly unlikely that people would use the untreated surface water body as their main source of drinking water, we also evaluated human health risk from non-drinking water exposure pathways in surface water, such as swimming in and ingesting fish caught from a water body at that manganese concentration. Our analysis found that:
    - The risk from swimming and fishing in a surface water body at a Mn concentration of 1 mg/L is well within acceptable EPA risk assessment guidelines for adults and children. In

fact, the Mn water concentration could be about 40-fold higher than 1 mg/L and still be health protective under this scenario.

- Of course, Mn water concentrations of 40 mg/L are much higher than what is typical in the US, and much higher than what would be expected in surface water bodies upstream of a surface potable water supply withdrawal, including in streams which receive treated discharge from coal mining operations, since federal requirements limit the concentration of Mn in the discharge to 2 mg/L on a monthly average.
- **Therefore, overall, we conclude that the best available scientific information for manganese provides evidence that:**
    1. **The proposed 0.3 mg/L criterion is unnecessary for the protection of human health;**
    2. **The current 1 mg/L criterion is protective for human consumption, even in the rare scenario where untreated surface water is used as a sole drinking water source; and**
    3. **Concentrations even 40-fold higher than 1 mg/L manganese are protective for more typical surface water human exposure pathways such as swimming and fishing**.