

<h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p>		<p>INDEPENDENT REGULATORY REVIEW COMMISSION</p>	
<p>(All Comments submitted on this regulation will appear on IRRC's website)</p>			
<p>(1) Agency:</p> <p>Department of Environmental Protection</p>			
<p>(2) Agency Number: 7</p> <p>Identification Number: 588</p>		<p>IRRC Number: 3440</p>	
<p>(3) PA Code Cite: 25 Pa. Code Chapter 250</p>			
<p>(4) Short Title: Administration of the Land Recycling Program – Chromium (VI)</p>			
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Laura Griffin, (717) 772-3277; laurgriffi@pa.gov Secondary Contact: Lauren Imgrund, (717) 783-8727; limgrund@pa.gov</p>			
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input type="checkbox"/> Proposed Regulation <input checked="" type="checkbox"/> Final Regulation <input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation <input type="checkbox"/> Certification by the Governor <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>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. The final-form amendments to the Land Recycling Program regulations update the toxicity values for chromium (VI) (Cr(VI)), correct the omission of the mutagenic factors in the calculation of the residential direct contact medium-specific concentration (MSC), and update the Statewide health standard MSCs pertaining to cleanup of soil Cr(VI) contamination based on the United States Environmental Protection Agency’s (EPA) recent health effects assessment.</p>			
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>This final-form rulemaking is authorized under sections 104(a) and 303(a) of the Land Recycling and Remediation Standards Act (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 Act 2 authorizes the Environmental Quality Board (Board) to adopt Statewide health standards, appropriate mathematically valid statistical tests to define compliance with Act 2 and other regulations that may be needed to implement the provisions of Act 2. Section 303(a) of Act 2 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 of The Administrative Code of 1929 authorizes the Board to formulate, adopt and promulgate rules and regulations that are necessary for the proper work of the Department.</p>			

(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 final-form rulemaking is not mandated under Federal law, Federal regulation, or court order. 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 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 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 in 25 Pa. Code Chapter 250.

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 on November 20, 2021. *See* 51 Pa.B. 7173 (November 20, 2021).

(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 final-form 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. These changes, based on new Cr(VI) toxicity information and to correct the omission of the mutagenic factors in the residential direct contact calculation, update the Cr(VI) toxicity values and the resulting Statewide health standard direct contact soil MSCs for Cr(VI).

There are several public interests justifying this final-form regulation.

The public benefits from having groundwater and soil MSCs that reflect up-to-date science and toxicological information. The Board first promulgated the Land Recycling Program regulations in Chapter 250 in 1997 following the enactment of Act 2. *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 releases and unlawful disposal of Cr(VI) may impact residents of this Commonwealth. 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. As new research on Cr(VI) is developed, it provides the basis to protect residents of this Commonwealth through site cleanup requirements.

Cr(VI) is a form of the metallic element chromium and is generally produced by industrial processes such as electroplating, stainless-steel production, leather tanning, textile manufacturing, and wood

preservation. Cr(VI) has toxic effects on human health because it acts as both a carcinogen (causes cancer) and a systemic toxicant (non-carcinogen). Additionally, Cr(VI) is a mutagen which means it harms an organism's cells by permanently changing genetic material, thus causing mutations and potentially increasing the frequency of diseases such as cancer.

The changes to the Cr(VI) MSCs in this final-form 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 Cr(VI). The Department routinely reviews the MSC values and toxicity values to ensure the MSCs represent the most current and accurate science. During this routine review, the Department identified recently updated science on Cr(VI). On August 1, 2024, the U.S. Environmental Protection Agency (EPA) established new science in its Integrated Risk Information System (IRIS) regarding the toxicity of Cr(VI) that could be used to update the Cr(VI) soil MSCs. The Department also discovered the mutagenic factors were inadvertently omitted from the calculation of the residential soil direct contact Cr(VI) MSC in the rulemaking finalized in 2021. *See* 51 Pa.B. 7173 (November 20, 2021). Recognizing the toxic nature of Cr(VI) and the discovery that a more protective residential MSC is possible, the Board is proceeding with a stand-alone rulemaking to more responsively update the toxicity values and corresponding MSCs for Cr(VI).

The Board is currently in the process of updating the standards for a wide variety of regulated substances in Chapter 250 through a separate, broader rulemaking. However, the changes in this rulemaking for Cr(VI) cannot be added to that broader rulemaking, which is nearly finished with the rulemaking process. The public comment period for the rulemaking already in progress ended on September 11, 2024, and entirely new amendments may not be proposed in the final rulemaking. The public needs the opportunity to review and provide comment on the new Cr(VI) values and the science they are based on prior to finalization of the changes. Therefore, to ensure the most up-to-date and accurate science is applied to environmental cleanups in this Commonwealth in the most efficient and transparent means possible, the Board is updating the Cr(VI) cleanup standards in Chapter 250 as a stand-alone rulemaking.

The benefits of this final-form 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. By implementing Act 2, the final-form rulemaking benefits the public because it allows for more efficient and more expedient remediation and reuse of contaminated sites.

(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). Federal standards adopted under Act 2 are typically maximum contaminant levels (MCLs) promulgated by the 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 the Land Recycling Program regulations in 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. Act 2 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 Act 2, providing an additional option.

The existing regulations and this final-form regulation 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 final-form regulation 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 the Land Recycling Program regulations in Chapter 250 by reference, this rulemaking will not require the Department to update any other regulations. For example, 25 Pa. Code Chapter 245 (relating to Administration of Storage Tank and Spill Prevention Program) requires that various components of storage tank spill corrective actions conform 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 consulted with the Cleanup Standards Scientific Advisory Board (CSSAB) during the development of this final-form 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 Cleanup Standards Scientific Advisory Board 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.

The draft proposed rule was presented to and reviewed by the CSSAB at its October 30, 2024, meeting. At that meeting, the CSSAB voted unanimously to support moving the proposed regulation forward to the Board. The CSSAB was briefed on the comments received on the proposed rulemaking and

reviewed the draft final regulation at its October 22, 2025, meeting. The CSSAB provided no comments or feedback at that meeting.

(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 final-form regulation will affect owners of contaminated sites, operators of commercial and industrial facilities, including small businesses, where Cr(VI) is released into the environment 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 final-form rulemaking will also protect public health by minimizing exposure to Cr(VI) released into the shared environment.

No particular category of person, business or organization is expected to be substantially or adversely affected by the final regulation. The types of businesses that may be affected by this rulemaking include commercial and industrial facilities, including small businesses, that use Cr(VI) and redevelopers of brownfield sites.

As mentioned in the response to Question 10, Cr(VI) is a form of the metallic element chromium and is generally produced by industrial processes such as electroplating, stainless-steel production, leather tanning, textile manufacturing, and wood preservation. Due to the limited industrial uses for Cr(VI), small businesses are unlikely to make up a substantial portion of the commercial facilities that use Cr(VI). Because of the broad potential reach of this final-form rulemaking, the Department cannot reasonably specify 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 just under 300 contaminated properties across the Commonwealth each year. However, the number of Cr(VI) cleanups represents a much smaller subset (less than 1%) of those properties. 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 are not expected to increase costs or provide any significant savings for the regulated community. Chapter 250 regulations contain MSCs for 400 regulated substances. The MSCs are divided into two environmental media: groundwater and soil. For example, see §§ 250.304 and 250.305 (relating to MSCs for groundwater; and MSCs for soil.) Cr(VI) has MSCs for both soil and groundwater. The soil MSCs provide standards for direct contact with soil (including exposure via ingestion and inhalation of contamination attached to soil particulates) and the soil-to-groundwater exposure pathway. The groundwater MSCs provide standards related to human consumption of groundwater or the inhalation of volatile substances in groundwater. Toxicity values listed in databases maintained by Federal agencies, including the EPA and U.S. Department of Health Agency for Toxic Substances and Disease Registry, are used in calculating MSCs. Under this amendment, the direct contact soil MSC values for Cr(VI) change due to an update in the toxicity values used to calculate the MSCs and to correct the omission of the mutagenic factors in the residential direct contact calculation. The update to the Cr(VI) toxicity values results in a decrease in the residential soil direct contact numeric value and an increase in the nonresidential soil direct contact value. Decreasing 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.

Changes in these values reflect updated information related to the toxicity of Cr(VI) and recognize that these updated standards are better representative of Cr(VI)'s health-based contact limits.

The financial impact on a given site remediation depends on 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.

Accordingly, the Department believes that there will be little if any adverse impact to any particular category of person, business (including small businesses) or organization. Please also see the response to Question 10, regarding benefits, and to Question 24, 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.

The final-form amendments to the Land Recycling Program regulations impact any person addressing a release of Cr(VI) at a property, whether voluntarily or as a result of an order by the Department, but do 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 final-form rulemaking will not affect the voluntary nature of Act 2.

The types of businesses that may be affected by this final-form rulemaking include commercial and industrial facilities that use Cr(VI) and redevelopers of brownfield sites. Small businesses also make up a small number of commercial and industrial facilities that use Cr(VI). Not all 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. However, the number of Cr(VI) cleanups represents a smaller subset (less than 1%) of those properties. The Department does not expect that these amendments will impact the number of remediations voluntarily completed or those that must be completed because of Department enforcement actions.

As noted in the response to Question 15, while these amendments do 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 the Chapter 250 Land Recycling Program regulations. The Department expects the impact of the updates 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 final-form amendments to the Statewide health standard MSCs reflect the latest toxicological data on health effects to humans exposed to Cr(VI). Updating the MSCs provides assurance that the MSCs are protective of human health and potentially affected individuals, including residents, large and small business owners, and other organizations interested in buying and redeveloping contaminated sites.

More broadly, this regulation will benefit all individuals in the Commonwealth. The amendments to the Statewide health standard MSCs reflect the latest toxicological data on human health effects that can occur when humans are exposed to Cr(VI). Updating the MSCs based on the latest toxicological data provides assurance that the MSCs are protective of human health and minimizes exposure to harmful substances. Individuals who may most directly benefit from this final-form rule are property owners who plan to remediate contaminated land, neighbors living or working in close proximity to a contaminated brownfield site, and remediators and developers who want to purchase, remediate, and build on a contaminated brownfield site.

In consideration of financial and economic impacts, the amendments to the Chapter 250 regulations are not expected to increase costs or provide any significant savings for the regulated community. The update to the Cr(VI) toxicity values results in a decrease in the residential soil direct contact numeric value and an increase in the nonresidential soil direct contact value. Decreasing 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. Changes in these values reflect updated information related to the toxicity of Cr(VI) and recognize that these updated standards are better representative of Cr(VI)'s health-based contact limits.

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. However, the number of Cr(VI) cleanups represents a smaller subset (less than 1%) of those properties. The Department does not expect that these amendments will impact the number of remediations voluntarily completed or those that must be completed because of Department enforcement actions.

Furthermore, 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 will be insignificant.

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 final-form rulemaking. They include protecting the public with updated MSCs reflecting the latest toxicological data for Cr(VI).

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 Cr(VI). 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.

The Department anticipates little if any cost or adverse effects from this amendment. The update to the Cr(VI) toxicity information results in a decrease in the residential soil direct contact numeric value and an increase in the nonresidential soil direct contact value. Decreasing 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. Changes in these values reflect updated information related to the toxicity of Cr(VI) and recognize that these updated standards are better representative of Cr(VI)'s health-based contact limits.

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. However, the number of Cr(VI) cleanups represents a smaller subset (less than 1%) of those properties.

The cost impact on a given site remediation will depend on 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 will 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 update to the Cr(VI) toxicity values results in a decrease in the residential soil direct contact numeric value and an increase in the nonresidential soil direct contact value. Decreasing 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. Changes in these values reflect updated information related to the toxicity of Cr(VI) and recognize that these updated standards are better representative of Cr(VI)'s health-based contact limits.

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. However, the number of Cr(VI) cleanups represents a smaller subset (less than 1%) of those properties.

The cost impact on a given site remediation will depend on 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 final-form 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 final 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 final-form regulation is not expected to increase costs or result in significant savings. Please also see the response to Question 19.

(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 final 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 final-form regulation 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 final amendments 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	\$125,881,000	\$134,693,000
Environmental Program Management 161-10382	\$35,739,000	\$39,714,000	\$42,510,000	\$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	\$23,893,000	\$25,595,000
Storage Tank Fund 210-20073	\$4,404,000	\$4,788,000	\$5,897,000	\$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.

The types of businesses that may be affected by this final-form rulemaking include industrial and commercial facilities that use Cr(VI) and redevelopers of brownfield sites. Small businesses make up some of the commercial facilities that use Cr(VI). The Land Recycling Program Chapter 250 regulations 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, the Department cannot identify further specifics on the types and numbers of small businesses that will 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. Changes to the cleanup standards numeric values do not create any liability or obligation related to those changes. Instead, a person's liability can arise, for example, under other statutes while Act 2 and Chapter 250 provide the means to resolve the 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.

This final-form regulation does not add any new procedures, recordkeeping, or compliance efforts.

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

This final-form regulation is 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 soil and groundwater conditions 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 standard MSCs.

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 businesses, potential grants or loans for the assessment and remediation of soil and groundwater contamination at eligible properties.

Also, see the response to Question 15 for further discussion of potential effects to small businesses.

(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 final-form regulation, which is to update the Cr(VI) MSCs based on current scientific information. Background and site-specific cleanup standards are available alternatives to the regulated community and will not be affected by the updates to the Statewide health MSCs in this final-form regulation. As discussed above in the responses to Questions 9, 10, and 14, Act 2 requires that the Department evaluate data related to current MSCs and the Board promulgate new standards, where necessary.

(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 final-form regulation does 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 final-form 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 final-form 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 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:

The final 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) The establishment of less stringent compliance or reporting requirements for small businesses;

This final-form 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) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

Please see the response to Question 27(a).

c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Please see the response to Question 27(a).

d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and

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

e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Small businesses, small organizations and small governmental jurisdictions are not exempt from any provisions of the regulations. The Land Recycling Program regulations do not account for 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 Land Recycling Program regulations in Chapter 250 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, Provisional Peer-Reviewed Toxicity Values (PPRTV), 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.

Information from these sources 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.

For this regulation, the EPA’s [Integrated Risk Information System](http://iris.epa.gov/ChemicalLanding/&substance_nmbr=144#values) (IRIS) Database for the Cr(VI) toxicity information was used to determine the updated Cr(VI) toxicity values. The final oral reference dose, oral slope cancer factor, inhalation reference concentration, and inhalation unit risk for Cr(VI) are available on the EPA’s IRIS website at http://iris.epa.gov/ChemicalLanding/&substance_nmbr=144#values.

Because Cr(VI) is both a carcinogen and a systemic (noncarcinogenic) toxicant, and exposure can be via inhalation or oral exposure (ingestion), there are four individual values calculated in the process of determining the residential direct contact numeric value. These values are the carcinogenic inhalation value, noncarcinogenic inhalation value, carcinogenic ingestion value, and the noncarcinogenic ingestion value. These four individual values are compared and the lowest of the four calculated values is included in Table 4A in Chapter 250 as the direct contact numeric value. The equations used to calculate the values for inhalation and ingestion of Cr(VI) in soils can be found in Sections 306 and 307 of Chapter 250 (§§ 250.306 and 250.307).

The equation from § 250.306(b)(2) used to calculate the lowest residential soil direct contact numeric value to be included in Table 4A is:

$$MSC = \frac{TR \times AT_c \times 365 \text{ days/year}}{CSF_o \times Abs \times EF \times AIF_{adj} \times CF}$$

Where:

TR = Target risk (1×10^{-5})	AT_c = Averaging time for carcinogens (70 yr)
CSF_o = Oral cancer slope factor (Table 5B)	Abs = absorption (1)
EF = Exposure frequency (250 days/yr)	CF = Conversion factor (1×10^{-6} kg/mg)

The mutagenic term that was missing from the calculation in the previous rulemaking is AIFadj. This is the age dependent adjustment factor and ingestion factor. This term is calculated using a combination of age specific exposure factors including the ingestion rate, body weight, and length of exposure of children at three age ranges. The calculation error was corrected by recalculating the Cr(VI) soil direct contact numeric values using the full equation provided above.

There are also four individual values calculated in the process of determining the nonresidential direct contact numeric value. As with the residential calculations, these values are the carcinogenic inhalation value, noncarcinogenic inhalation value, carcinogenic ingestion value, and the noncarcinogenic ingestion value. These four individual values are compared and the lowest of the four calculated values is included in Table 4A as the direct contact numeric value. The equations used to calculate the values for inhalation and ingestion of Cr(VI) in soils can be found in §§ 250.306 and 250.307.

The equation from § 250.306(b)(1) used to calculate the lowest nonresidential soil direct contact numeric value to be included in Table 4A is:

$$MSC = \frac{TR \times AT_c \times 365 \text{ days/year}}{CSF_n \times Abs \times EF \times IFadj \times CF}$$

Where:

TR = Target risk (1 x 10 ⁻⁵)	AT _c = Averaging time for carcinogens (70 yr)
CSF _o = Oral cancer slope factor (Table 5B)	Abs = absorption (1)
EF = Exposure frequency (180 days/yr)	IFadj = Ingestion Factor (15.6 mg-yr/kg-day)
CF = Conversion factor (1 x 10 ⁻⁶ kg/mg)	

The non-residential equation does not include the mutagenic factor so the only change to this calculation in this final-form rulemaking is the inclusion of the updated oral cancer slope factor.

Final amendments to the Physical and Toxicological Properties for Inorganic Regulated Substances table (Table 5B in Chapter 250) update the oral reference dose, oral slope cancer factor, inhalation reference concentration, and inhalation unit risk for Cr(VI) by replacing them with the updated values for Cr(VI) identified in the EPA’s IRIS database.

The updated toxicity values from EPA’s IRIS database are inserted into Table 5B and used in the equations identified above from §§ 250.306 and 250.307 to calculate the updated Cr(VI) soil direct contact numeric values that have been amended in Table 4A. These numeric values are used by remediators to establish the soil MSC for use at each site.

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

A. The length of the public comment period: 30 days

B. The date or dates on which any public meetings or hearings will be held: None held

- | | |
|---|---|
| C. The expected date of delivery of the final-form regulation: | <u>Quarter 2, 2026</u> |
| D. The expected effective date of the final-form regulation: | <u>Upon publication</u>
<u>in the <i>Pennsylvania Bulletin</i></u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>Upon publication</u>
<u>in the <i>Pennsylvania Bulletin</i></u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>Not applicable</u> |

(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.