Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency:

Department of Environmental Protection

(2) Agency Number: 7

Identification Number: 575

IRRC Number**: 3409**

(3) PA Code Cite:

25 Pa. Code Chapter 250

(4) Short Title:

Administration of the Land Recycling Program

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Laura Griffin, (717) 772-3277; laurgriffi@pa.gov
Secondary Contact: Lauren Imgrund, (717) 783-8727; limgrund@pa.gov

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Environmental Protection's (Department) Land Recycling Program implements standards for the cleanup of soil and groundwater contamination from releases of various toxic and carcinogenic chemicals. Every three years, the Department is required by regulation to evaluate new scientific information and as necessary, propose changes to the medium-specific concentrations (MSC) that are a part of the statewide health standard.

This final regulation: adds Per- and Polyfluoroalkyl substances (PFAS) compounds; updates the models, values, and attainment methods for the statewide health standard for lead in soil; revises the methods for attaining toxicity values for polycyclic aromatic hydrocarbon (PAH) compounds; updates the interpretation of toxicity values from the Health Effects Assessment of Summary Tables (HEAST) database; and adopts more stringent toxicity values for nineteen compounds based on United States Environmental Protection Agency (EPA) guidance.

Finally, the regulation will clarify that drinking water maximum contaminant levels (MCL) and health advisory levels (HAL) become effective as MSCs upon publication of the final MCL or HAL by the EPA or the Department.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized under sections 104(a) and 303(a) of the Land Recycling and Remediation Standards Act (the Land Recycling Act or Act 2) (35 P.S. §§ 6026.104(a) and 6026.303(a)), and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20). Section 104(a) of the Land Recycling Act authorizes the Environmental Quality Board (Board) to adopt statewide health standards, appropriate mathematically valid statistical tests to define compliance with the Land Recycling Act and other regulations that may be needed to implement the provisions of the Land Recycling Act. Section 303(a) of the Land Recycling Act authorizes the Board to promulgate statewide health standards for regulated substances for each environmental medium and methods used to calculate the standards. Section 1920-A authorizes the Board to 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 EPA and the Department signed the One Cleanup Program Memorandum of Understanding (One Cleanup Program) under the agency's 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 the Department to ensure, among other things, that voluntary responses conducted under Act 2 are protective of human health and the environment and that the Department review every report relating to the investigation, assessment and clean-up of a site submitted by a remediator. The One Cleanup Program encourages the Department to regularly review the efficacy of the Land Recycling Program's regulations codified at 25 Pa. Code Chapter 250.

State law requires the promulgation of this rulemaking. Section 303(a) of the Land Recycling Act (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." 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." Chapter 250, section 304(c) (relating to MSCs for groundwater) requires "[n]ew or revised MCLs or HALs promulgated by the Department or the EPA shall become effective immediately for any demonstration of attainment completed after the date the new or revised MCLs or HALs become effective." Since the last rulemaking to update the Land Recycling Program's regulations, the EPA has established new MCLs for PFAS compounds perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), hexafluoropropylene oxide (HFPO) dimer acid, perfluorobutane sulfonate (PFBS), perfluorohexane sulfonate (PFHxS), and perfluornonanoic acid (PFNA). The EPA has published new HALs for PFAS compounds HFPO dimer acid ammonium salt (Gen-X) and the potassium salt of PFBS. These new MCLs and HALs must be incorporated into the regulations.

The Department's regulations at 25 Pa. Code § 250.11 (relating to periodic review of MSCs) require the Department to regularly review new scientific information that relates to the basis of the MSCs and to propose appropriate regulations to the Board 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 upon publication in the *Pennsylvania Bulletin* on November 20, 2021. See 51 Pa.B. 7173.

(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.

The 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 Board, when necessary. The rulemaking is also necessary to incorporate several Federal MCLs and HALs published for PFAS compounds, as well as to adopt updated EPA models and the EPA's default variables for calculating soil values for lead. Finally, this rulemaking is necessary to update and improve the methods for identifying the most current and scientifically valid toxicity values, particularly the selection of HEAST values.

There are several public interests that justify the need for this rulemaking.

The elimination of public health and environmental hazards on existing commercial and industrial land across the Commonwealth is vital to their use and reuse as sources of employment, housing, recreation and open-space areas. The reuse of industrial land is an important component of a sound land-use policy that will help prevent the needless development of prime farmland, open-space areas and natural areas and reduce public costs for installing new water, sewer and highway infrastructure.

The Administration of the Land Recycling Program regulations provide standards used during the cleanup of contaminated sites in Pennsylvania. These standards apply to all releases of regulated substances that are addressed under the Land Recycling Act, the Hazardous Sites Cleanup Act (35 P.S. §§ 6020.101—6020.1305), the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003), the Storage Tank and Spill Prevention Act (35 P.S. §§ 6021.101—6021.2104), and the Clean Streams Law (35 P.S. §§ 691.1—691.1001). Releases of regulated substances not only pose a threat to the environment but also could affect the health of the public if they are inhaled or ingested. With new research being conducted every day, it is necessary that the residents of Pennsylvania be adequately protected with site cleanup requirements based on the most up-to-date information.

Chemical substances that can have toxic or carcinogenic effects, as defined under Act 2 and the regulations promulgated thereunder, are widespread in use and potential contamination of soil and groundwater from accidental spills and unlawful disposal can impact almost any resident of the Commonwealth. Examples of substances that contain toxic or carcinogenic properties include gasoline and petroleum products, solvents, elements used in manufacture of metals and alloys, pesticides, herbicides, and some dielectric fluids previously contained in transformers and capacitors.

The Land Recycling Act requires the Board to establish by regulation a uniform statewide health standard that can be used to eliminate any substantial present or probable future risk to human health and the environment. The original standard was promulgated in 1997 and codified in Chapter 250. Section 104(a) of the Land Recycling Act explicitly recognizes that this standard would need to be updated over time as better science became available and as the need for clarification or enhancement of the program became apparent. Updating the standard serves the public, as the Department is able to use the most up-to-date health and scientific information to establish the cleanup standard for exposure to substances that cause cancer or have other toxic effects on human health. The statewide health standard is expressed as

a list of MSCs, which apply to either soil or groundwater contamination and to residential and non-residential exposure scenarios as authorized under the Land Recycling Act.

The changes in the MSCs in these amendments to Chapter 250 serve both the public and the regulated community as they provide clear information on what is required at contaminated sites. Having access to that information allows the public to know the acceptable level of contamination at a site based on the intended use of the property, and it provides remediators with a uniform endpoint to the remediation process. Because each site and situation is unique, it is necessary to provide different MSCs for: 1) specific constituents in groundwater at points of compliance, 2) specific constituents in soil, where there may be direct contact through ingestion or inhalation, and 3) specific constituents in soil that may leech into groundwater. Each of these MSCs is based on the physical and toxicological properties of a specific regulated substance, which are based on scientific sources of information.

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 while still protecting public health and safety.

(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 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).

(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 will not affect Pennsylvania's ability to compete with other states.

The 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 used to determine the completion of soil and groundwater cleanup. The Land Recycling Act provides for a generic statewide health standard that can be used as an efficient way to clean up sites, particularly where small spills and releases contaminate soil. However, the ability to conduct a risk analysis to establish a cleanup value on an individual site basis is also available through the site-specific cleanup standard under Land Recycling Act, providing an additional option.

The existing regulations and this final 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 will 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 will not require the Department to update any other regulations separate from 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. The purpose of the CSSAB is to assist the Department and the Board in developing statewide health standards, determining the appropriate statistically and scientifically valid procedures and risk factors to be used, and providing other technical advice as needed to implement Act 2. Members of the CSSAB typically have a background in engineering, biology, hydrogeology, statistics, medicine, chemistry, toxicology, or other related scientific education or experience. Some members of the CSSAB represent small businesses and other members work as environmental consultants and attorneys and represent small business clients.

During the public comment period on the previous Chapter 250 rulemaking, the Board received several comments regarding the values proposed for lead. Most of the commentators expressed concern with the proposed increase in the non-residential direct contact numeric value for lead in surface soil in Table 4A. The primary reason for this concern was the use of 10 µg/dL as a target blood lead level (TBLL). Due to the large number of comments and concerns, the Department published an Advanced Notice of Proposed Rulemaking (ANPR) in the October 30, 2021, issue of the *Pennsylvania Bulletin* to solicit information necessary to prepare this proposed rulemaking. Specifically, the Department requested information which could be used to evaluate the proposed updates to the lead models used to calculate the soil lead MSCs, potential changes to model input parameters, and potential changes to the statistical tests used to demonstrate attainment of the Statewide health standard for lead in soil at Act 2 remediation sites. During the submission period for the ANPR, the Department received comments from three individuals that were considered during the development of this rulemaking.

The Department presented initial concepts for this rulemaking to the CSSAB at its August 11, 2021, meeting. At this meeting, the CSSAB and the Department agreed that the CSSAB should form two workgroups: one to work through the various issues on lead and another to work through the concerns regarding PAH toxicity values.

The CSSAB Lead workgroup reviewed the various issues raised during the previous rulemaking comment period as well as the ANPR. These issues included the target blood lead level, the various inputs to be used in the new models, and the use of averaging for attainment of the direct contact values. The CSSAB PAH workgroup addressed questions regarding the relative potency factors (RPFs) in comparison to the various other toxicity value sources. Both workgroups developed whitepapers which were presented at CSSAB meetings on June 30 and August 11, 2022, and are attached to this document.

During CSSAB meetings on October 10, 2022, January 23, 2023, and May 31, 2023, CSSAB members had the opportunity to review and provide feedback on draft proposed regulatory amendments to Chapter 250. The Department worked with the CSSAB to resolve their concerns. Following these

presentations and discussions, the CSSAB voted on January 23, 2023, to concur with the Department's recommendation to move the proposed regulation forward to the Board for consideration. After making additional updates to the draft regulation to address changes to the HEAST values and to add the PFAS compound PFHxA, the CSSAB reviewed and affirmed their decision to support the Department on May 31, 2023.

Land Recycling Program staff presented the comments and responses as well as the draft final regulation during CSSAB meetings on April 23, 2025, July 16, 2025, and March 31, 2026. CSSAB members reviewed and provided feedback on the changes between proposed and final, as well as responses to the comments on Chapter 250. There was no opposition to this rulemaking expressed by the members of the CSSAB.

All of the documents and discussions from the CSSAB meetings are available on the CSSAB website: https://www.dep.pa.gov/PublicParticipation/AdvisoryCommittees/Cleanup%20and%20Brownfields%20Advisory%20Committees/CSSABoard/Pages/default.aspx. These can be found either under "Archived meetings" or "Agendas and Handouts."

(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 the Land Recycling Program regulations will affect property 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 whose current or future use is impaired by a real or perceived contamination. This rulemaking will also protect 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 adversely affected by the updates to Chapter 250. The types of businesses affected could include gasoline service stations, fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations, and redevelopers of brownfield sites. There are approximately 12,000 facilities in the Commonwealth that contain regulated underground and above ground storage tanks, including gasoline stations and fuel distribution and storage facilities. Some of these facilities include 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 regulation, it is difficult for the Department to identify further specifics on the types and numbers of small businesses that will potentially be affected by releases of regulated substances.

The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to just under 300 contaminated properties across the Commonwealth per year. 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 the Chapter 250 regulations are not expected to increase costs or provide any significant savings for the regulated community. Language changes made to numerous sections of the regulation provide clarity in the regulatory requirements and ensure references in the regulation are appropriate and consistent. MSCs have been promulgated for 400 regulated substances and are divided into two environmental mediums: soil and groundwater. The same regulated substance may have standards in both mediums. The soil MSCs provide standards for direct contact and ingestion of soil. The

groundwater MSCs provide standards related to human consumption of groundwater or use of groundwater for agricultural purposes. The MSC values for many regulated substances are being changed due to a variety of reasons. The most common reason for changes is due to changes in toxicity values. Approximately 45% of the changes to the MSC tables for soils lower the current values and the other 55% increase those values. Approximately half of the changes to the groundwater table for organic substances lower the current values while the other half increase those 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 financial impact on a given site remediation will depend on the specific regulated substances being remediated and the specific soil and groundwater conditions at the site. For example, a site with a tight clay soil profile may not allow contaminants to spread horizontally or vertically. Therefore, the amount of soil to be excavated in this situation will not significantly change to meet a lower or higher MSC value. However, it is important to note that the site remediator always has the option of using a site-specific cleanup standard.

Most small businesses that the Department can identify as possibly being affected by this regulation are owners of small gasoline stations. In addition, many of these businesses are required to participate in the Underground Storage Tank Indemnification Fund, which provides insurance coverage for the costs to clean up releases from regulated underground storage tank systems, regardless of the MSC value used at the site.

Developers or remediators planning to build new residential developments may be impacted by this change. It is unlikely to impact individual residents. Overall, no type of person or business is expected to be adversely affected by the updates to Chapter 250.

Accordingly, the Department believes that there will be little if any adverse impact to 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.

These amendments to the land recycling regulations will impact 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 will 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 will not affect the voluntary nature of Act 2.

The types of businesses that may need to comply with the regulations include gasoline service stations, fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations, and redevelopers of brownfield sites. There are approximately 12,000 facilities in the Commonwealth that contain regulated underground and aboveground storage tanks, including gasoline stations and fuel distribution and storage facilities. Some of these facilities include small gasoline station owners. Small businesses 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 remediations completed can vary from year to year. On average, remediators apply the Act 2 remediation standard to just under 300 contaminated properties across the Commonwealth per

year. The Department does not expect that the amendments will 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 will not likely impact a specific category of person or company, the amendments will still affect many types of responsible parties who need to address contamination under Chapter 250. The Department expects the impact of the 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 item (15) above.

(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 human health effects when exposed to hazardous and toxic chemicals. This assures potentially affected residents of the Commonwealth and persons interested in buying and redeveloping contaminated sites that the MSCs are protective of human health.

The amendments to the Chapter 250 regulations are not expected to increase costs or provide any significant savings for the regulated community. The MSC values for many regulated substances are being changed due to a variety of reasons. The most common reason is due to changes in toxicity values. Approximately 45% of the changes to the MSC tables for soils (Tables 3a, 3b, and 4a) lower the current values and the other 55% increase those values. Approximately half of the changes to groundwater table for organic substances (Table 1) lower the current values while the other half increase those 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. On average, remediators apply the Act 2 remediation standard to just under 300 contaminated properties across the Commonwealth per year. The Department does not expect that the amendments will impact the number of remediations voluntarily completed or the number that must be completed because of Department enforcement actions.

Under the Land Recycling Act, remediators can choose from three different cleanup standards: background, statewide health or site-specific. Updating statewide health standard MSCs will not affect cleanup options available to remediators under other cleanup standards.

The Department believes that there will be little if any adverse financial, economic, or social impact to small businesses.

The amendments to the Statewide health MSCs will 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.

This rulemaking will benefit the public by reducing public exposure to several PFAS. PFAS are potentially linked to a number of adverse health effects, including high cholesterol, developmental effects including low birth weight, liver toxicity, decreased immune response, thyroid disease, kidney disease, ulcerative colitis and certain cancers, including testicular cancer and kidney cancer. This rulemaking will add or update groundwater standards for some PFAS (adding Gen-X chemicals, PFBS potassium salt, PFBA, PFHxS, PFNA, and PFHxA, updating PFOA (MCL), PFOS (MCL), and PFBS (HAL)) utilizing the MCLs and HALs the EPA published, and newly published toxicity data. Soil

standards for those same PFAS will be added or updated using the underlying data from the EPA HALs and MCLs, as well as the newly published IRIS data. Having these new and updated MSCs will allow remediators to address PFAS groundwater and soil contamination. This will also benefit remediators wishing to remediate contaminated sites, who tend to be owners, operators or purchasers, or their contractors, of properties and facilities at or near, military bases, municipalities, and other locations that used or stored fire-fighting foam or other PFAS-containing materials.

These amendments update various aspects of how the direct contact values for lead are calculated. As described in the whitepaper on lead developed by the CSSAB, and adopted by the Department, the models will be updated, the target blood lead level (TBLL) will be decreased to 5 µg/dl, and attainment of the direct contact value will be adjusted. These amendments include updating the models to EPA's most up-to-date Integrated Exposure Uptake Biokinetic (IEUBK) model and their Adult Lead Model (ALM) from the outdated and obsolete Uptake Biokinetic (UBK) and Society for Environmental Geochemistry and Health (SEGH) models, currently in use by the Department.

In addition to model updates, this rulemaking includes updating the TBLL for lead. The previous models both proposed using a higher TBLL, the UBK model included a target of 10 µg/dl in children while the SEGH model target was 20 µg/dl in adults. This rulemaking utilizes 5 µg/dl as the default TBLL because it is the default value used in the IEUBK and ALM models that were developed by the EPA Superfund Program. This rulemaking's use of the default values associated with the EPA Superfund Program's most current soil lead models, including the TBLL, ensures that the most up to date science is being applied to environmental cleanup sites in Pennsylvania. The Department's Land Recycling Program is closely aligned with the EPA's Superfund Program regarding the use of toxicity information, cleanup processes, and risk-based analyses. The receptor in both models is children, with the IEUBK model receptor being children from zero to 84 months of age while the ALM receptor is a fetus in the womb of an exposed adult.

This amendment adds the averaging of attainment samples in order to attain the lead direct contact value under the Statewide health standard. This attainment test is limited to those sites that are attaining only the direct contact lead value and conforms to the methods utilized by both the IEUBK and ALM. These changes will benefit the public by improving the assessment of lead in soil.

This rulemaking will update the process for choosing toxicity values for PAH (polycyclic aromatic hydrocarbon) chemicals. As outlined in the whitepaper provided by the CSSAB PAH Workgroup and adopted by the Department, when the EPA updated the toxicity value for Benzo[a]pyrene (BaP) in IRIS in January 2017, the supporting documents specifically referred to the EPA's 1993 guidance document on use of relative potency factors for determining the toxicity of six other PAH compounds. These compounds include Benzo[a]anthracene, Benzo[b]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenz[a,h]anthracene, and Indeno[1,2,3-c,d]pyrene. The whitepaper and the guidance document indicate that the toxicity of these six PAHs should be calculated as a factor of the toxicity of BaP. The whitepaper notes that the current toxicity values for PAHs in Chapter 250 are values calculated by California and others using these RPFs in relation to the previously published (replaced in 2017) BaP toxicity value. Using the RPFs in relation to the current BaP toxicity value brings the most current science to Chapter 250. This will benefit the public by bringing these MSC values into the range of detectable concentrations which will allow more remediators to address releases of these compounds and reduce public contact with these compounds. PAHs are typically located in areas where fossil fuels have been burned and are often found in asphalt.

Finally, this rulemaking will update the method for determining MSCs for 19 compounds by choosing subchronic toxicity values over chronic toxicity values. The EPA has provided guidance over the last few years to update some of the toxicity values that should be used to more accurately represent the risk from certain compounds. The EPA's Office of Land and Emergency Management (OLEM) issued a memo in May of 2021 based on recommendations from OLEM's Human Health Regional Risk Assessment Forum's (OHHRRAF) Toxicity Workgroup. This memo recommends using subchronic toxicity values in place of chronic toxicity values (which are typically used for calculating MSC values) for 19 compounds. The rulemaking will adopt those recommendations to adopt more conservative toxicity values for those compounds.

The EPA also provided guidance to the Department regarding the use of certain values from the EPA's Health Effects Assessment Summary Tables (HEAST) database. The HEAST database has not been updated in over 25 years (last updated in 1997) and as IRIS and PPRTV published values, any values for those same compounds are considered to be rescinded by default. The EPA clarified that any compounds evaluated within IRIS and PPRTV that specifically state that a value could not be calculated are also considered to be rescinded. Therefore, several HEAST toxicity values are removed from Tables 5A and 5B. These changes benefit the public by more accurately evaluating the toxicity of these compounds and using more conservative values which are more protective of exposure.

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

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

As described 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 seven chemical compounds (HFPO Dimer acid and its ammonium salt, PFBA, PFHxS, PFHxA, PFNA, and Potassium salts of 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 (such as testicular, kidney), liver effects (such as tissue damage), immune effects (such as antibody production), thyroid effects, and others such as cholesterol. The amendments will also streamline Act 2 remediations.

These benefits outweigh any costs and adverse effects 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 ensure 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 will allow remediators to address more PFAS compound groundwater and soil contamination.

The Department anticipates little if any cost or adverse effects from this proposal. The soil numeric values represent a decrease for approximately 45% of the values and an increase for 55% of the values. For groundwater, the changes reflect a decrease for approximately 50% of the values and an increase in approximately 50% 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 just under 300 contaminated properties across the Commonwealth per year. The cost impact on a given site remediation will 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 amendments to the Chapter 250 regulations are not expected to increase costs or provide any significant savings for the regulated community associated with compliance, or any legal, accounting or consulting procedures. The soil numeric values represent a decrease for approximately 45% of the values that will change and an increase for 55% of the values that will change. For groundwater, the changes reflect a decrease for approximately 50% of the values that will change and an increase in approximately 50% of the values that will change. 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 just under 300 contaminated properties across the Commonwealth per year. The cost impact on a given site remediation will 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.

This rulemaking will 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. In some cases, local governments are remediators; however, as with all other types of remediators, the regulation 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.

These amendments are not expected to impact costs or savings for state government agencies. In some cases, state government agencies are remediators; however, as with all other types of remediators, the regulation is not expected to increase costs or result in significant savings.

Please also see the response to Question 19 above.

(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 the Chapter 250 regulations 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 2025-26	FY +1 2026-27	FY +2 2027-28	FY +3 2028-29	FY +4 2029-30	FY +5 2030-31
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:						
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:						
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 (2022-23)	FY -2 (2023-24)	FY -1 (2024-25)	Current FY (2025-26)
Environmental Protection Operations 160-10381	$102,719,000	$116,450,000	$117,001,000	$134,693,000
Environmental Program Management 161-10382	$35,739,000	$39,714,000	$40,195,000	$45,486,000
Industrial Land Recycling Fund 689-60080	$362,000	$238,000	$277,000	$474,000
Hazardous Sites Cleanup Fund 201-20069	$22,837,000	$23,378,000	$21,867,000	$25,595,000
Storage Tank Fund 210-20073	$4,404,000	$4,788,000	$1,327,000	$6,198,000

(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 the Department can identify as potentially being affected by this rulemaking are owners of small gasoline stations. In addition to gasoline stations, the types of businesses affected could include fuel distribution facilities, commercial facilities that use toxic or carcinogenic chemicals, manufacturing operations and redevelopers of brownfield sites. There are approximately 12,000 facilities in the Commonwealth that contain regulated underground and aboveground storage tanks, including gasoline stations and fuel distribution and storage facilities. Some of these facilities include small gasoline station owners. Small businesses also make up some of the commercial facilities that use toxic or carcinogenic substances. Due to the broad potential reach of this regulation, it is difficult for the Department to identify further specifics on the types and numbers of small businesses that would potentially be affected by releases of regulated substances.

(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.

These amendments to the Chapter 250 regulations do not add any new procedures, recordkeeping, or compliance efforts.

(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. The cost impact on a given site remediation depends on the specific regulated substances being remediated and the specific soil and groundwater conditions at the site.

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 will be covered by

insurance because many of these businesses are required by 35 P.S. § 6021.704(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 tank systems, 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 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 regulation, which is to update various MSCs based on current scientific information. Background and site-specific cleanup standards are available and are not affected by the updates to the Statewide health MSCs. As discussed above in the responses to Questions 9 and 10, Act 2 requires that the Board and the Department evaluate data related to current MSCs and promulgate new standards, where necessary. Further, Act 2 and Chapter 250 regulations require the Department to incorporate applicable Federal standards and the EPA's MCLs and 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 developed to meet the needs of any 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. These alternatives are the background and site-specific cleanup standards in Chapter 250 and will 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 performance 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 any adverse impact on small businesses; therefore, no regulatory methods were considered to minimize any adverse impact on small businesses. Background and site-specific cleanup standards are available and not affected by the updates to the statewide health MSCs.

(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 site-specific standard). See 35 P.S. §§ 6026.302(e), 6026.303(h), and 6026.304(n). As a result, the Department and the Board have limited ability to alter schedules, deadlines and reporting requirements. In addition, reporting obligations under Act 2 generally apply only to the Department (in other words, 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 27(a).

(c) Please see the response to Question 27(a).

(d) The Land Recycling Program's regulations do not have design or operation standards. Act 2 does not authorize relaxing MSC values for specific categories of remediators.

(e) Small businesses, small organizations and small governmental jurisdictions are not exempt from any provisions of the regulations. The Land Recycling Program's regulations do 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.

The Land Recycling Act and the Chapter 250 regulations require the periodic update of the statewide health standard to be based 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, Provisional Peer-Reviewed Toxicity Values (PPRTV), the Health Effects Assessment Summary Tables (HEAST), Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles, and California EPA Cancer Potency Factors and Chronic Reference Exposure Levels.

This information is extensively published by the EPA (IRIS - https://iris.epa.gov/AtoZ/?list_type=alpha) and (PPRTV - https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments), the United States Centers for Disease Control (minimum risk levels (MRLs) for hazardous substances - https://wwwn.cdc.gov/TSP/MRLS/mrlsListing.aspx), 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.

This rulemaking will add or update groundwater standards for some PFAS (adding Gen-X chemicals, PFBS potassium salt, PFBA, PFHxS, PFNA, and PFHxA, updating PFOA (MCL), PFOS (MCL), and PFBS (HAL)) utilizing the MCLs and HALs EPA published, and newly published toxicity data. Soil standards for those same PFAS will be added or updated using the underlying data from the EPA HALs and MCLs, and the newly published IRIS data. These new and updated MSCs will allow remediators to address PFAS groundwater and soil contamination.

The amendments to this regulation update various aspects for how the direct contact values for lead are calculated. As described in the attached whitepaper on lead developed by the CSSAB, the models will be updated, the TBLL will be decreased to 5 µg/dl, and attainment of the direct contact value will be adjusted. These amendments update the models to use the EPA's most up-to-date IEUBK model and their ALM from the outdated and obsolete UBK and SEGH models currently in use by the Department. In addition to model updates, this regulation will update the TBLL. The previous models both proposed use of a higher TBLL; the UBK model included a target of 10 µg/dl in children, while the SEGH model target was 20 µg/dl in adults. This rulemaking uses 5 µg/dl as the default TBLL because it is the default value used in the IEUBK and ALM models that were developed by the EPA's Superfund Program. The receptor in both models is children: the IEUBK model receptor is children from zero to 84 months of age while the ALM receptor is a fetus in the womb of an exposed adult. This rulemaking's use of the default values associated with the EPA Superfund Program's most current soil lead models, including the TBLL, ensures that the most up to date science is being applied to environmental cleanup sites in Pennsylvania. The Department's Land Recycling Program is closely aligned with the EPA's Superfund Program regarding the use of toxicity information, cleanup processes, and risk-based analyses. This regulation also allows the use of averaging of attainment samples to attain the lead direct contact value under the Statewide health standard. This attainment test is limited to those sites that are attaining only

the direct contact lead value and conforms to the methods utilized by both the IEUBK and ALM. These changes will benefit the public by improving the assessment of lead in soil.

This rulemaking will update the process for choosing toxicity values for PAH chemicals. As outlined in the attached whitepaper provided by the CSSAB PAH Workgroup, when the EPA updated the toxicity value for BaP in IRIS in January 2017, the supporting documents specifically referred to the EPA's 1993 guidance document on the use of relative potency factors for determining the toxicity of six other PAH compounds. These compounds include Benzo[a]anthracene, Benzo[b]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenz[a,h]anthracene, and Indeno[1,2,3-c,d]pyrene. The whitepaper and the guidance document indicate that the toxicity of these six PAHs should be calculated as a factor of the toxicity of BaP. The whitepaper notes that the current toxicity values for PAHs in Chapter 250 are values calculated by California and others using these RPFs in relation to the previously published (replaced in 2017) BaP toxicity value. Using the RPFs in relation to the current BaP toxicity value ensures the Land Recycling Program's regulations in Chapter 250 use the most current science.

Finally, this rulemaking updates the method for determining MSCs for 19 compounds by choosing subchronic toxicity values over chronic toxicity values. The EPA has provided guidance over the last few years to update some of the toxicity values that should be used to most conservatively evaluate the risk from certain compounds. The EPA's OLEM issued a memo in May of 2021 based on recommendations from the OHHRRAF Toxicity Workgroup that recommends using subchronic toxicity values in place of chronic toxicity values (which are typically used for calculating MSC values) for 19 compounds. The rulemaking will follow those recommendations to adopt more conservative toxicity values for those compounds.

The EPA also provided guidance to the Department regarding the use of some Health Effects Assessment Summary Tables (HEAST) values. The HEAST database has not been updated since 1997. As values are published in IRIS and the PPRTV database, any values in HEAST for those same compounds were considered to be rescinded from HEAST by default. It has been clarified through conversations with the EPA that any compounds evaluated within IRIS and PPRTV that specifically state that a value could not be calculated should also be considered rescinded by the EPA. Consequently, several HEAST toxicity values are deleted from Tables 5a and 5b. See the attached document titled "Explanation for Removal of HEAST Toxicity Values" for additional detail.

Additional information can be accessed at the following:

- EPA's PFAS MCL Rule (For PFOA, PFOS, and PFHxS toxicity values), https://www.federalregister.gov/documents/2024/04/26/2024-07773/pfas-national-primary-drinking-water-regulation and https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas

- EPA's Drinking Water Health Advisories (for Gen-X and PFBS chemicals), https://www.epa.gov/sdwa/drinking-water-health-advisories-has

- EPA's Recommendations on the Use of Chronic or Subchronic Noncancer Values for Superfund Human Health Risk Assessments, https://semspub.epa.gov/src/document/HQ/100002839

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

A. The length of the public comment period:	60 days
B. The date or dates on which any public meetings or hearings will be held:	August 19, August 27 and September 4, 2024
C. The expected date of delivery of the final-form regulation:	Quarter 3, 2026
D. The expected effective date of the final-form regulation:	Upon publication in the *Pennsylvania Bulletin*
E. The expected date by which compliance with the final-form regulation will be required:	Upon publication in the *Pennsylvania Bulletin*
F. The expected date by which required permits, licenses or other approvals must be obtained:	Not applicable

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

The Department evaluates the continuing effectiveness of the Land Recycling Program and the Chapter 250 regulations on an ongoing basis. Section 250.11 requires the Department to regularly review new scientific information that relates to the basis of the MSCs and to propose appropriate regulations to the Board whenever necessary, but not later than 36 months from the effective date of the most recently promulgated regulations. These efforts include ongoing tracking of remediations completed under the program and an annual program report.