

<h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p>		<p><i>INDEPENDENT REGULATORY REVIEW COMMISSION</i></p>
<p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		
<p>(1) Agency: Environmental Protection</p>		<p>IRRC Number: 3251</p>
<p>(2) Agency Number: 7 Identification Number: 552</p>		
<p>(3) PA Code Cite: 25 Pa. Code Chapter 250</p>		
<p>(4) Short Title: Administration of the Land Recycling Program</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Laura Griffin, (717) 783-8727; laurgriffi@pa.gov Secondary Contact: Jessica Shirley, (717) 783-8727; jessshirley@pa.gov</p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input type="checkbox"/> Proposed Regulation</p> <p><input checked="" type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p>	<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p>	
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>This rulemaking amends 25 Pa. Code Chapter 250 (relating to administration of the land recycling program) by updating Statewide health standard medium-specific concentrations (MSCs) pertaining to cleanup of soil and groundwater contamination for many contaminants. The Department of Environmental Protection (DEP or Department) recommended these updates as part of its three-year review. This rulemaking also adds MSCs for three new contaminants, namely Perfluorooctanoic Acid (PFOA), Perfluorooctance Sulfonate (PFOS), and Perfluorobutane Sulfonate (PFBS). These contaminants are within the Per- and Poly-fluoroalkyl Acid (PFAS) family of compounds for which the U.S. Environmental Protection Agency (EPA) has published toxicological data. The rulemaking also clarifies administrative elements of Chapter 250.</p>		
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>This rulemaking is authorized under sections 104(a) and 303(a) of the Land Recycling and Environmental Remediation Standards Act (Act 2) (35 P.S. §§ 6026.104(a) and 6026.303(a)), which direct the Environmental Quality Board (EQB) to adopt and amend periodically by regulation Statewide health standards for regulated substances for each environmental medium, including any health-based standards adopted by the Federal government by regulation or statute, and health advisory levels (HAL), and which direct the EQB to promulgate appropriate mathematically valid statistical tests to define compliance with Act 2, and other regulations as necessary to implement the provisions of Act 2; and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), which authorizes the EQB to</p>		

formulate, adopt and promulgate rules and regulations that are necessary for the proper work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This rulemaking is not mandated under Federal law. Federal law, however, encourages states to develop programs for voluntary clean-up of contaminated sites. See 42 U.S.C. § 9628 (relating to State response programs). On April 21, 2004, the U.S. Environmental Protection Agency (EPA) and the Department signed the One Cleanup Program Memorandum of Understanding (One Cleanup Program) under the agencies' authority under the Federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. § 9601—9675) and Act 2 (35 P.S. 6026.101—6026.908), respectively, that requires DEP to ensure, among other things, that voluntary responses conducted under Act 2 are protective of human health and the environment, and that DEP review every report relating to the investigation, assessment and clean-up of a site submitted by a remediator. The One Cleanup Program encourages DEP to regularly review the efficacy of Chapter 250.

State law requires the promulgation of this rulemaking. Section 303(a) of Act 2, 35 P.S. § 6026.303(a), mandates that “[t]he Environmental Quality Board shall promulgate Statewide health standards for regulated substances for each environmental medium,” and that “[t]he standards shall include any existing numerical residential and nonresidential health-based standards adopted by the Department and by the Federal Government by regulation or statute, and health advisory levels [HAL].” The term “HAL” is defined in section 103 of Act 2 (35 P.S. § 6026.103) as “[t]he health advisory levels published by the United States Environmental Protection Agency for particular substances.” When section 303(a) and this definition of HALs are read in context, they require the EQB to adopt, as an MSC, a HAL once published by EPA. In 2016, EPA published HALs for PFOS and PFOA. For both substances, the EQB has included in this rulemaking the standards from those HALs as Act 2 groundwater standards and has used the underlying data from those HALs to develop soil standards. For PFBS, the EQB has used both groundwater and soil MSCs that incorporate data for its calculations from an EPA Provisional Peer-Reviewed Toxicity Value (PPRTV) study, which EPA published in April 2021. For PFBS, PFOS, and PFOA, Section 250.306 (relating to ingestion numeric values) provides the applicable formulas under which the Department calculates the soil and groundwater MSCs.

This rulemaking is also required under 25 Pa. Code § 250.11 (relating to periodic review of MSCs), which requires DEP to regularly review new scientific information that relates to the basis of the MSCs and to propose appropriate regulations to the EQB whenever necessary, but not later than 36 months from the effective date of the most recently promulgated regulations. The most recent of these rulemakings took effect on August 26, 2016. See 46 Pa.B. 5655 (August 26, 2016).

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

This rulemaking is needed to comply with the Department's obligation under 25 Pa. Code § 250.11 to review scientific information that serves as the basis for Act 2 MSCs and to propose appropriate changes to the EQB, when necessary. This rulemaking is also necessary to incorporate the HALs published by EPA regarding PFOS and PFOA. Finally, this rulemaking is needed to clarify a variety of

administrative components related to different reports necessary to comply with Chapter 250 site remediation requirements.

There are several public interests justifying the need for this rulemaking.

First, the public benefits from having groundwater and soil MSCs that reflect up-to-date science and toxicological information. The changes in the MSCs in this rulemaking serve both the public and the regulated community because they provide MSCs based on the most up-to-date health and scientific information for substances that cause cancer or have other toxic effects on human health. The EQB first published Chapter 250 regulations in 1997. See 27 Pa.B. 4181 (August 16, 1997). Section 104(a) of Act 2, 35 P.S. § 6026.104(a), recognizes that these standards must be updated over time as better science becomes available and as the need for clarification or enhancement of the program becomes apparent.

Potential contamination of soil and groundwater from accidental spills and unlawful disposal can impact almost any resident of this Commonwealth. Many of the chemical substances addressed in this rulemaking are systemic toxicants or carcinogens as defined under Act 2 and, in some cases, are widespread in use. Examples of substances that contain toxic or carcinogenic properties include gasoline and petroleum products, solvents, elements used in the manufacture of metals and alloys, pesticides, herbicides, and some dielectric fluids previously contained in transformers and capacitors. Releases of regulated substances not only pose a threat to the environment, but also could affect the health of the general public if inhaled or ingested. New research on many of these substances is frequently developed and provides the basis for protection of the residents of this Commonwealth through site cleanup requirements.

Although most of the changes to soil numeric values in this rulemaking decrease, 17% of the values increase. Increases in values reflect updated information related to exposure limitations to the substances and acknowledge that a higher standard is better representative of those substances' exposure thresholds.

Second, the public benefits from the promulgation of soil and groundwater MSCs for PFOS, PFOA and PFBS because the MSCs allow remediators to address groundwater and soil contamination; thereby, reducing public exposure to the contaminants. These remediators tend to be owners, operators or purchasers – or their contractors – of properties and facilities including, or located in the vicinity of, military bases, municipalities, and other locations that used or stored fire-fighting foam. EPA reports that contamination from these chemicals has also been associated with manufacturing textiles, food packaging, personal care products, and other materials such as cookware that are resistant to water, grease and stains. See Fact Sheet, EPA, PFOA & PFOS Drinking Water Health Advisories (November 2016) (available at https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf).

Third, remediators benefit from the amendments that clarify administrative elements of Act 2, making for a more efficient and streamlined remediation process.

The benefits of this rulemaking are difficult to quantify because, unlike other statutory or permitting schemes, Act 2 does not prevent contamination but instead provides remediators with a variety of options to address sites that have existing contamination. In that sense, this rulemaking, consistent with Act 2, benefits the public because it allows for more efficient and more expedient remediation and reuse of contaminated areas.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

No provisions in this rulemaking are more stringent than Federal cleanup standards. In fact, Act 2 prohibits any standards that are more stringent than Federal standards. Act 2 states that “[t]he department shall not establish procedures for determining attainment of remediation standards where maximum contaminant levels and health advisory levels have already been established for regulated substances.” See 35 P.S. § 6026.301(c) (related to determining attainment). Act 2 further states that “standards adopted under this section [Section 303 Statewide health standard] shall be no more stringent than those standards adopted by the Federal Government.” See 35 P.S. § 6026.303(a) (relating to Statewide Health Standard). Federal standards typically are MCLs promulgated by EPA to address drinking water under the Federal Safe Drinking Water Act.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania’s ability to compete with other states?

The updates to Chapter 250 do not affect Pennsylvania’s ability to compete with other states.

The existing Chapter 250 regulations provide a uniform Statewide health standard that is not available in many other states. In comparison, the Federal government and many states do not have similar generic cleanup values and instead require a site-specific risk analysis at every site to establish a numeric value that is then used to determine the completion of soil and groundwater cleanup. Act 2 provides for a Statewide health standard that can be used as an efficient way to clean up sites, particularly where small spills and releases contaminate soil. This does not negate the opportunity to conduct a risk analysis. Act 2 also provides the ability to conduct a risk analysis to establish a cleanup value on an individual-site basis through the site-specific cleanup standard.

The existing regulations and this rulemaking promote and facilitate the remediation and redevelopment of idle and underutilized commercial and industrial sites while protecting the public health and the environment.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The rulemaking does not directly affect any of the Department’s existing regulations or any regulations promulgated by other state agencies. While some Department regulations incorporate elements of Chapter 250 by reference, this rulemaking does not require the Department to update any other regulations separate from Chapter 250. For example, Chapter 245 regulations (relating to Administration of Storage Tank and Spill Prevention Program) require that various components of storage tank spill corrective actions comport with site investigation or remediation requirements within Chapter 250.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. (“Small business” is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Department worked with the Cleanup Standards Scientific Advisory Board (CSSAB) during the development of this rulemaking. CSSAB, established by Section 105 of Act 2 (35 P.S. § 6026.105), consists of persons representing a cross-section of experience, including engineering, biology, hydrogeology, statistics, medicine, chemistry, toxicology and other related fields. The purpose of the CSSAB is to assist the Department and the EQB in developing Statewide health standards, to determine the appropriate statistically and scientifically valid procedures and risk factors to be used, and to provide other technical advice as needed to implement Act 2. During CSSAB meetings on August 1, 2018, February 13, 2019, June 12, 2019, and October 29, 2019, CSSAB members were given the opportunity to review and provide feedback on draft regulatory amendments to Chapter 250. CSSAB members were also given the opportunity to review and provide feedback on the final rulemaking at the July 30, 2020 and December 16, 2020 meetings. The Department also worked with the CSSAB to resolve concerns and agreed to evaluate additional suggestions during the next review cycle for this rulemaking. Following the presentations and discussions in 2018 and 2019, the CSSAB issued a letter related to the regulatory amendments included in the rulemaking. Specifically, the CSSAB noted concern related to the MSCs for vanadium.

A listing of CSSAB members and minutes of CSSAB meetings are available on the Department’s website at www.dep.pa.gov (select “Public Participation,” then “Advisory Committees,” then “Cleanup and Brownfields Advisory Committees,” then “Cleanup Standards Scientific Advisory Board”).

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The amendments to Chapter 250 affect owners of contaminated sites, operators of commercial and industrial facilities where hazardous substances are spilled onto soil or are released into groundwater, and purchasers of historically contaminated brownfield sites that are intended for redevelopment. A brownfield site is a property that’s current or future use is impaired by a real or perceived contamination. This rulemaking also protects public health by minimizing exposure to substances released into the shared environment.

Overall, no particular category of person, business or organization is expected to be substantially or adversely affected by the updates to Chapter 250. A majority of the small businesses that DEP can identify as potentially being affected by this proposal are owners of small gasoline stations. For many of the impacted businesses, the costs are absorbed through insurance policies because many of these businesses are required under section 704(a)(1) of the Storage Tanks and Spill Prevention Act (35 P.S. § 6021.704(a)(1) (relating to establishment of fund)) to participate in the Underground Storage Tank Indemnification Fund. This fund provides insurance coverage for the costs to clean up releases from underground storage tanks, regardless of the MSC value used at the site.

In addition to gasoline stations, fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations, and redevelopers of brownfield sites may be affected by this rulemaking.

There are approximately 12,000 facilities in this Commonwealth that contain regulated underground and above ground storage tanks, including gasoline stations, and fuel distribution and storage facilities. Of those 12,000 facilities, a portion includes small gasoline station owners. Small businesses also make up some of the commercial facilities that use toxic or carcinogenic substances. Because of the broad potential reach of this rulemaking, DEP cannot reasonably identify further specifics on the number of small businesses that would potentially be affected by property contamination. The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth. Generally, any cost related to a given site remediation depends in large part on which regulated substances are being remediated and what the specific soil and groundwater conditions are at the site.

The changes to Chapter 250 are not expected to increase costs nor provide any significant savings for the regulated community. Chapter 250 contains MSCs for 400 regulated substances. The MSCs are divided into two environmental media: groundwater and soil. See, for example, §§ 250.304 and 250.305 (relating to MSCs for groundwater; and MSCs for soil.) The same regulated substance – for example, Trichloroethylene (TCE) – may have standards in both soil and groundwater. The soil MSCs provide standards for direct contact with, and ingestion of, soil. The groundwater MSCs provide standards related to human consumption of groundwater or the inhalation of volatile substances in groundwater.

Under this rulemaking, the MSC values for many regulated substances are being changed for a variety of reasons. The two most common reasons for the changes are Federal agency (including EPA and U.S. Department of Health Agency for Toxic Substances and Disease Registry) changes in toxicity values that are used in calculating MSC values, and a change in the EPA's underlying assumption of a person's average daily consumption of water from 2 liters a day (L/day) to 2.4 L/day. The soil numeric values represent a decrease for approximately 83% of the values and an increase for 17% of the values. For groundwater, the changes reflect a decrease for approximately 92% of the values and an increase in approximately 8% of the values. Lowering the values may indicate that a more stringent cleanup is required at a site and increasing the values may indicate that a less stringent cleanup is required at a site.

The financial impact on a given site remediation depends on the regulated substances being remediated and the soil and groundwater conditions at a particular site. For example, a site with a tight clay soil profile might not allow contaminants to spread horizontally or vertically, in which case the amount of soil to be excavated would not significantly change to meet a lower or higher MSC value.

In addition to the changes in MSCs, this rulemaking includes amendments to provide clarity to the administrative requirements and to ensure that references to various guidance and other sources are appropriate and consistent. These amendments streamline the remediation process for the Department and for developers.

Accordingly, the Department believes that there would be little if any adverse impact to any particular category of person, business (including small businesses) or organization. Please also see the response to item (10), above, regarding benefits; and to item (24), below, for more information regarding small businesses.

(16) List the persons, groups or entities, including small businesses that will be required to comply with the regulation. Approximate the number that will be required to comply.

This amendment to Chapter 250 impacts any person addressing a release of a regulated substance at a property, whether voluntarily or as a result of an order by the Department but does not impact any particular category of person with additional or new regulatory obligations. Under Act 2, a remediator may voluntarily select the standard to which to remediate. To complete a remediation, a person must then comply with all relevant remediation standards and administrative requirements. This rulemaking does not affect the voluntary nature of Act 2.

The types of businesses that may need to comply with the regulations include gasoline stations, fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations and redevelopers of brownfield sites. There are about 12,000 facilities in this Commonwealth that contain regulated underground and aboveground storage tanks, including gasoline stations and fuel distribution and storage facilities. Some of these facilities would include small gasoline station owners. Small businesses would also make up some of the commercial facilities that use toxic or carcinogenic substances. Not all of these facilities have releases or accidental spills that result in a cleanup obligation.

The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth. The Department does not expect that the amendments would impact the number of remediations voluntarily completed or those that must be completed as a result of Department enforcement actions.

As noted above in the response to Question 15, while these amendments would not likely impact a specific category of person or company, the amendments would still affect many types of responsible parties who need to address contamination under Chapter 250. The Department expects the impact of these updates to Chapter 250 to be insignificant on persons and businesses that are attempting to complete the remediation process under Chapter 250.

Please also see the response to Question 15.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The amendments to the Statewide health MSCs reflect the latest toxicological data on health effects on humans exposed to hazardous and toxic chemicals. Updating the MSCs in this manner helps to assure potentially affected residents of this Commonwealth and persons, including businesses, small businesses and other organizations, interested in buying and redeveloping contaminated sites, that the MSCs are protective of human health.

Financially and economically, the Department expects the amendments to Chapter 250 to result in insignificant costs increases and insignificant cost savings for the regulated community. Generally, investigation and cleanup costs vary greatly based on the severity of the contamination, the size of the site, the complexity of the remediation strategy, and the cleanup standard selected. Thus, accurate costs and savings cannot be determined at this time because such cost analysis must be based on site-specific considerations evaluated on case-by-case bases.

Under this rulemaking, the MSC values for many regulated substances are being changed for a variety of reasons. The two most common reasons for the changes are Federal agency (including EPA and U.S. Department of Health Agency for Toxic Substances and Disease Registry) changes in toxicity values that are used in calculating MSC values and a change in the EPA's underlying assumption of a person's average daily consumption of water from 2 L/day to 2.4 L/day. The soil numeric values represent a decrease for approximately 83% of the values and an increase for 17% of the values. For groundwater, the changes reflect a decrease for approximately 92% of the values and an increase in approximately 8% of the values. Lowering the values may indicate that a more stringent cleanup is required at a site and increasing the values may indicate that a less stringent cleanup is required at a site. The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth. The Department does not expect the amendments would impact the number of remediations voluntarily completed or the number of remediations that must be completed because of Department enforcement actions.

Further, the updates to Statewide health standard MSCs do not affect a remediator's ability to choose one or a combination of cleanup standards.

The Department believes that any potential impacts to the regulated community would be insignificant.

This rulemaking will benefit all citizens of the Commonwealth. The amendments to the Statewide health MSCs reflect the latest toxicological data on human health effects that can occur when humans are exposed to hazardous and toxic chemicals. Updating the MSCs, based on the latest toxicological data, helps to assure potentially affected residents of this Commonwealth and persons, including businesses, small businesses and other organizations, interested in buying and redeveloping contaminated sites, that the MSCs are protective of human health.

Not only does this rulemaking update existing MSCs, but it also adds groundwater standards for PFOS and PFOA from the HALs EPA published in 2016 and soil standards for PFOS and PFOA using the underlying data from the EPA HALs, as well as the groundwater and soil PFBS MSCs generated using EPA's PPRTV data. Having these new MSCs allows remediators to address PFOS, PFOA and PFBS groundwater and soil contamination. This benefits the public by lessening public exposure to these contaminants. This also benefits remediators wishing to remediate contaminated sites, who tend to be owners, operators or purchasers – or their contractors – of properties and facilities include, or are at or near, military bases, municipalities, and other locations that used or stored fire-fighting foam.

Remediators benefit from the amendments that clarify many of the administrative elements of Act 2, making for more efficient and streamlined Act 2 remediations.

Please also see the response to Question 10.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

As described more fully in the responses to Questions 10 and 17, there are important benefits to this rulemaking. They include protecting the public with updated MSCs reflecting the latest toxicological data, adding new MSCs for 3 chemical compounds (PFOS, PFOA and PFBS), exposure to which, according to EPA, could cause adverse effects in humans, including developmental effects to a fetus during pregnancy or to infants during breastfeeding, cancer (e.g., testicular, kidney), liver effects (e.g.,

tissue damage), immune effects (e.g., antibody production), thyroid effects, and others (e.g., cholesterol). The amendments will also streamline Act 2 remediations.

These benefits outweigh any costs of the rulemaking, which the Department expects to be insignificant. The amendments to the Statewide health MSCs reflect the latest toxicological data on human health effects that can occur when humans are exposed to hazardous and toxic chemicals. Updating the MSCs in this manner helps to assure potentially affected residents of this Commonwealth and persons, including businesses, small businesses and other organizations, interested in buying and redeveloping contaminated sites, that the MSCs are protective of human health. In particular, the rulemaking allows remediators to address PFOS and PFOA groundwater and soil contamination.

The Department anticipates little if any cost or adverse effects from this rulemaking. The soil numeric values represent a decrease for approximately 83% of the values and an increase for 17% of the values. For groundwater, the changes reflect a decrease for approximately 92% of the values and an increase in approximately 8% of the values. Lowering the values may indicate a more stringent cleanup is required at a site and increasing the values may indicate a less stringent cleanup is required at a site. The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth.

The cost impact on a given site remediation would depend on the regulated substances being remediated and the soil and groundwater conditions at the site. For example, a site with a tight clay soil profile might not allow contaminants to spread horizontally or vertically, in which case the amount of soil to be excavated would not significantly change to meet a lower or higher MSC value.

Please also see the responses to Questions 10 and 17.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Department anticipates little, if any, expenses or savings from this rulemaking. The soil numeric values represent a decrease for approximately 83% of the values and an increase for 17% of the values. For groundwater, the changes reflect a decrease for approximately 92% of the values and an increase in approximately 8% of the values. Lowering the values may indicate a more stringent cleanup is required at a site and increasing the values may indicate a less stringent cleanup is required at a site. The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth. The cost impact on a given site remediation would depend on the regulated substances being remediated and the soil and groundwater conditions at the site. For example, a site with a tight clay soil profile might not allow contaminants to spread horizontally or vertically, in which case the amount of soil to be excavated would not significantly change to meet a lower or higher MSC value.

The rulemaking does not require any new legal, accounting or consulting procedures.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The amendments are not expected to impact costs or savings for local governments. Although, in some instances, local governments are remediators; however, as with all other types of remediators, this rulemaking is not expected to increase costs or result in significant savings.

Please also see the response to Question 19 above.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The amendments are not expected to impact costs or savings for state government agencies. Although, in some instances, state government agencies are remediators; however, as with all other types of remediators, this rulemaking is not expected to increase costs or result in significant savings.

Please also see the response to Question 19.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The amendments to Chapter 250 do not require any additional recordkeeping or paperwork. No new or revised forms or reports are required.

(22a) Are forms required for implementation of the regulation?

No new or revised forms or reports are required.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here**. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

No new or revised forms or reports are required.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

This amendment is not expected to impact costs or savings.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Savings	\$0	\$0	\$0	\$0	\$0	\$0
COSTS:	\$0	\$0	\$0	\$0	\$0	\$0
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Costs	\$0	\$0	\$0	\$0	\$0	\$0
REVENUE LOSSES:	\$0	\$0	\$0	\$0	\$0	\$0
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
Total Revenue Losses	\$0	\$0	\$0	\$0	\$0	\$0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 2017-18	FY -2 2018-19	FY -1 2019-20	Current FY 2020-21
Environmental Protection Operations 160-10381	\$89,215,000	\$93,190,000	\$84,023,000	\$94,202,000
Environmental Program Management 161-10382	\$29,413,000	\$30,932,000	\$27,920,000	\$32,041,000
Industrial Land Recycling Fund 689-60080	\$289,000	\$263,000	\$273,000	\$352,000
Hazardous Sites Cleanup Fund 202-20070	\$23,750,000	\$22,738,000	\$24,000,000	\$24,000,000
Storage Tank Fund 210-20073	\$4,886,000	\$4,484,000	\$3,563,000	\$3,878,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.

A majority of the small businesses that DEP can identify as potentially being affected by this proposal are owners of small gasoline stations. In addition to gasoline stations, fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations, and redevelopers of brownfield sites may be affected by this rulemaking. There are about approximately 12,000 facilities in this Commonwealth that contain regulated underground and above ground storage tanks, including gasoline stations, and fuel distribution and storage facilities. Of those 12,000 facilities, some would include small gasoline station owners. Small businesses would also make up some of the commercial facilities that use toxic or carcinogenic substances. Chapter 250, and this rulemaking, have the potential to impact a broad universe of businesses, persons and organizations, any of which could need to address contamination at any given time. Because of the breadth of reach of Chapter 250, DEP cannot identify further specifics on the types and numbers of small businesses that would potentially be affected by property contamination. Act 2 and Chapter 250 are unique from other statutes and regulations because they do not create permitting or corrective action obligations. Instead, Act 2 and Chapter 250 provide remediators options to address contamination and any associated liability that arises under other statutes. For example, adding PFOS to the Chapter 250 Appendix does not create any liability or obligation related to PFOS. Instead, a person's liability arises under the Clean Stream Law while Act 2 and Chapter 250 provide that person the means to resolve their Clean Streams law liability and to address the contamination. In this way, Act 2 and Chapter 250 do not create new obligations that will impact a particular category of person like a new permitting obligation or corrective action regulation would.

- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

The amendments to the Chapter 250 regulations do not add any new procedures, recordkeeping or compliance efforts. The rulemaking clarifies in Section 250.12 (relating to professional seal) that reports submitted as part of the Act 2 process that contain information or analysis that constitutes professional geologic or engineering work under the Engineer, Land Surveyor, and Geologist Registration Law must be sealed by a professional geologist or engineer. Existing sections 250.204(a), 250.312(a) and 250.408(a) (relating to final report; final report; and remedial investigation report) require that “[i]nterpretations of geologic and hydrogeologic data shall be *prepared* by a professional geologist licensed in this Commonwealth.” (emphasis added). The amendment in section 250.12 would moot any concern over what it means to “prepare” one of these reports.

- (c) A statement of probable effect on impacted small businesses.

The amendments to the Chapter 250 regulations are not expected to increase costs or provide any significant savings for small businesses. As noted above in response to Question 15, many of the small businesses that may be impacted by this rulemaking are gasoline stations, and for many of these businesses, the costs would be covered by insurance because many of these businesses are required by

Section 704(a)(1) of the Storage Tanks and Spill Prevention Act to participate in the Underground Storage Tank Indemnification Fund. This fund provides insurance coverage for the costs to clean up releases from underground storage tanks, regardless of the MSC value used at the site.

Small businesses that handle hazardous substances can use pollution prevention techniques available through various assistance programs to prevent spills that would result in contamination of soil and groundwater. In addition, background and site-specific cleanup standards are available and not affected by the updates to the Statewide health MSCs.

In addition to the Underground Storage Tank Indemnification Fund coverage, the Pennsylvania Department of Community and Economic Development (DCED), primarily through its Industrial Sites Reuse Program, offers many entities that are eligible for brownfield financial assistance, which includes small business, potential grants or loans for the assessment and remediation of soil and groundwater contamination at eligible properties.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The Department is unaware of any less intrusive or less costly alternative methods of achieving the purpose of the rulemaking, which is to update various MSCs based on current scientific information. Background and site-specific cleanup standards are available alternatives to the regulated community and would not be affected by the updates to the Statewide health MSCs in this rulemaking. As discussed above in the responses to Questions 9, 10, and 14, Act 2 requires that the EQB and DEP evaluate data related to current MSCs and promulgate new standards, where necessary. Further, Act 2 requires DEP to incorporate applicable Federal standards, such as EPA's PFOS and PFOA standards (published in 2016), and EPA's HALs.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The amendments to Chapter 250 do not include special provisions to meet the needs of the groups listed because the amendments are not expected to adversely affect any listed group. Please see the responses to Questions 15, 17, and 24 regarding expected impacts of this rulemaking.

(26) Include 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.

No alternative regulatory provisions were considered and rejected. The least burdensome acceptable alternatives – which is required by statute and regulation – have been selected. The amendments in this rulemaking are required under Act 2 and the existing Chapter 250 regulations, which require the periodic update of the Statewide health standard. Alternatives to meeting MSCs in Act 2 remediations already exist. They are the background and site-specific cleanup standards in Chapter 250, and would not be affected by the updates to the Statewide health MSCs in this rulemaking.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

The amendments are not expected to have a significant impact on small businesses; therefore, no regulatory methods were considered to minimize adverse impacts.

(a) This rulemaking does not affect any Act 2 compliance requirements. Under Act 2, a remediator may voluntarily select the standard to which to remediate. To complete a remediation, a person must then comply with all relevant technical and administrative requirements. Act 2 establishes the schedules related to reports necessary to comply with those remediation standards. See, for example, the notice and review provisions in sections 302(e), 303(h) and 304(n) of Act 2 (relating to background standard; Statewide health standard; and sight-specific standard). See 35 P.S. §§ 6026.302(e), 6026.303(h), and 6026.304(n). As a result, the Department and the EQB have limited ability to alter schedules, deadlines and reporting requirements. In addition, reporting obligations under Act 2 generally apply only to the Department (i.e., the Department must review and approve a submitted report within a particular timeframe) and not to other parties.

(b) Please see the response to Question 24(a).

(c) Please see the response to Question 24(a).

(d) Chapter 250 does not have design or operation standards. Act 2 does not authorize relaxing MSC values for particular categories of remediators.

(e) Small businesses, small organizations and small governmental jurisdictions were considered but are not exempt from any provisions of the regulations. Chapter 250 does not take into account the size or nature of a particular entity that may own a contaminated site and the need to address it under Act 2.

(28) If data is the basis for this regulation, please 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 documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Act 2 and the Chapter 250 regulations require the periodic evaluation of the MSCs. The Department bases this evaluation on nationally recognized, peer-reviewed toxicological data, including cancer slope and unit risk factors, reference dose values and reference concentrations published under the Integrated Risk Information System (IRIS), the National Center for Environmental Assessment, EPA’s PPRTV data, the Health Effects Assessment Summary Tables, Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles, and California EPA Cancer Potency Factors and Chronic Reference Exposure Levels.

This information is published by the EPA (https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha) and (<https://hhpprtv.ornl.gov/>), the United States Centers for Disease Control (<https://www.atsdr.cdc.gov/mrls/mrllist.asp>), and the California Office of Environmental Health Hazard Assessment (<https://oehha.ca.gov/chemicals>) and is used by all state environmental and health departments in the country for conducting risk assessments for potential exposure to contaminants in soil and groundwater.

Additional information can be accessed at:
EPA’s [2018 Drinking Water Standards and Advisory Tables](#) (for PFOA and PFOS toxicity values)
EPA’s [Provisional Peer Reviewed Toxicity Values](#) (PPRTV) Database (for PFBS toxicity values)

(29) Include a schedule for review of the regulation including:

- | | |
|---|--|
| A. The length of the public comment period: | <u>75 days</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>None held</u> |
| C. The expected date of delivery of the final-form regulation: | <u>Quarter 2, 2021</u> |
| D. The expected effective date of the final-form regulation: | <u>Upon publication in the Pennsylvania Bulletin</u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>Upon publication in the Pennsylvania Bulletin</u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>N/A</u> |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department regularly evaluates the continuing effectiveness of Chapter 250 because 25 Pa. Code § 250.11 requires the Department to regularly review new scientific information that relates to the basis of the MSCs; and, that the Department propose appropriate regulations to the EQB, whenever necessary, but not later than 36 months from the effective date of the most recently promulgated regulations. DEP's efforts in this regard include ongoing tracking of remediations completed under the program and annual preparation of a program report.