

<h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p>		<p><i>INDEPENDENT REGULATORY REVIEW COMMISSION</i></p>
<p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		
<p>(1) Agency: Environmental Protection</p>		<p>IRRC Number:</p>
<p>(2) Agency Number: 7 Identification Number: 572</p>		
<p>(3) PA Code Cite: 25 Pa. Code Chapter 250</p>		
<p>(4) Short Title: Administration of the Land Recycling Program Vanadium MSC Rule</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Laura Griffin, (717) 783-8727; laurgriffi@pa.gov Secondary Contact: Kate Cole, (717) 783-8727; kacole@pa.gov</p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation <input 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>This rulemaking proposes to amend 25 Pa. Code Chapter 250 (relating to administration of the land recycling program) to update the toxicity value for vanadium and update the Statewide health standard medium-specific concentrations (MSCs) pertaining to cleanup of soil and groundwater vanadium contamination. The current toxicity value for vanadium has a high level of uncertainty and has resulted in a residential direct contact value that is near the lower end of the naturally occurring concentration range of vanadium in soil. This rulemaking proposes a change to the toxicity value based on a methodology that has less uncertainty, is endorsed by the U.S. Environmental Protection Agency (EPA), and avoids unnecessary expense for remediators when remediating properties contaminated with vanadium.</p>		
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>This proposed rulemaking is authorized under sections 104(a) and 303(a) of the Land Recycling and Environmental Remediation Standards Act (Act 2) (35 P.S. §§ 6026.104(a) and 6026.303(a)), which direct the Environmental Quality Board (Board) to adopt and amend periodically by regulation Statewide health standards for regulated substances for each environmental medium, including any health-based standards adopted by the Federal government by regulation or statute, and health advisory levels (HALs), that direct the Board to promulgate appropriate mathematically-valid statistical tests to define compliance with Act 2, and other regulations as necessary to implement the provisions of Act 2; and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), which authorizes the Board to formulate, adopt and promulgate rules and regulations that are necessary for the proper work of the Department of Environmental Protection (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 proposed rulemaking is not mandated under Federal law. Federal law, however, encourages states to develop programs for voluntary clean-up of contaminated sites (see 42 U.S.C. § 9628 (relating to State response programs)). On April 21, 2004, the U.S. Environmental Protection Agency (EPA) and the Department of Environmental Protection (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 to 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 Chapter 250.

Under 25 Pa. Code § 250.11 (relating to periodic review of MSCs), the Department is required 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 proposed 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 proposed changes, based on new vanadium toxicity information, would update the vanadium toxicity value and the resulting Statewide health standard MSCs for vanadium.

There are several public interests justifying this proposed rulemaking.

The public benefits from having groundwater and soil MSCs that reflect up-to-date science and toxicological information. The changes in the vanadium MSCs in this proposed 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 vanadium, which has toxic effects on human health. The Board first promulgated 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 spills and unlawful disposal may impact residents of this Commonwealth. Vanadium is a systemic toxicant (non-carcinogen) as defined under Act 2 and is used in various industrial processes. 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 vanadium is developed, it provides the basis to protect residents of this Commonwealth through site cleanup requirements. Through discussions with the Cleanup Standards Scientific Advisory

Board (CSSAB) and public comments received on the last amendment to the Chapter 250 rulemaking, *see* 51 Pa.B. 7173, it was determined that an alternative toxicity value for vanadium is necessary and scientifically appropriate.

The Department last updated the vanadium toxicity value in 2016 based on EPA's Provisional Peer-Reviewed Toxicity Value (PPRTV) database which is considered a "Tier 2 Source" in § 250.605(a). 46 Pa.B. 5655. The PPRTV value for vanadium is based on a sodium metavanadate study and has generated a residential direct contact value that is near the lower end of the naturally occurring concentration range of vanadium in soil, according to a study by the United States Geological Survey. A cleanup value this low makes it difficult for remediators to determine if vanadium soil concentrations are naturally occurring or are related to a vanadium release at their site. Use of the PPRTV value has also impeded utilization of the Department's Management of Fill Policy.

The update to the vanadium toxicity value in this proposed rulemaking would result in increases to the groundwater, soil direct contact, and soil-to-groundwater numeric values. These proposed numeric value increases reflect updated scientific information related to the toxicity of vanadium and accurately align with the risk from exposure. EPA has determined that there is a high level of uncertainty associated with the development of the PPRTV toxicity value, which is why it is so low. The alternative to using the PPRTV toxicity value for vanadium is to use the EPA's Integrated Risk Information System (IRIS) vanadium pentoxide value and apply a molecular weight conversion. The PPRTV value is based on a sodium metavanadate study, which can only be used as an elemental vanadium value because of the molecular weight conversion done in the study. The IRIS vanadium pentoxide value is also a vanadium compound value that, by using the same molecular weight conversion, can also be used as an elemental vanadium value. The only difference is that the Department has performed the molecular weight conversion.

The IRIS value is preferred over the PPRTV value because it has less uncertainty associated with it and it is a "Tier 1 Source" for toxicity values according to § 250.605(a), which means it has gone through a more rigorous peer review process. EPA has endorsed the use of the IRIS vanadium pentoxide value in conjunction with a molecular weight conversion by using it to develop their vanadium Regional Screening Level (RSL).

The benefits of this proposed rulemaking are difficult to quantify because, unlike other statutory or permitting structures, 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, the proposed rulemaking, consistent with Act 2, benefits the public because it may reduce harmful exposure and result in efficient and 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 in this proposed rulemaking are more stringent than Federal cleanup standards. 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 [Section 303 Statewide health standard] shall be no more stringent than those standards adopted by the Federal Government." See 35 P.S. § 6026.303(a) (relating to Statewide Health

Standard). Federal standards typically are maximum contaminant levels promulgated by EPA to address drinking water under the Federal Safe Drinking Water Act.

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

The proposed updates to Chapter 250 would not affect Pennsylvania's ability to compete with other states.

The existing Chapter 250 regulations provide a uniform Statewide health standard that is not available in many other states. However, several other states, such as Alaska, Indiana, Maine, Hawaii, New Jersey, Virginia, and Iowa, use the vanadium pentoxide IRIS value with a molecular weight conversion to calculate their cleanup or screening values for vanadium. Although EPA uses this process to calculate a screening value for vanadium in their RSL table, they, along with many other states do not calculate generic cleanup values and instead require a site-specific risk analysis at every site to establish a numeric value that is then used to determine the completion of soil and groundwater cleanup. Act 2 provides for a Statewide health standard that can be used as an efficient way to clean up sites, particularly where small spills and releases contaminate soil. This does not negate the opportunity to conduct a risk analysis. Act 2 also provides the ability to conduct a risk analysis to establish a cleanup value on an individual-site basis through the site-specific cleanup standard.

The existing regulations and the proposed 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 proposed rulemaking would not directly affect any of the Department's existing regulations, policies, or any regulations promulgated by other state agencies. While some Department regulations incorporate elements of Chapter 250 by reference, this proposed rulemaking would not require the Department to update any other regulations separate from Chapter 250. For example, Chapter 245 regulations (relating to Administration of Storage Tank and Spill Prevention Program) require that various components of storage tank spill corrective actions comport with site investigation or remediation requirements within Chapter 250. While not a regulation, another example is the Department's policy, "Management of Fill," Document No. Document No. 258-2182-773, which incorporates some of the Chapter 250 numeric values by direct reference.

(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 proposed rulemaking. CSSAB, established by Section 105 of Act 2 (35 P.S. § 6026.105), consists of persons representing a cross-section of experience, including engineering, biology, hydrogeology, statistics, medicine, chemistry, toxicology and other related fields. The purpose of the CSSAB is to assist the Department and the Board in developing Statewide health standards, determining the appropriate statistically and scientifically valid procedures and risk factors, and providing other technical advice as needed to implement Act 2. The proposed rule was

presented to and reviewed by the CSSAB at the October 4, 2021 meeting. The Department received a letter of support for this rulemaking from the CSSAB on October 12, 2021. A list of CSSAB members and CSSAB meeting minutes are available on the Department's website at www.dep.pa.gov (select "Public Participation," then "Advisory Committees").

The Department also received input from the PA Chamber of Business and Industry (Chamber) regarding their concerns with the current toxicity value for vanadium and resulting MSC values. The Department received the Chamber's input during the public comment period for the previous Chapter 250 proposed rulemaking in 2020, which the Chamber reiterated in its comments to the Independent Regulatory Review Commission (IRRC) during IRRC's consideration of the final-form rulemaking on September 23, 2021.

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

No particular category of person, business or organization is expected to be substantially or adversely affected by the proposed updates to Chapter 250. The types of businesses that may be affected by this proposed rulemaking include commercial and industrial facilities that use vanadium and redevelopers of brownfield sites.

Small businesses account for a portion of the commercial facilities that use vanadium. Because of the unknown application of this proposed rulemaking, the Department cannot reasonably identify further specifics on the number of small businesses that would potentially be affected by property contamination. The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth each year. However, the number of vanadium cleanups represents a smaller subset of those properties. Generally, any cost related to a 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 proposed changes to Chapter 250 are not expected to increase costs for the regulated community. Chapter 250 contains MSCs for 400 regulated substances. The MSCs are divided into two environmental media: groundwater and soil. *See* 25 Pa. Code §§ 250.304, 250.305 (relating to MSCs for groundwater; and MSCs for soil.) Vanadium has MSCs in 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 EPA and U.S. Department of Health Agency for Toxic Substances and Disease Registry, are used in calculating MSC. Under this proposal, the MSC values for vanadium change due to an update in the vanadium toxicity value used to calculate the MSCs. The update to the vanadium toxicity value results in increases to the groundwater, soil direct contact, and soil-to-groundwater numeric values.

Value increases reflect updated scientific information related to the toxicity of vanadium and recognize that the updated values accurately align with the risk from exposure. Value increases can also prevent impracticable remediation requirements for sites where existing vanadium standards are lower than naturally occurring concentrations.

The financial impact on a 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 excavated would not significantly change to meet a lower or higher MSC value.

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

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

This proposed amendment to Chapter 250 would impact any person addressing a release of vanadium at a property, whether voluntarily or as a result of an order by the Department but would not impact any particular category 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 proposed rulemaking would not affect the voluntary nature of Act 2.

The types of businesses that may need to comply with the regulations include industrial and commercial facilities that use vanadium and redevelopers of brownfield sites. Small businesses would also account for some of the commercial facilities that use vanadium. Not all of these facilities have releases or accidental spills that result in a cleanup obligation.

The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth each year. However, the number of vanadium cleanups represents a smaller subset of those properties. The Department does not expect the proposed amendments to 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 the proposed amendments would not likely impact a specific category of person or company, the amendments would still affect many types of responsible parties who need to address vanadium contamination under Chapter 250. The Department expects the impact of the proposed updates to Chapter 250 to be insignificant on persons and businesses attempting to complete the remediation process under Chapter 250.

Please also see the response in Section 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 proposed amendments to the Statewide health MSCs reflect the latest toxicological data regarding human exposure to vanadium. 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 proposed rulemaking will benefit all individuals in the Commonwealth. The proposed amendments to the Statewide health MSCs reflect the latest toxicological data on human health effects that can occur when humans are exposed to vanadium. 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 proposed rule are property owners who plan to remediate contaminated land, neighbors living or working in close proximity to a contaminated brownfield site, remediators and developers who want to purchase, remediate, and build on a contaminated brownfield site, and others.

The Department anticipates the proposed amendments to Chapter 250 will not induce negative economic impacts because the proposed MSCs more accurately align with exposure risk and remedy impracticable remediation requirements for sites where existing vanadium standards are lower than naturally occurring concentrations. The update to the vanadium toxicity value results in increases to the groundwater, soil direct contact, and soil-to-groundwater numeric values. These proposed numeric value increases reflect updated scientific information related to the toxicity of vanadium and accurately align with the risk from exposure.

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

The Department believes that any potential impacts to the regulated community would be insignificant. Further, the proposed updates to Statewide health standard MSCs would not affect a remediator's ability to choose one or a combination of cleanup standards.

Please also see the response to Question 10.

(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 proposed rulemaking. The benefits include protecting the public with updated MSCs that reflect the latest toxicological data for vanadium and add new MSCs for vanadium. The proposed amendments also helps to streamline Act 2 remediations.

These benefits outweigh any costs and adverse effects of the proposed rulemaking, which the Department expects to be insignificant.

The proposed amendments to the Statewide health MSCs reflect the latest toxicological data on human health effects that can occur when humans are exposed to vanadium. Updating the MSCs in this manner

provides assurance that the MSCs are protective of human health to potentially affected individuals, including residents, large and small businesses, and other organizations interested in buying and redeveloping contaminated sites.

The Department does not anticipate adverse financial impacts from this proposal. While the update to the vanadium toxicity value results in increases to the groundwater, soil direct contact, and soil-to-groundwater numeric values, these proposed numeric value increases reflect updated scientific information related to the toxicity of vanadium and accurately align with the risk from exposure.

The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth each year.

The cost impact on a given site remediation would 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.

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 vanadium toxicity value results in increases to the groundwater, soil direct contact, and soil-to-groundwater numeric values. These proposed numeric value increases reflect updated scientific information related to the toxicity of vanadium and accurately align with the risk from exposure.

The number of completed remediations vary each year. On average, remediators apply the Act 2 remediation standard to approximately 800 contaminated properties across the Commonwealth. 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 proposed rulemaking would 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.

Local governments are not expected to incur costs or savings due to the proposed amendments. 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.

State government is not expected to incur costs or savings due to the proposed amendments. 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 proposed amendments to Chapter 250 do not require any additional recordkeeping or paperwork. No new or revised forms or reports are required.

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

No new or revised forms or reports are required.

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

No new or revised forms or reports are required.

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

This amendment is not expected to impact costs but may result in savings.

	Current FY 2021-22	FY +1 2022-23	FY +2 2023-24	FY +3 2024-25	FY +4 2025-26	FY +5 2026-27
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

*The estimated fiscal savings associated with the implementation and compliance with the proposed regulation is infeasible to calculate because each remediation is highly variable due to site-specific conditions and the number of completed remediations vary each year.

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

Program	FY -3 2018-19	FY -2 2019-20	FY -1 2020-21	Current FY 2021-22
Environmental Protection Operations 160-10381	\$93,190,000	\$84,023,000	\$94,202,000	\$98,036,000
Environmental Program Management 161-10382	\$30,932,000	\$27,920,000	\$32,041,000	\$34,160,000
Industrial Land Recycling Fund 689-60080	\$257,000	\$273,000	\$282,000	\$618,000
Hazardous Sites Cleanup Fund 202-20070	\$23,062,000	\$24,000,000	\$24,000,000	\$24,000,000
Storage Tank Fund 210-20073	\$4,484,000	\$3,563,000	\$4,300,000	\$3,986,000

(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 proposed rulemaking include industrial and commercial facilities that use vanadium and redevelopers of brownfield sites. Small businesses account for a portion of the commercial facilities that use vanadium. Chapter 250, and this proposed rulemaking, have the potential to impact a broad universe of businesses, persons, and organizations, any of which may need to address contamination at any given time. Because of the application of Chapter 250, the Department cannot identify further specifics on the types and numbers of small businesses that would potentially be affected by property contamination. Act 2 and Chapter 250 are unique from other statutes and regulations because they do not create permitting or corrective action obligations. Instead, Act 2 and Chapter 250 provide remediators options to address contamination and any associated liability that arises under other statutes. Changes to the numeric values in the Chapter 250 Appendix does 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 provides the means to resolve the liability imposed by those statutes 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 in the way that a new permitting obligation or corrective action regulation would.

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

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

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

See the response to Question 15 above.

Small businesses that handle hazardous substances can use pollution prevention techniques available through various assistance programs to prevent spills that would result in contamination of soil and groundwater. In addition, background and site-specific cleanup standards are available and not affected by the proposed updates to the Statewide health 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 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 proposed rulemaking, which is to update the vanadium MSCs based on current scientific information. Background and site-specific cleanup standards are available alternatives to the regulated community and would not be affected by the proposed updates to the Statewide health MSCs in this proposed rulemaking. As discussed above in the responses to Questions 9, 10, and 14, Act 2 requires that the Board and the Department evaluate data related to current MSCs and 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 proposed amendments to Chapter 250 are not expected to adversely impact the needs of the listed groups and as a result, this proposed rule does not include special provisions for their behalf. However, individuals identifying with these groups benefit from the implementation of MSCs, which protect human health and reduce the threat of exposure to sites with existing contamination. Please see the responses to Questions 15, 17, and 24 regarding expected impacts of this proposed 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 are required by statute and regulation, have been selected. The amendments in this proposed 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 that already

exist in Chapter 250 and would not be affected by the proposed updates to the Statewide health MSCs in this proposed rulemaking.

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

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

The proposed amendments are expected to have an insignificant impact on small businesses; therefore, no regulatory methods were considered to minimize adverse impacts.

(a) This proposed 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 19(a).

(c) Please see the response to Question 19(a).

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

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

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

Act 2 and the Chapter 250 regulations require the periodic evaluation of the MSCs. In this proposed rulemaking the Department based its 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, and Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles.

This information is published by the EPA (https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha) and (<https://hhpprtv.ornl.gov/>), the United States Centers for Disease Control (<https://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.

Additional information can be accessed at:

EPA's Integrated Risk Information System (IRIS) Database, <https://www.epa.gov/iris>, for the vanadium toxicity information was used to determine the proposed vanadium toxicity value.

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

- | | |
|---|--|
| A. The length of the public comment period: | <u>30 days</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>None planned</u> |
| C. The expected date of delivery of the final-form regulation: | <u>Quarter 2, 2023</u> |
| D. The expected effective date of the final-form regulation: | <u>Upon publication in the Pennsylvania Bulletin</u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>Upon publication in the Pennsylvania Bulletin</u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>Not applicable</u> |

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

The Department regularly evaluates the continuing effectiveness of Chapter 250 as required by 25 Pa. Code § 250.11. The Department must regularly review new scientific information that relates to the basis of the MSCs and 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 Department's efforts in this regard include ongoing tracking of remediations completed under the program and annual preparation of a program report.