Final Report:

Part 201: Stakeholder Recommendations for Updating Michigan's Generic Cleanup Criteria

November 2014

Prepared for
Director Dan Wyant
Michigan Department of Environmental Quality

Submitted by
Public Sector Consultants
Lansing, Michigan
www.pscinc.com

Under the direction of
Criteria Stakeholder Advisory Group (CSA)

With assistance from
Michigan Department of Environmental Quality
Michigan Department of Community Health

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Background

In March of 2014, the Michigan Department of Environmental Quality (MDEQ) hired Public Sector Consultants Inc. (PSC) of Lansing, Michigan, to facilitate a public involvement process to review and make recommendations related to the generic cleanup standards contained in the administrative rules promulgated under Part 201 of the Michigan Natural Resource and Environmental Protection Act. Numerous activities have been undertaken over the last four years related to updating the Part 201 generic cleanup criteria.

Summary of Part 201 Cleanup Criteria Actions Since 2010

In 2010, the Michigan Legislature amended Part 201 to require, among other things, that the MDEQ update the cleanup criteria rules within two years of the legislation's effective date to take into account recent scientific information. In addition, in 2011, Michigan's Office of Regulatory Reinvention reinforced the legislative mandate and recommended updating the cleanup criteria rules. In 2012, the legislature extended the deadline for revising the cleanup criteria rules to December 31, 2013. The MDEQ initiated a stakeholder process in 2012 thorough the Collaborative Stakeholder Initiative to improve and reinvent the cleanup program including updates to the cleanup criteria rules. Important progress was made during this stakeholder process that lead to adoption of significant amendments to Part 201, including the adoption of best practices. It also resulted in the rescission of most of the very prescriptive Part 201 Rules. However, many issues related to the cleanup criteria remained unresolved even after a second stakeholder process was undertaken in 2013. Although a criteria-related rule package and generic criteria for 309 hazardous substances were promulgated on December 30, 2013, most updates to the cleanup criteria have not been implemented. Ultimately, through the Joint Committee on Administrative Rules, the state legislature directed that the MDEQ update cleanup criteria.

Selection of the Criteria Stakeholder Advisory Group

PSC proposed a stakeholder involvement process, which was subsequently approved by MDEQ, that would engage a group with diverse interests representing business/industry, environmental organizations, state/local government, private environmental consultants/attorneys, university scientists, and local/state government officials who had a direct stake, implementation experience, or scientific knowledge related to cleanup standards. PSC advised the MDEQ on potential candidates and Dan Wyant, director of the MDEQ, appointed members in what became known as the Criteria Stakeholder Advisory Group or CSA (see Exhibit 1).

Director's Charge to the CSA

In the CSA's initial meeting on March 6, 2014, Director Wyant laid out the charge to the group. The CSA was to initially determine if the generic cleanup criteria under Part 201 needed to be updated. If it decided that an update was needed, then the CSA was to identify the guiding principles that should be used as the basis for updating the criteria, and apply the principles to select sources for toxicological and chemical/physical aspects of hazardous substances as well as appropriate exposure assumptions. In addition, Wyant charged the CSA with proposing how and at what frequency the generic cleanup criteria should be updated in the future. Wyant indicated that the MDEQ would cooperate and provide assistance to the CSA in its deliberations and that PSC would provide technical and administrative support and facilitation for the CSA. However, Director Wyant emphasized the recommendations would only be those of the CSA members. While he acknowledged that he had the ultimate responsibility to initiate changes to the cleanup criteria, Wyant indicated he would place great weight on consensus recommendations of the CSA.

Criteria Stakeholder Advisory Group Members

Exhibit 1 details the CSA membership:

EXHIBIT 1. CSA Members*

Industry		
Auto	Ed Peterson	General Motors
Energy	Ravi Adibhatla	Consumers Energy
Chemical	Rob Rouse	Dow Chemical
Resource Extraction	Kristen Mariuzza	Lundin Eagle Mine
Office of Regulatory Reinvention		
Environmental Advisor Rules Committee	Troy Cumings	Warner, Norcross & Judd LLP
Environmental		
Environmental Consulting	Brad Venman	NTH Consultants
Environmental Consulting	Karen Hathaway	Horizon Environmental
Environmental Group	James Clift	Michigan Environmental Council
Public Health		
Michigan Department of Community Health	Dr. Corinne Miller	Bureau of Epidemiology
Academia		
Toxicology/Environmental Science	Dr. James Trosko	Michigan State University
Local Unit of Government	Matt Naud	City of Ann Arbor

*Two additional CSA members were initially appointed but were unable to participate when the original target completion date was substantially extended.

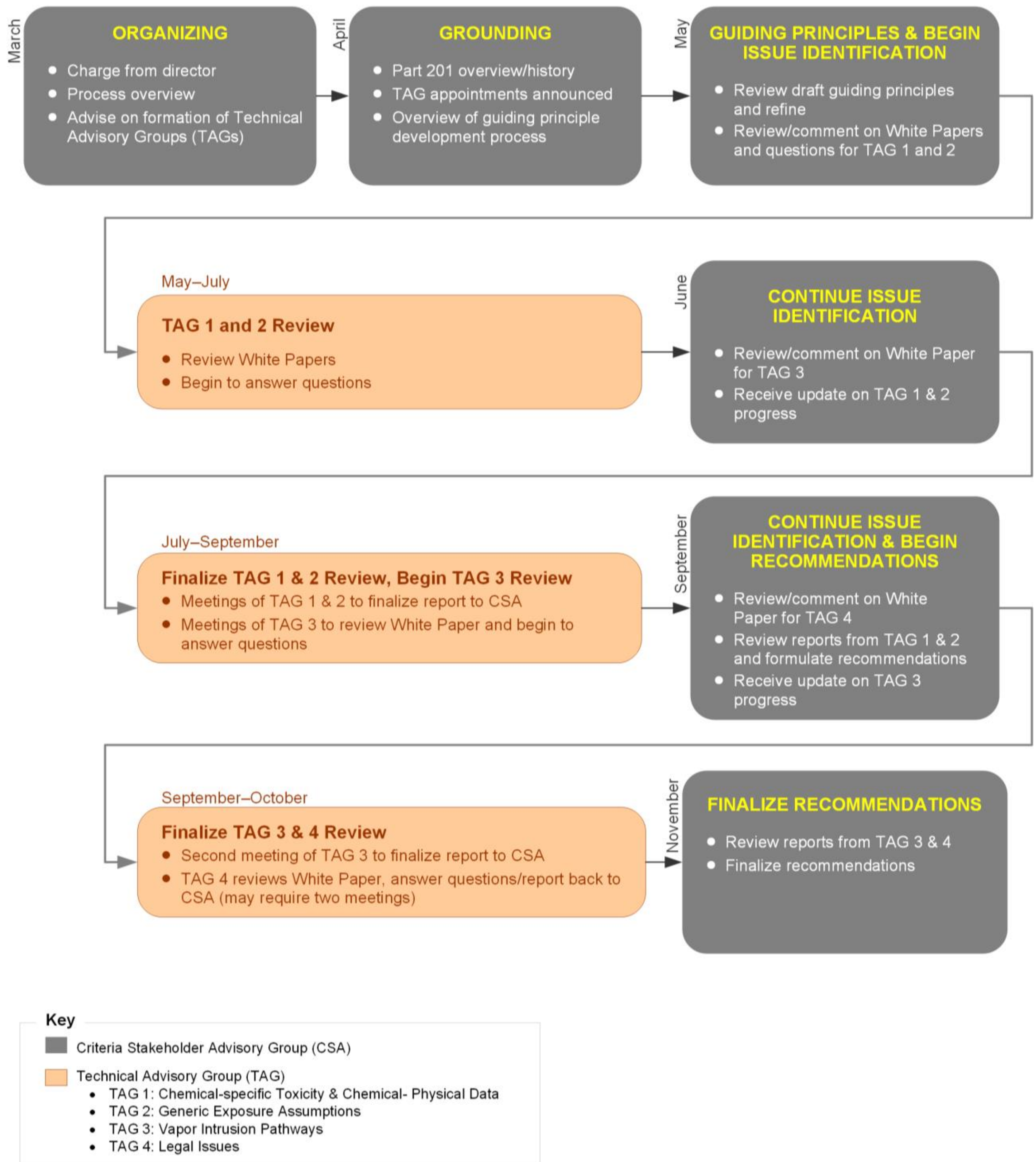
Operating Procedures of CSA and Technical Advisory Groups

At its second meeting, the CSA reviewed and recommended changes to the operating procedures proposed by PSC. The final procedures established that the CSA would operate on the basis of consensus recommendations agreed on by a supermajority, which required seven of 11 members concurring. Dissenting opinions from consensus recommendations would be noted in the final report and an opportunity given to provide reasons of opposition. The CSA participated in the selection of four Technical Advisory Groups (TAGs), the first three of which related to the joint Administrative Rules Committee directive, namely in the areas of: (1) chemical/physical and toxicological properties; (2) exposure pathway assumptions; and (3) vapor intrusion. A final, fourth TAG was formed to address various legal issues that were expected to arise with the final recommendations. The legal TAG was comprised of two members from the CSA, a representative of the Michigan Attorney General, and a private sector law firm. The CSA provided questions to the legal TAG and its responses are attached as Appendix D to this report.

With recommendations from PSC, CSA members, and the MDEQ, four to seven members were appointed by MDEQ to each TAG to create a diverse group of academic, public agency, and private consulting technical experts. Preference was given to individuals who had previously participated in generic criteria reviews. The CSA reviewed White Papers prepared by PSC on the first three TAG issues and approved questions that were transmitted to TAGs 1, 2, and 3. Unlike the CSA, the TAGs were not directed to reach consensus proposals or responses to the CSA, but rather provide a range of responses to the CSA questions if unanimity was not possible. The meetings of the four technical TAGs were facilitated by PSC, who also prepared the reports for the final approval of each TAG.

Exhibit 2 summarizes the public involvement/stakeholder process that was used to generate the recommendations by the CSA included in this report.

EXHIBIT 2. MDEQ Part 201 Stakeholder Process



Introduction

In March 2014, the CSA—comprised of industry, academia, government, and nonprofit representatives (see Exhibit 1)—was convened to review the existing rules and determine if the generic cleanup criteria should be updated. If the CSA concluded the criteria should be updated, it was charged to: (1) identify guiding principles to base criteria updates on; (2) apply those guiding principles in the selection of exposure assumptions used in updating the criteria, and; (3) provide recommendations for updating the toxicological and chemical/physical aspects of the cleanup criteria in Part 201 rules.

The CSA has concluded that the criteria in Part 201 rules should be updated. In addition to responding to the specific charges outlined above, the CSA believes statements on the following points need to be considered when the MDEQ reviews the CSA recommendations included in this report:

- Purpose and use of generic cleanup criteria
- Comparison of Michigan cleanup criteria to nearby states
- Encouraging site-specific cleanups
- Improved public communication of Part 201 requirements

In some cases, the following statements contain underlying assumptions that the CSA established as a common framework for evaluating options. In other cases, these statements helped the CSA describe their collective view on how the program is understood by this group of diverse stakeholders who have been actively engaged in the application of Part 201 throughout the state for several years and/or have specific experience/expertise on how to evaluate the risks associated with reuse of contaminated sites. For one statement, encouraging site-specific cleanups, the CSA believes that with expanded opportunities for site-specific cleanups, many of the past concerns and issues related to Michigan's generic cleanup criteria can be appropriately addressed.

Purpose and Use of Generic Cleanup Criteria

Generic cleanup criteria are used for a variety of purposes under Part 201, but most importantly, the criteria are designed to provide protection of public health and the environment. Generic cleanup criteria remain a valuable tool for the property transaction process to assess liability risk related to the potential presence of hazardous substances. Generic criteria are also used by property owners and responsible parties to remedy the potential for unacceptable human or natural resource exposure to hazardous substances by meeting acceptable MDEQ standards. Generic criteria, when used alone or in combination with engineering controls, provide an important level of certainty and simplification to the regulatory process for those seeking to return brownfield property to productive use.

Comparison of Michigan Cleanup Criteria to Nearby States

Due to differing purposes and regulatory processes, it is difficult to compare Michigan's cleanup standards to those of other states or the U.S. Environmental Protection Agency (EPA). The EPA and other states use conservative standards as an initial screening tool to determine if additional action should be taken at a site. If it is determined that further actions must be taken, they use site-specific assessments to define the measures needed to ensure protection of public health and the environment. These site-specific cleanup measures may not be as restrictive as the initial screening criteria based on the potential for exposure.

Only Michigan uses the generic cleanup criteria under Part 201 in the property transfer process to assess a prospective purchaser's potential transactional liabilities as well as all other responsibilities and requirements under the statute. Additionally, only Michigan uses generic cleanup criteria as final cleanup numbers if a site-specific option is not pursued. Simply adopting the conservative, initial screening criteria used by other states and the EPA for Michigan's generic cleanup criteria without modification could result in the expenditure of excess time and resources for minimal, if any, additional benefit to public health or the environment. Thus, for example, one recommendation in this report is to expand the data sources used for exposure assumptions in Michigan's generic cleanup criteria from national averages that are used by other states and the EPA, to include Michigan or regional data that better reflect actual conditions in Michigan when possible.

It is critically important during this reevaluation of the Part 201 rules that the generic cleanup criteria be appropriately calibrated to ensure that sites of real concern are identified and addressed—and that sites with minimal potential for public health or environmental harm are not inadvertently brought into the Part 201 process. Incorporating sites into Part 201 with very low or no risk to public health and the environment reduces the public resources needed to address those sites that pose a significant threat, and places Michigan at an economic disadvantage compared to other states in private sector investments available for the redevelopment of brownfield properties.

Encouraging Site-specific Cleanups

Given the variability of facilities and use-specific conditions in Michigan, further state actions need to be taken to make site-specific cleanups more viable by reducing the uncertainties with MDEQ's approval process, and the time and costs required to prepare and review applications.

Improved Public Communication of Part 201 Requirements

Part of the problem in effectively communicating Michigan's Part 201 cleanup requirements is due to the public confusion over the terms used to describe cleanup standards in the statute and rules. While these terms as defined in Part 201 have sound legal justification and precedent, they are nonetheless often misunderstood by the general public. The term "generic cleanup criteria" creates an expectation and assumption that any cleanup level that exceeds the generic numerical value is not sufficiently protective. The term "site-specific cleanup criteria" can suggest that a standard less protective than the generic cleanup number is being applied. Both generic and site-specific criteria provide for protection of public health and the environment, and either cleanup criteria can be used to:

- Determine whether a property is considered a "facility" as defined in Part 201 and thus subject to the statute's requirements
- Trigger additional site characterization and/or response activities
- Establish final cleanup values

When describing generic criteria cleanup levels to the general public, the MDEQ should use terms like "response screening levels" (RSLs), "response activity screening criteria" (RASC) or similar terms that more accurately reflect how generic criteria are generated and applied.

The use of a more descriptive term could better communicate to the public the protective exposure assumptions (and the related uncertainties) used to calculate the generic Part 201 screening levels. In addition, a more descriptive term would reinforce with local and state government officials, MDEQ staff, affected businesses, and the public that site-specific limited closures are as protective of the public health, safety, welfare and environment. Improved risk management communication can help support the MDEQ's risk management decision making and the credibility of Part 201 screening levels while acknowledging the limitations of generic criteria.

Guiding Principles

The Criteria Stakeholder Advisory Group provided a series of questions to each of the four TAGs appointed by MDEQ. In some cases, the TAGs outlined guiding principles the individual TAGs used to develop its proposals to the CSA.

The following guiding principles were prepared by the CSA prior to receipt of the specific TAG reports. This was completed as the first step in the evaluation of proposed changes in the approach and/or assumptions used to generate revised generic cleanup criteria. Similar principles developed by the TAGs are more specific, but in general the CSA believes the principles cited by the TAGs are consistent with the following guiding principles adopted by the CSA:

- The chemical/physical data, and toxicity values used for developing the criteria need to be based upon the best available, soundest scientific information—the sources of which are widely recognized reference documents.
- The process used for the selection of national or international databases needs to be clearly identified. Any decisions to use the data from certain studies and not others (or in some cases the blending of study results) needs to rely on sound science and be transparent enough for an independent reviewer to readily determine how final values were developed.
- Exposure assumptions used to develop the generic criteria need to be reasonable and practical and, where reliable data exist, be based upon regional (or preferably Michigan-specific) data where feasible, rather than national data. Where variations in input parameters are known for different regions of the state, either by historic data or proven studies, the rules should allow for adjustments to the generic criteria. Alternatively, multiple criteria could be calculated using the various applicable ranges of input data and the user would select the appropriate criteria based on their site location.
- The generic cleanup criteria need to be protective of public health and natural resources such that there are no unacceptable exposures to hazardous substances. Generic criteria are to be protective of the most sensitive toxic effect in a given exposure pathway for the hazardous substance in question. It is important to recognize the relative risk of the specific hazardous substance compared to those of the risks routinely encountered by people.

Recommendations

The recommendations of the Criteria Stakeholder Advisory Committee are in four parts. The first three are responsive to the specific proposals from the three Technical Advisory Groups in the areas of proposed changes: chemical-specific toxicity and chemical/physical data (TAG 1); generic exposure assumptions (TAG 2); and vapor intrusion pathways (TAG 3). The last set of recommendations from CSA respond to the MDEQ director's charge to propose a process for periodic future generic cleanup criteria updates, which resulted in the formation of a legal group (TAG 4).

Unless otherwise noted, each recommendation was unanimously supported by all CSA members. In the event a member did not support the recommendation, the member was given the opportunity to provide a brief explanation of their dissent in the report. If a proposed recommendation did not receive supermajority support of CSA members (seven out of 11 members), no single CSA recommendation is made and alternatives are presented for consideration in the TAG reports. In each case, the full TAG reports are appended as adopted by the TAG members. The CSA final consensus recommendations use the same numbers as the TAG 1 and TAG 2 reports, preceded by the TAG number (as an example, the final CSA recommendation 1.3 responds to recommendation number 3 in the TAG 1 Report). The CSA did not take any action to approve or disapprove the final report of each TAG that are appended, but did review the three reports with representatives of each TAG. The CSA did, however, address each numbered recommendation contained in the TAG reports. In the case of TAG 3 (vapor intrusion) the CSA endorsed the process outlined in the final TAG 3 Report.

Chemical-specific Toxicity and Chemical/Physical Data (TAG 1)

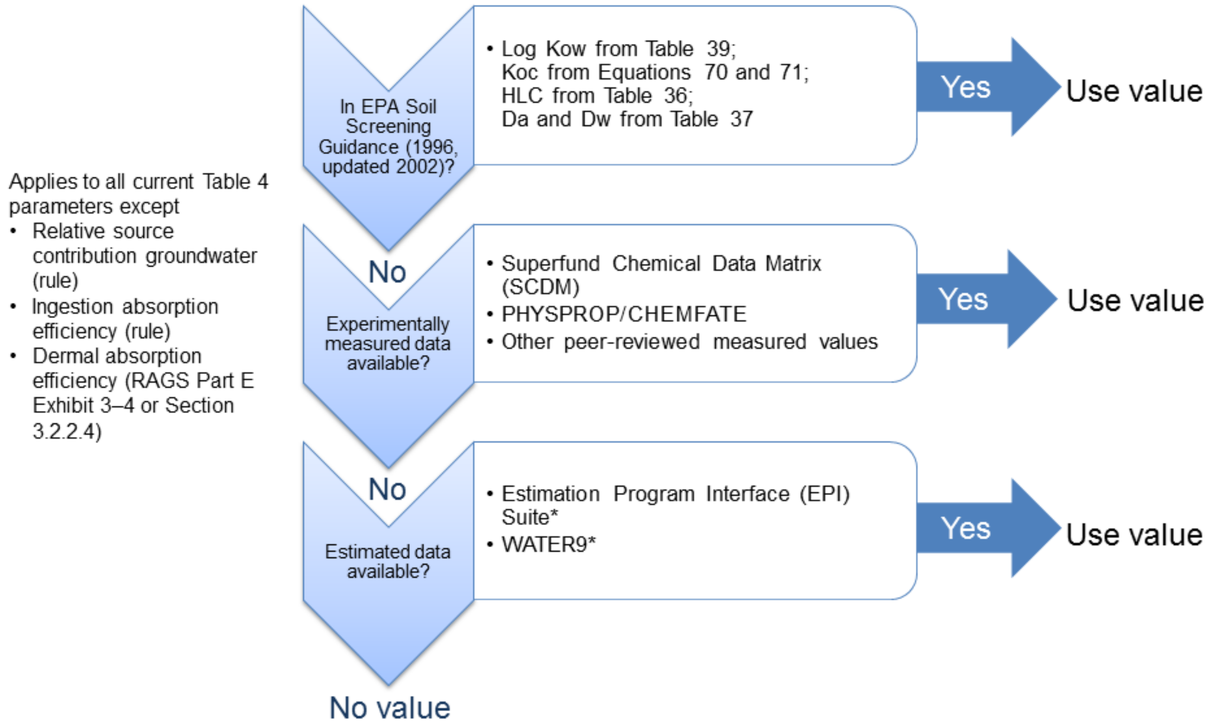
TAG 1 met six times in June and July 2014 to review, discuss, and develop responses and proposals related to nine questions that were outlined in the Chemical-specific Toxicity and Chemical/Physical Data White Paper prepared by PSC with review and comment from the CSA. The appended TAG 1 Report provides details on the questions, responses and discussion as well as proposals for consideration by the CSA on the chemical/physical parameters and toxicity data used to derive Part 201 generic criteria. There were a total of 12 proposals developed by TAG 1 for consideration by the CSA and the following represent the CSA consensus recommendations to MDEQ.

Recommendation 1.1

The CSA has reviewed the proposed TAG 1 decision frameworks with respect to toxicity and chemical/physical parameters (TAG 1 Appendices A and B) and recommends that the framework proposed for toxicity values (TAG 1 Appendix B) be adopted by MDEQ with the following exception: the "MDEQ Value (existing)" be removed from Tier 1 (TAG 1 Appendix B) and maintained in Tier 4 to better reflect the CSA's opinion that it is a very rare instance when a toxicity value would need to be independently evaluated and changed by MDEQ. There are other established peer-reviewed sources for toxicity values, and an independent MDEQ evaluation would only be appropriate in those situations where other toxicity sources had not had the opportunity to complete a timely update based upon widely recognized, new scientific information.

After review of the changes proposed by TAG 1 to the current method for determining chemical/physical parameters, the CSA recommends continued use of the current method (existing data sources) for these parameters as shown in Exhibit 3.

EXHIBIT 3. CSA Alternative: Chemical/Physical Value Decision Framework



*Estimated values should be derived using the above estimation program(s), or programs that supersede these programs, e.g., WATER9 replaced WATER8 subsequent to the publication of the SSG.

Recommendation 1.2

The MDEQ should include a short reference for each value and chemical/physical parameter in Table 4 of the generic criteria rules that identifies the source of the values and that also indicates, when relevant, whether physical parameters are measured or modeled. A more detailed explanation of the reference could be stored in a separate table or other resource, as this would give each value greater transparency. A similar model is being used by the Ministry of the Environment and Climate Change in Ontario, Canada, and the MDEQ should consider this format while designing its updated tables.

Recommendation 1.3

The MDEQ should provide more opportunity for stakeholders to give feedback on what data and methodology could be considered in selecting parameters or developing toxicity values when the MDEQ determines it is necessary for the agency to develop such values.

Recommendation 1.4

When administrative rules are updated, the inhalation toxicity terms in the VSIC, PSIC, GVIIC, and SVIIC equations and relevant rule language should be changed to allow the MDEQ the flexibility to select inhalation toxicity values that differ from those developed by the MDEQ's Air Quality Division (AQD), considering best available science and practices. The MDEQ's Remediation and Redevelopment Division (RRD) staff should not have to evaluate all inhalation toxicity values, though some attention should be given to those that are based upon the AQD's most minimal data requirements at the time they are evaluated. Inhalation toxicity value reference sources should be included in Table 4 in the rules.

Recommendation 1.5

The MDEQ should adopt the CSA modified decision framework previously identified in Exhibit 3.

The Michigan Environmental Council's (MEC) representative on the CSA does not support this consensus recommendation. That representative's view is that the proposed rule should not dictate which source the MDEQ must use when deriving chemical/physical values. The department should be authorized to use the guiding principles outlined in Recommendations 1.8 and 1.12 to decide which source is the most appropriate for deriving a specific value. Therefore, the department should be able to deviate from the hierarchy set forth in the chemical/physical value framework if they clearly articulate the reason(s) they find an alternative source of information to be more appropriate.

Recommendation 1.6

The MDEQ should utilize the chemical update worksheet (Appendix D in the appended Tag 1 Report) to collect information and as a communication tool, a Web-friendly version (e.g., a PDF) should be placed on the MDEQ website.

Recommendation 1.7

The CSA believes that the tiered approach as recommended by TAG 1 adequately addresses the use of international data sources when North American data sources do not provide adequate information on specific chemicals.

Recommendation 1.8

The CSA concurs with data sources supported by TAG 1 for chemical/physical parameters and toxicity values consistent with the fundamental data source characteristics presented below, with one exception noted (these characteristics are consistent with, and in many cases more detailed than, the guiding principles adopted by the CSA cited earlier in this report). Note that the CSA changed the TAG 1 report subheading to "Consistency" rather than "Comprehensive" and modified the description that follows that subheading to reflect its belief that it is more important that data sources be consistent rather than just more comprehensive.

Peer-reviewed—Every effort should be made to identify and use peer-reviewed data sources populated with information that has been developed using the best available science and practices. Scholarly review by experts in the field ensures data meet necessary quality standards prior to publication.

Subject to notice and comment—Toxicity values that are developed by non-MDEQ sources through a process that allows public review and comment are preferred. (Note: It is desirable to allow affected stakeholders [and affected Michigan citizens and regulated community members] input when changing Table 4 values.) In general, chemical/physical data do not undergo public review and comment procedures.

Derived through relevant and accepted methods—Priority should be given to sources that provide chemical/physical and toxicity data based on similar methods as those used for Tier 1 and Tier 2, contain values which are peer reviewed, available to the public, and transparent about the methods and processes used to develop the values.

Consistency—To help ensure greater consistency of the data used in developing the risk-based values for chemical/physical or toxicity data, the MDEQ should utilize sources that use consistent methods between sources for development of the data. This helps to assure greater consistency of the data used in developing the risk-based values.

Credible data—Sources that are respected and trusted by the international scientific community are preferred.

Regularly maintained—Science evolves. Regular review and updating of the chemical toxicity information will ensure that it represents the best available science and practices in that field. For example, two recent guidance documents are good resources to consider in selection or development of toxicity values: EPA Framework for Human Health Risk Assessment to Inform Decision Making, and National Research Council (2014) Review of EPA's Integrated Risk Information System (IRIS).

Based on experimental data—Chemical data presented in scientific literature and the many compiled documents and database resources can vary in method of derivation. Experimental chemical/physical data, where relevant to applied environmental conditions, are preferred over extrapolated, modeled, or estimated data. Similarly, experimental toxicity data are preferred, with the understanding that the scientific field is moving away from traditional, whole-animal experimental studies to higher throughput and less resource-intensive in vitro, array, and computer-based toxicity data.

Recommendation 1.9

Age-dependent adjustment factors (ADAFs) should be used with toxicity values for those carcinogens identified as mutagenic by the EPA or any agency/scientific body, as long as it is conducted in accordance with EPA guidelines on identifying mutagenic mode and evaluated by the MDEQ.

Recommendation 1.10

The MDEQ should first determine whether a chemical is considered carcinogenic to humans by the EPA and International Agency for Research on Cancer (IARC). If it is to be regulated as a carcinogen, then potential route-specific differences in carcinogenicity should be considered and evaluated. If it is non-carcinogenic, then only the reference dose (RfD) and reference concentration (RfC) candidate values would be assembled to select an RfD and an RfC.

Recommendation 1.11

The criteria should be footnoted to denote whether the carcinogenic or non-carcinogenic algorithms are used to calculate the final criteria for a chemical.

Recommendation 1.12

Deviation from EPA methodology should be allowed where there is good information to suggest that the EPA's methodology or data are not consistent with current best science. When these modifications are made by the MDEQ, there should be an opportunity for public input and comment.

Note: TAG 1 did not prepare a recommendation to Question 8 which stated, *"Should an independent evaluation (by the MDEQ) of the chemical-specific data be conducted even if a value is published in the primary database of the hierarchy?"* In the written response to the question, however, TAG 1 indicated that MDEQ should be able to perform independent evaluations of a value published in the primary database of the hierarchy. While the CSA agrees, it wants to point out that is the CSA's opinion that it is a very rare instance that an IRIS toxicity value would need to be independently evaluated and changed by MDEQ. Since there is an established EPA process for updating IRIS toxicity values, it would only be under those conditions where EPA did not have the resources to complete a timely revision that was supported by widely recognized, new scientific information.

Generic Exposure Assumptions (TAG 2)

TAG 2 met eight times from June to September 2014 to review, discuss, and develop responses and recommendations related to 11 questions that were outlined in the White Paper prepared by PSC and reviewed by the CSA. Those questions addressed generic exposure pathway assumptions used to derive Part 201 generic criteria. PSC's White Paper served as the framework for the TAG's discussions. The attached TAG 2 Report—Updating Exposure Pathway Assumptions and Data Sources—presents the TAG's discussions, findings, and recommendations. There were a total of 14 proposals developed by TAG 2 for consideration by the CSA, and the following represent the CSA recommendations to MDEQ.

Recommendations 2.1, 2.2, and 2.3

The CSA recommends the following as the appropriate receptors, guidance, and descriptive language to use for residential land use generic criteria:

2.1: Receptor: Use an age-adjusted child plus adult receptor that, at present, assumes exposure across two age bins, except in the case of developmental toxicants.

2.2: Guidance: Use EPA information to develop a process to account for those chemicals, or classes of chemicals, that have documented developmental or reproductive effects.

2.3: Descriptive Language: Use current Part 201 rules (R299.49 (DD)) that allows the agency to regulate developmental and reproductive toxicants to protect sensitive subpopulations from these substances on a chemical-specific basis. For developmental and reproductive toxicants, the MDEQ should evaluate if the age-adjusted child plus adult receptor is protective of childhood and early-life-stage exposures on a chemical-specific basis.

Recommendation 2.4

Age-dependent adjustment factors for the chemicals recommended by the EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, March 2005 (and most recent updates) should be used to address early-life exposure from mutagenic carcinogens.

Recommendation 2.5

A periodic review of the list of mutagenic chemicals should be included in the criteria update process to ensure that the MDEQ uses updated information, reflecting the best available science and includes additional mutagenic carcinogens as they are identified by EPA.

Recommendation 2.6

The MDEQ should consider the impact of Part 201 generic criteria on other programs such as drinking water programs. For example, the Michigan Safe Drinking Water Act or SDWA (1976 PA 399) does not recognize a distinction between residential and other drinking water standards. A chemical-specific drinking water standard, currently established by the SDWA, applies to water for both residential and nonresidential use.

Recommendation 2.7

For all updated values, the TAG recommends a process and decision framework for selection of the generic exposure assumptions that is transparent and provides opportunities for meaningful public input.

Recommendation 2.8

The CSA recommends a process for publicly reviewing and updating the algorithms and exposure parameters for generic cleanup criteria once every three years or less, consistent with the legal requirements for the promulgation of administrative rules and adequate opportunity for public review and comment. The specific alternative processes for updating are outlined in the appended Legal TAG 4 Report.

Recommendation 2.9

The CSA supports the use of data sources for the generic exposure assumptions for reasonable and relevant scenarios that best meet the fundamental data source characteristics as follows, herein referred to as Data Quality Objectives (DQOs).

Relevant and Applicable to Michigan: The extent to which the information is relevant and applicable to Michigan generic criteria development (e.g., representative of Michigan population and conditions, currency of the information, adequacy of the data collection period).

Clear and Comprehensive: The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented.

Sound and Credible: The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information is reasonable for, and consistent with, the intended application, and are regularly maintained, subject to peer review, and the best available science.

Transparent and Objective: The data are published or publicly available and free from conflicts of interest.

Certainty: The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized, including peer review and agreement of studies.

Recommendation 2.10

The CSA recommends evaluating Michigan-specific data, EPA sources, and other sources against current generic exposure values to select values that best meet the DQOs and consistent with the decision framework.

Recommendation 2.11

The CSA recommends using Michigan-specific data to generate values for the exposure parameters when it is available and best meets the DQOs.

Recommendation 2.12

As a starting point, the CSA recommends the use of the identified values TAG 2 presents in Table A (Appendix B) of its report, and the use of the decision framework proposed by TAG 2 to establish and confirm values for all exposure factors, including those recommended by the TAG 2.

Recommendation 2.13

The CSA recommends that the MDEQ include the basis and percentile for each value presented in Tables A and B of the TAG 2 report.

In addition, the CSA recommends that MDEQ continue to evaluate and actively pursue the use of probabilistic approaches to ensure that the combination of exposure factors eventually selected for an exposure scenario represents a reasonable maximum exposure (RME). Specifically, the CSA recommends that prior to seeking public input on any generic residential or nonresidential exposure scenario and its corresponding exposure factors, a probabilistic analysis be used to assess the validity of the final combination of selected point-estimate exposure factors, where feasible.

Recommendation 2.14

To the extent possible, the CSA recommends that the MDEQ provide a detailed description of each value in a technical support document that includes DQOs, citations, and calculations.

Vapor Intrusion Criteria (TAG 3)

TAG 3 met four times between July and September 2014 to review and discuss the vapor intrusion investigation process under Part 201. Following review by the CSA, Public Sector Consultants provided the TAG with a White Paper on vapor intrusion regulatory issues. The White Paper included five questions for the TAG to address in their deliberations.

In answering these questions, the TAG concluded, and the CSA agrees, that the vapor intrusion criteria and guidance under Part 201 should be revised.

Recommendation 3.1

The CSA recommends that the MDEQ use a tiered approach as the most appropriate process to investigate whether or not there is a vapor intrusion pathway that poses an unacceptable risk.

Recommendation 3.2

The CSA accepts and encourages MDEQ to adopt the investigative approach detailed in the series of exhibits provided in the TAG 3 report endorsed by all TAG 3 members.

Key Legal Issues for Updating Generic Cleanup Criteria (TAG 4)

TAG 4 reviewed the legal options for updating generic cleanup criteria under Part 201. The TAG members agreed upon the following general principles:

- The need to expand public participation and review of proposed changes
- A publicly announced time frame to establish the frequency of future updates
- Timely opportunities to allow changes in cleanup criteria that reflect new scientific information

TAG members did not achieve consensus on whether just the algorithms alone, or specific criteria (i.e., Table 4) and periodic updates to criteria, need to be established by rule. Generally, the TAG agreed that the Administrative Procedures Act (APA) would likely need to be followed, but to what degree was debated. On the question of the algorithms, criteria, and updates, two opinions from TAG 4 are presented for consideration by the CSA:

Opinion (Alternative) 1: Place the algorithms, inputs, and resulting tables into the rules (including future updates to inputs) pursuant to Part 201 and the APA.

Although Section 20120a does not explicitly state that the MDEQ must establish cleanup criteria through rules, other sections of Part 201 show the legislature's intent that the MDEQ should do so. Further, following the rule-promulgation process to establish criteria is likely required by the APA. Every court to analyze the definition of a "rule" under the APA has held that the term is to be read broadly, while any exceptions are to be read narrowly. The current state of the law, interpreting the one exception that is potentially relevant (although the cases are somewhat inconsistent), likely would lead to the conclusion that the exception does not apply to establishing generic cleanup criteria under Part 201.

Opinion (Alternative) 2: Place the algorithms in the rule; publish the inputs along with a process for revising those inputs similar to a process outlined in the TAG 4 Report. Therefore, there would always be a table of the criteria based on the current inputs plugged into the algorithms as established by rule.

If the rule includes the algorithm and a method of publishing and revising the inputs to the algorithms, and the resulting value table (that included a robust public participation component), the rule would survive any challenge under the APA.

Recommendation 4.1

After CSA review of the TAG 4 Report and considerable discussion by the CSA of the two alternatives outlined, the CSA reached a consensus recommendation that the MDEQ should proceed with the update of the Generic Cleanup Criteria under Part 201 following Option 1 by placing the algorithms, inputs, and resulting tables into the rules (including future updates to inputs) pursuant to Part 201 and the APA. In addition, the CSA supports the consensus recommendations of TAG 4 with respect to the general principles that should be followed during adoption of the updated cleanup criteria.

The Michigan Environmental Council's (MEC) representative on the CSA does not support this consensus recommendation and objects to its fairness. At least two other divisions of the MDEQ make decisions regarding the "inputs" as they pertain to health impacts outside the rule process. Parties responsible for the cleanup of a contaminated parcel pursuant to MCLA 324.21020b are allowed within a site-specific cleanup to advocate for the change to health impacts inputs outside the rule process, but members of the public do not have the ability to do so.

Appendices

Appendix A: TAG 1 Final Report: Updating Chemical/Physical Parameters and Toxicity Data
Appendix B: TAG 2 Final Report: Updating Exposure Pathway Assumptions and Data Sources
Appendix C: TAG 3 Final Report: Updating Part 201 Vapor Intrusion Criteria
Appendix D: TAG 4 Final Report: Key Legal Issues for Updating Michigan's Generic Cleanup Criteria

Appendix A:

TAG 1 Final Report: Updating Chemical/ Physical Parameters and Toxicity Data

Final Report:
Part 201: Updating Chemical/Physical Parameters and Toxicity Data

August 2014

Prepared for
The Criteria Stakeholder Advisory Group (CSA)

Submitted by
TAG 1: Chemical/Physical Parameters and Toxicity Data

In collaboration with
Public Sector Consultants
Lansing, Michigan
www.pscinc.com

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Appendices **13**

- **Appendix A:** Chemical/Physical Value Decision Framework
- **Appendix B:** Toxicity Value Decision Framework
- **Appendix C:** Four-year Update Cycle
- **Appendix D:** Chemical Update Worksheet
- **Appendix E:** Soil Screening Guidance Background and Rationale for Differing Views

Introduction

Technical Advisory Group 1 (TAG) met six times in June and July 2014 to review, discuss, and develop responses and recommendations related to nine questions that were outlined in the White Paper prepared by Public Sector Consultants Inc. (PSC) addressing chemical/physical parameters and toxicity data used to derive Part 201 generic criteria.[1] PSCs' White Paper served as the framework for the TAG's discussions. This final report to the Criteria Stakeholder Advisory Group (CSA) presents the TAG's discussions, findings, and recommendations.

WHITE PAPER AND REVIEW PROCESS

Overall, the group's impression of the White Paper was positive. Members reported that it is well designed, and that it provided sufficient guidance to the group on where members should be focused. However, the group requested insertion of a brief explanation at the beginning of the White Paper on this project and the Michigan Department of Environmental Quality's (MDEQ) goal of updating the Part 201 rules. As a result, PSC proposed the following language be inserted into the White Paper:

"The Cleanup Criteria Rules are authorized pursuant to Part 201, Environmental Remediation, of the Natural Resources and Environmental Protection Act (NREPA), 1994 PA 451, as amended (MCL 324.101 to 324.90106). The 2010 amendments (2010 PA 228) to Part 201 included the requirement for the Michigan Department of Environmental Quality (MDEQ), to evaluate and revise the cleanup criteria, and incorporate knowledge gained through research and studies in the areas of fate and transport and risk assessment. The MDEQ shall also take into account best practices from other states, reasonable and realistic conditions, and sound science, as required by Section 20120a(18) of NREPA. To that end, the MDEQ has established a Criteria Stakeholder Advisory Group (CSA) to provide input for the process. The CSA consists of professionals from academia, the private sector, and nongovernmental organizations.

The workgroup is charged to review the existing rules, and determine if the criteria should be updated. If the workgroup supports updating the criteria, the charge will be to:

- Identify guiding principles to be used as the basis for updating the criteria;
- Apply the guiding principles in the selection of assumptions to be used in updating the criteria; and
- Provide recommendations to the director of the MDEQ for updating the toxicological and physical chemistry aspects of the cleanup criteria rules."

When TAG members reviewed the nine questions formulated by the CSA and presented in the White Paper, they suggested a realignment for several questions and a clarification on one. Specifically, the group recommended looking at Question 1 and 5 together, and similarly grouping Questions 2 and 4 and Questions 4 and 6, and seeking clarification on Question 7.

This report is organized with each White Paper question posed, the background discussion, and the resulting recommendations.

[1] White Paper: Chemical/Physical Parameters and Toxicity Data, Public Sector Consultants, May 2014.

TECHNICAL ADVISORY GROUP MEMBERS

Exhibit 1 details the TAG membership:

EXHIBIT 1. TAG Members

John Buchweitz, PhD, DABT	Michigan State University
Steve Crider, MS	Barr Engineering Co.
Jennifer Gray, PhD	Michigan Department of Community Health
Betty Locey, PhD, DABT	ARCADIS
Eric Wildfang, PhD	Michigan Department of Environmental Quality
Lisa Yost, MS, DABT	ENVIRON Corporation

WHITE PAPER QUESTIONS

The TAG was asked to review and address the following questions and issues:

1. Is the process utilized by the MDEQ since 2002 to select chemical-specific values including toxicity values and physical chemistry parameters appropriate? If not, what should be changed?
2. Have the most robust and reputable data sources been selected to generate the data needed to establish the numeric values under Part 201 rules, or are there alternative databases that should be used?
3. What recommendations should be considered for updating the chemical-specific values, given the directive to use best practices, reasonable and realistic conditions, and sound science? How do these terms relate to changes in toxicity data and chemical/physical parameters?
4. What minimum set of standards, if any, should define acceptable data sources?
5. Should a hierarchy of data sources be established? If not, please provide a rationale. If so, what should the hierarchy of sources be, and are there any circumstances under which deviations from the hierarchy should be allowed?
6. Can the Technical Advisory Group provide a descriptive level of quality that could be used as a framework for selecting data sources?
7. Should the MDEQ-derived "toxicity values" be consistent with or based upon federal (i.e., U.S. Environmental Protection Agency (EPA)) methodology and data? If so, are there any circumstances under which deviations from the federal (i.e., EPA) methodology and data should be allowed?
8. Should an independent evaluation of the chemical-specific data be conducted even if a value is published in the primary database of the hierarchy?
9. For chemical/physical parameters, should experimentally-derived estimates take precedence over theoretically-derived estimates?

SUMMARY OF TAG RECOMMENDATIONS

A subset of toxicity values and some chemical/physical parameters promulgated in Part 201 are outdated. In general, the TAG recommendations define a framework that allows for the identification of toxicity values and chemical/physical parameters that represent the best available science, best practices (from U.S. Environmental Protection Agency, other federal agencies, and other states and countries), reasonable and realistic conditions, and sound science, as required by Section 20120a(18) of the Natural Resources and Environmental Protection Act. Recommendations also include flexibility for program changes within a reasonable time frame as the science evolves, and ways to increase transparency in the process.

The TAG identified a list of acceptable sources for chemical/physical parameters and toxicity values and proposed two decision frameworks (see Appendices A and B). An alternative to the framework in Appendix A was proposed by a member who believes that EPA's Soil Screening Guidance (SSG) recommendations for the selection of most chemical/physical parameters are still more robust and scientifically sound than any other subsequent EPA guidance. The rationale this TAG member provided and the responses to comments from other members who oppose using SSG as the primary source are included in Appendix E.

For the decision frameworks a tiered list of reference sources for toxicity values is included for consideration by the CSA. In addition, the TAG recommends that additional referencing be added to MDEQ Table 4—Toxicological and Chemical/physical Data: Part 201 Generic Cleanup Criteria and Screening Levels—and that the basis for each value be provided on the MDEQ's website for interested users.

A process and timeline for the MDEQ to update the December 2013 version of Table 4 and the resulting Part 201 Generic Cleanup Criteria and Screening Levels was developed by the TAG (Appendix C). It would to allow for an open submission period (e.g., three years) and a petition process for chemicals to be considered for update in Years 1, 2, and 3 based on availability of relevant new scientific information. In Year 3, the MDEQ would identify which chemicals would be updated based upon available information; in Year 4, the department would allow a comment period and then move through the legislative rule process (the question of how updates will be structured in a legal context is being examined by TAG 4 – Legal). Also proposed is a new chemical update worksheet to assist in updating chemical/physical parameters and toxicity data (Appendix D).

The TAG definition of "update" for purposes of TAG 1 discussions was limited to chemical/physical values and toxicity values and resulting criteria, not equations themselves or exposure inputs, which were beyond the scope of this group. The TAG understands that other areas of the Part 201 cleanup criteria rules are currently under review by the other TAGs and may result in additional considerations as to how criteria "updates" are ultimately defined by the CSA. For the purposes of TAG 1, the "four year update cycle" was developed and is presented in the context of reviewing the chemical/physical and toxicological data to determine if the current values represent the best available data.

A total of 12 recommendations are offered for the CSA's consideration.

Questions, Answers, and Recommendations

The following section presents each White Paper question, a summary of the TAG's discussion, and recommendations. Note that several questions were realigned by the TAG consistent with the information being discussed and the overlap among topics. This report organizes the questions as they were considered and addressed by the TAG.

Question 1

Is the process utilized by the MDEQ since 2002 to select chemical-specific values including toxicity values and physical chemistry parameters appropriate? If not, what should be changed?

Summary Answer: Yes, but there is opportunity for improvement. The TAG agrees with the MDEQ and other practitioners that many of the chemical/physical parameters and toxicity values currently promulgated in Part 201 should be updated, as appropriate, to be consistent with the best available science, and that a process should be established for periodic updates to these values to insure that they continue to be based on the best available science. The TAG developed and recommends two new decision frameworks to update toxicity values and chemical/physical parameters (Appendices A and B) underpinned with transparency and best available science. An alternative view provided by a TAG member for updating chemical/physical parameters is also outlined in Appendix E.

Recommendation 1: The MDEQ should adopt the decision-making frameworks as proposed**.** As indicated above and highlighted throughout the discussion sections of this document, an alternative view emerged for prioritizing EPA's SSG recommendations for the selection of chemical/physical values.

Recommendation 2: The MDEQ should include a short reference for each value and chemical/physical parameter in Table 4 that identifies the source of the values and that also indicates whether physical parameters are measured or modeled when relevant. A more detailed explanation of the reference could be stored in a separate table or other resource as this would give each value greater transparency. A similar model is being used by the Ontario Ministry of the Environment, Canada, and the MDEQ should consider this format while designing its updated tables.

Recommendation 3: The MDEQ should provide more opportunity for stakeholders to give feedback on what data and methodology could be considered in selecting parameters or developing toxicity values when the MDEQ determines it is necessary to develop such values.

Recommendation 4: When administrative rules are updated, the inhalation toxicity terms in the VSIC, PSIC, GVIIC, and SVIIC equations and relevant rule language should be changed to allow the MDEQ the flexibility to select inhalation toxicity values that differ from those developed by the MDEQ's Air Quality Division (AQD), considering best available science and practices. The MDEQ's Remediation and Redevelopment Division (RRD) staff should not have to evaluate all inhalation toxicity values, though some attention should be given to those that are based upon the AQD's most minimal data requirements at the time they are evaluated. Inhalation toxicity value reference sources should be included in Table 4.

Discussion

The TAG discussed the MDEQ's legislative mandate to update its process for selecting chemical/physical parameters and toxicity values, and concurs that the process should be made easier to update, occur more frequently, be more transparent, incorporate the best science available, and allow for professional judgment. The issue of using the best available science and allowing for professional judgment in the process are included in the discussion on developing a tiered list of reference sources in Question 5 below.

Chemical/Physical Parameters

In considering physical chemistry parameters, the group acknowledged the underlying issue of deciding whether the process should rely more on model-based values or on experimentally values. There was agreement within the TAG that experimentally-derived (measured) values are preferred, so long as the methods used in the experiment are clearly presented and are carried out at acceptable temperature and pressure. However, there was disagreement on how to select a value from among multiple valid measured values when these values differ significantly. This disagreement ultimately concluded in two different perspectives on how and where EPA's SSG recommendations on chemical/physical parameters should be used in a decision framework. While the MDEQ seeks to utilize experimental data whenever possible, the department also values consistency and would prefer an updated process to allow for both—especially considering staff resources and the time it takes for these updates to occur. The data source used first by the MDEQ is ChemIDplus: a free, Web-based search system that provides access to the structure and nomenclature authority files used for the identification of chemical substances cited in National Library of Medicine (NLM) databases—including the TOXNET® system. ChemIDplus also has structure searching and direct links to resources at NLM, federal agencies, U.S states, and scientific sites. The database contains more than 400,000 chemical records, of which more than 300,000 include chemical structures.

ChemIDplus reports both experimental data and estimates derived through modeling. One concern with model approaches is that they can derive estimates outside the range of experimental values, resulting in an inaccurate representation of the chemical's behavior for the criteria calculations.

At least one TAG member suggested that the default chemical/physical parameter values should continue to be based on the U.S. Environmental Protection Agency's (EPA) recommendations from the SSG, with allowance for parameter-specific deviations where scientifically justified. Discussion on the rationale for MDEQ's existing use of EPA's SSG recommendations and examples of why at least one TAG member believes the SSG approach is technically sound and superior to values from EPI Suite and ChemIDPlus are included in Appendix E.

Toxicity Values

When updating toxicity values, the MDEQ's preference is to utilize best available science and research. The department recognizes that members of the regulated industry can help provide this information and play a valuable role. Allowing for more public comment is another way to improve the transparency of the process. For example, the MDEQ's Air Quality Division (AQD) announces a short list of chemicals to be updated each month and seeks public input on these chemicals for a specific time period before updating the value. Additionally, the EPA Scientific Advisory Board recently released recommendations for process improvements to EPA's Integrated Risk Information System (IRIS). This document was available to TAG members and the group considered these recommendations when developing a new update process for the MDEQ.

The group also reviewed the MDEQ AQD's air control rules, which are currently being updated. A TAG member indicated there is a new procedure proposed to create the initial list, change a value, or to add or delete a chemical from the list. Group members indicated that Initial Threshold Screening Levels (ITSLs) and Inhalation Unit Risk Factors (IURFs) are values that are developed by the AQD that are used to calculate the Part 201 volatile soil inhalation criteria (VSIC), particulate soil inhalation criteria (PSIC), groundwater volatilization indoor air inhalation criteria (GVIIC), and soil volatilization indoor air inhalation criteria (SVIIC). The equations, as currently presented in the Part 201 administrative rules, use these exact terms, ITSL and IURF. MDEQ's RRD uses these AQD values to calculate inhalation-based criteria.

Historically, an effort has been made by the MDEQ to identify peer-reviewed data sources populated with information developed using the best available science and consistent with the most current subject matter guidance. Preference was given to extensive and robust data sources having high credibility in the relevant scientific community. Both the data sources and the information on chemical-specific parameters have changed over the years. The documentation for sources of information used in the past was not routinely recorded and, in some cases, information on the source(s) used is simply not available today. The MDEQ has received recommendations in the past with respect to documenting the priority given to the use of a variety of available data sources.

Topics explored by the TAG include:

- **Rules vs. statute:** Is it better to have a revised Table 4 promulgated in rules, or included in statute? Members decided to let TAG 4 (Legal) explore the best approach (i.e., statute vs. rules, grandfather clause).
- **Timing of *updates*:** The toxicological, chemical, and physical parameters utilized by the MDEQ to calculate the cleanup criteria are currently promulgated as rules and can be found in Table 4 of R 299.50. Table 4 has not been fully updated since 2002. A TAG member indicated that the legislature and business community would support predictable updates, and agreement emerged among group members that it should occur more frequently. One challenge identified by the MDEQ is that the agency has struggled with what satisfies the definition of *update*. For purposes of this discussion, the TAG definition of *update* is limited to chemical/physical values and toxicity values and resulting criteria versus equations themselves.
- **Process for updating chemical/physical and toxicological data**: A proposal for the MDEQ to update Table 4 every four years emerged from the TAG (Appendix C). It would to allow for an open submission period (e.g., three years) and a petition process for chemicals to be considered for update in Years 1, 2, and 3 based on new or previously unavailable, relevant scientific information. In Year 3, the MDEQ would identify which chemicals would be updated, based upon available information; in Year 4, the department would allow a comment period and then move through the legislative rule process (if necessary). It was noted that the MDEQ has internally discussed annually posting candidates (e.g., five to ten chemicals a year that need to be re-evaluated). The candidate chemicals would come from an open submission period, a petition process for chemicals to be considered, and updated toxicity values that come through IRIS or other significant sources.

Question 5

Should a hierarchy of data sources be established? If not, please provide a rationale. If so, what should the hierarchy of sources be and are there any circumstances under which deviations from the hierarchy should be allowed?

Summary Answer: The MDEQ should use a tiered approach (Recommendation 1) that replaces the term *hierarchy* with the term *decision framework*. Transparency and flexibility are built into the decision frameworks.

Recommendation 5: The MDEQ should adopt the two proposed decision frameworks (Appendices A and B that loop back to best science and allows for professional judgment). See Appendix E for alternative view.

Recommendation 6: The MDEQ should utilize the chemical update worksheet (Appendix D) to collect information and as a communication tool—a Web-friendly version (i.e., a PDF) should be placed on MDEQ's website.

Discussion

The group reviewed the MDEQ data source hierarchy provided in the White Paper. The TAG agreed that, to be transparent and consistent in the process for determining the chemical/physical and/or toxicity parameters, it is essential to have a process that utilizes specific data sources. However, it agreed that the term *hierarchy* should be replaced with the term *decision framework*, using a tiered approach to more accurately reflect the proposed process chart. Additionally, a decision framework will allow for those outside of the MDEQ to arrive at (or duplicate) the same value as the department, while recognizing, however, that professional judgment and interpretation may not always allow for the precise replication of results.

The variability of model-based versus experimentally-derived values was discussed. To evaluate the impact of the proposed changes in sources of chemical/physical and toxicological data, the group examined the variability, or relative percentage difference, between the Framework-derived values and the current values (from MDEQ Table 4). A member had analyzed the percentage differences between current toxicity and chemical/physical values (from MDEQ Table 4) and those derived using the decision framework, and some large numerical differences (both negative and positive) appeared to exist. It was noted that some errors exist in the current Table 4 values but, since they are promulgated currently, little can be done to update them at this time. However, no analysis has been performed to determine the effect of the proposed toxicity value and chemical/physical value changes (either separately or combined) on the existing Part 201 criteria.

The group discussed the percentage differences and considered whether there is a certain level of variance that warrants further investigation and/or whether there is a subset of major chemicals with any level of variability that warrants further investigation. Additionally, the TAG considered what other criteria need to be used—besides the age of the data source—when moving away from the decision framework, and determining when best professional judgment is acceptable. While no conclusions or recommendations resulted from these discussions, members found the information valuable—which helped inform broader discussions. The TAG emphasized Recommendation 2: linking source information to the tables, and providing information on whether the data are experimental or modeled—which could be a valuable tool during the criteria update process. (Note to reader: This discussion is also relevant to Question 3).

Chemical/physical Parameters

Decision frameworks highlighting the proposed steps to update values were developed by a TAG member and are recommended by the group (Appendix B). Members like that the chart clarifies that the MDEQ use experimental data in lieu of modeled data. Members noted that when Table 4 is updated, it should indicate the data sources—including the version of the program—if applicable. One member identified that this proposed approach does not have the ability to choose among multiple valid experimental values and thus recommended that the SSG recommendations currently used in Part 201 continue to be prioritized first because it has successfully addressed this issue. See Appendix E for additional background and discussion.

Toxicity Values

The group noted that, when reviewing a chemical, toxicity values would be evaluated to see which one meets the determination of the best available science. Both peer-reviewed studies and unpublished industry studies that follow good laboratory practices would be acceptable and considered during an evaluation. After discussion of California EPA requirements, some members strongly encourage the MDEQ not to use the California values in situations where California has identified a carcinogen, but that finding has not been embraced or utilized by agencies outside of California.

Question 2

Have the most robust and reputable data sources been selected to generate the data needed to establish the numeric values under Part 201 rules, or are there alternative databases that should be used?

Summary Answer: Since many of the promulgated toxicity values have not been revised since 2002, they may not necessarily be based on the most robust and reputable data sources.

Recommendation 7: Update all values based on a tiered approach as described in response to Questions 1 and 5 above. Recommended resources should be expanded to include international data sources, including, but not limited to, European and Canadian sources.

Discussion

TAG members noted that when data on a chemical is limited there may be unpublished or proprietary references that companies may submit for the MDEQ's consideration, and that default values for certain chemical-specific parameters (such as absorption efficiency and relative source contribution) may be used for chemicals when chemical-specific data is unavailable. Therefore, additional reference sources should be available to the MDEQ to fill data gaps if the data meets the fundamental requirements of an acceptable data source (see Recommendation 8).

The current proposed list of resources for the physical and chemical properties is listed in Chemical/physical Value Decision Framework (Appendix A) and the current list of resources for toxicity values is included in the Toxicity Value Decision Framework (Appendix B).

Question 4

What data sources should the department consider in conducting these revisions? What minimum set of standards, if any, should define acceptable data sources?

Summary Answer: See Recommendation 8 below.

Recommendation 8: The TAG supported data sources for chemical/physical parameters and toxicity values consistent with the fundamental data source characteristics presented below:

- **Peer-reviewed:** Every effort should be made to identify and use peer-reviewed data sources populated with information that has been developed using the best available science and practices. Scholarly review by experts in the field ensures data meet necessary quality standards prior to publication.
- **Subject to notice and comment:** Toxicity values that are developed by non-MDEQ sources through a process that allows public review and comment are preferred. (Note: It is desirable to allow affected stakeholders [and affected Michigan citizens and regulated community members] input when changing Table 4 values.) In general, chemical/physical data do not undergo public review and comment procedures.
- **Derived through relevant and accepted methods:** Priority should be given to sources that provide chemical/physical and toxicity data based on similar methods as those used for Tier 1 and Tier 2, contain values which are peer reviewed, are available to the public, and are transparent about the methods and processes used to develop the values.
- **Comprehensive:** In the absence of the availability of a single, complete chemical information source for chemical/physical or toxicity data, the MDEQ should utilize data sources that provide the most robust coverage of the Part 201 hazardous substance list. This helps to assure greater consistency of the data used in developing the risk-based values.

- **Credible:** Data sources that are respected and trusted by the international scientific community are preferred.
- **Regularly maintained:** Science evolves. Regular review and updating of the chemical information will assure that it represents the best available science and practices in that field. For example, two recent guidance documents are good resources to consider in selection or development of toxicity values: EPA Framework for Human Health Risk Assessment to Inform Decision Making[2], and National Research Council (2014) Review of EPA's Integrated Risk Information System (IRIS)[3].
- **Based on experimental data:** Chemical data presented in the scientific literature and the many compiled documents and database resources can vary in method of derivation. Experimental chemical/physical data, where relevant to applied environmental conditions, are preferred over extrapolated, modeled, or estimated data. Similarly, experimental toxicity data are preferred, with the understanding that the scientific field is moving away from traditional, whole-animal experimental studies to higher throughput, less resource-intensive in vitro, array, and computer-based toxicity models.

Discussion

The TAG discussed the MDEQ's and the EPA's hazardous substance-specific toxicity and chemical/physical parameter reference sources presented and described in the White Paper. The MDEQ has identified and promulgated numeric values for the chemical/physical parameter and toxicity values required for developing the generic cleanup criteria for most Part 201 hazardous substances. To identify these values, the MDEQ has proposed to establish a preferred list of reference sources based on several fundamental characteristics described initially in the White Paper. Proposed revisions to these characteristics are offered above. Members also suggested using the terms "best available science" or "appropriate studies," rather than "defensible studies."

Question 6

Can the Technical Advisory Group provide a descriptive level of quality that could be used as a framework for selecting data sources?

Summary Answer: Yes. See Recommendations 7 and 8 above.

Discussion

On Question 6 (and Questions 2 and 4), the TAG determined that reputable data sources should be based on the characteristics described Recommendation 8. Specific to Question 6, the group discussed adding to the federal/state databases in the decision framework flow chart. Members recommended not restricting the MDEQ to only the data available today and suggested the flexibility to evaluate future sources in such areas as endocrine disruptor, in vitro, ex vivo, or in silico testing, and shifts in EPA philosophy.

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[2] USEPA 2014 available at http://www.epa.gov/raf/files/hhra-framework-final-2014.pdf
[3] NRC 2014 available at http://www.nap.edu/catalog.php?record_id=18764

Question 3

What recommendations should be considered for updating the chemical-specific values, given the directive to use best practices, reasonable and realistic conditions, and sound science? How do these terms relate to changes in toxicity data and chemical/physical parameters?

Summary Answer: Two decision frameworks that propose steps for meeting the requirements for best practices, reasonable and realistic conditions, and sound science were developed and endorsed by the TAG (Appendices A and B). Alternative view is highlighted in Appendix E.

In addition, age-dependent adjustment factors (ADAFs) should be used with toxicity values for those carcinogens identified as mutagenic by the EPA.

Discussion

See the Discussion sections provided under Questions 1 and 5, and Appendices A and B.

In addition, the TAG was asked by TAG 2 to assess the process to determine if a chemical has a mutagenic mode of action and to which substances should age-dependent adjustment factors (ADAF's) be applied (i.e., should Chromium VI be listed as a mutagenic chemical?).

Recommendation 9: Age-dependent adjustment factors (ADAFs) should be used with toxicity values for those carcinogens identified as mutagenic by the EPA or any agency/scientific body as long as it's conducted in accordance with EPA guidelines on identifying mutagenic mode and evaluated by the MDEQ.

Question 7

Should the MDEQ-derived "toxicity values" be consistent with or based upon federal (i.e., EPA) methodology and data? If so, are there any circumstances under which deviations from the federal (i.e., EPA) methodology and data should be allowed?

Question 7 was modified by the TAG to read as follows:

A. *If the EPA has not developed one or more toxicity values for a chemical, should the MDEQ attempt to evaluate developing the missing values?*

B. *If so, are there any circumstances under which deviations from the federal (i.e., EPA) methodology and data should be allowed?*

Summary Answer: Part A–Yes; the MDEQ should be allowed to develop and/or use toxicity values that were not derived by the EPA.

Part B–Yes; the MDEQ should be allowed to deviate from federal data when EPA data do not represent best available science. There are circumstances where EPA toxicity values are available, but not used to calculate generic criteria. Part 201 requires toxicity values be based on the best available science. The EPA, in general, has the resources to develop updated guidance, recommend methodologies, and derive toxicity values using those methodologies and the most current data. However, this is not the case for all toxicity values. Some recommended toxicity values are outdated and the EPA does not always speak with one voice. For example, the EPA Office of Drinking Water developed a Maximum Contaminant Level (MCL) many years ago that is not based on the most current science and is not consistent with newly revised values recommended in the EPA's Integrated Risk Information System (IRIS) database.

The TAG recommends tiered reference sources with the understanding that values will be reviewed to determine if it is reasonable to assume the values represent the best available science. For example, IRIS is identified as the preferred source, with the condition that if the value in question is either outdated or there is information indicating, that it should be modified. The recommended approach is summarized in Appendix B.

Recommendation 10: The MDEQ should first determine whether a chemical is considered carcinogenic to humans by the EPA and International Agency for Research on Cancer (IARC). If it is to be regulated as a carcinogen, then potential route-specific differences in carcinogenicity should be considered and evaluated. If it is noncarcinogenic, then only the reference dose (RfD) and reference concentration (RfC) candidate values would be assembled to select an RfD and an RfC.

Recommendation 11: The criteria should be footnoted to denote whether the carcinogenic or non-carcinogenic algorithms are used to calculate the final criteria for a chemical.

Recommendation 12: Deviation from EPA methodology should be allowed where there is good information to suggest that the EPA's methodology or data are not consistent with current best science. Where these modifications are made by the MDEQ, there should be an opportunity for public input and comment, as described in Appendix C.

Discussion

The group had three different interpretations of what is being asked in the first part of Question 7. Some participants thought it referred only to MDEQ-derived values and not broader data sources. Other participants said they thought this was about establishing guidelines when Michigan's standards are stricter than EPA standards, with a goal of generally *not* having stricter standards than the EPA. Others thought it was asking about addressing missing endpoint values in the federal standards.

In response, a MDEQ representative provided context that this question's origins were in using cumulative risk with combined exposure pathways versus specific pathway screenings. This has been a controversial issue in the past, but because of the limited time frame for this current stakeholder process, the CSA does not want the TAG to address this entire issue, including the algorithms. Instead, it preferred that the TAG focus on a limited portion of the issue, and address whether the MDEQ should be consistent with federal methodology or whether the MDEQ should adopt its own methodology.

The group modified the question, as indicated above.

Question 8

Should an independent evaluation (by the MDEQ) of the chemical-specific data be conducted even if a value is published in the primary database of the hierarchy?

Summary Answer: Yes. The TAG agreed such independent evaluations are appropriate and are proposed to the MDEQ within the decision frameworks. Each chemical can be subject to an independent evaluation if required in order to be consistent with the best available science. For example, if a toxicity value is available in IRIS, but that value is no longer consistent with the current best available science, either the MDEQ or other interested party can bring forward data to be considered in revising or deriving a more appropriate value. The group recommends that the words "by the MDEQ" be added to this question so that it reads as it does above. This clarifies that the independent evaluation is the MDEQ's independent evaluation, which is met by going through the decision framework.

Question 9

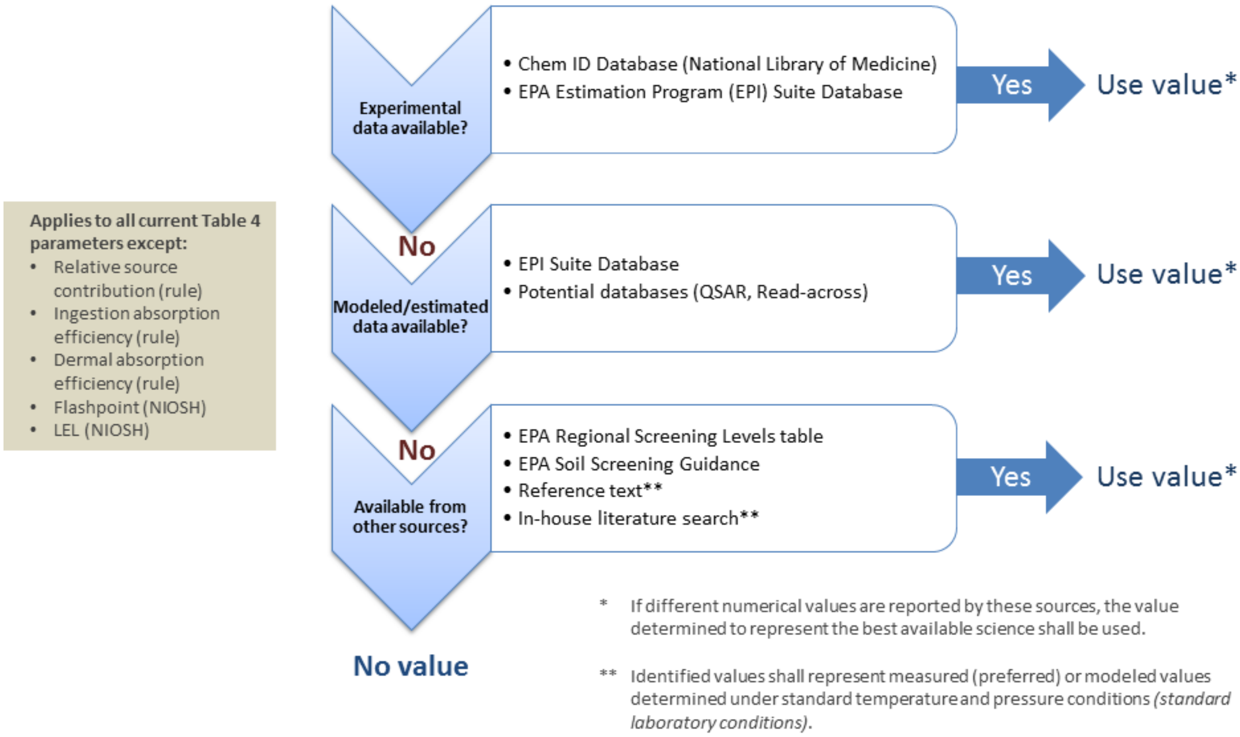
For chemical/physical parameters, should experimentally-derived values take precedence over theoretically-derived estimates?

Summary Answer: Generally, the TAG agrees that experimentally-derived values means experimental data that is the result of scientific experiments conducted in a controlled laboratory environment, typically at standard temperature and pressure; therefore, experimentally-derived values should take precedence over model theoretically-derived values whenever possible. The proposed decision frameworks establish which estimates take precedence when experimental data are unavailable (See discussion under Questions 1 and 5 and Appendices A and B). However, as discussed above, there was disagreement on how to select measured values from multiple valid measured values for chemical/physical parameters when these values differ significantly. This disagreement ultimately concluded in two different perspectives on how and where SSG should be used in a decision framework.

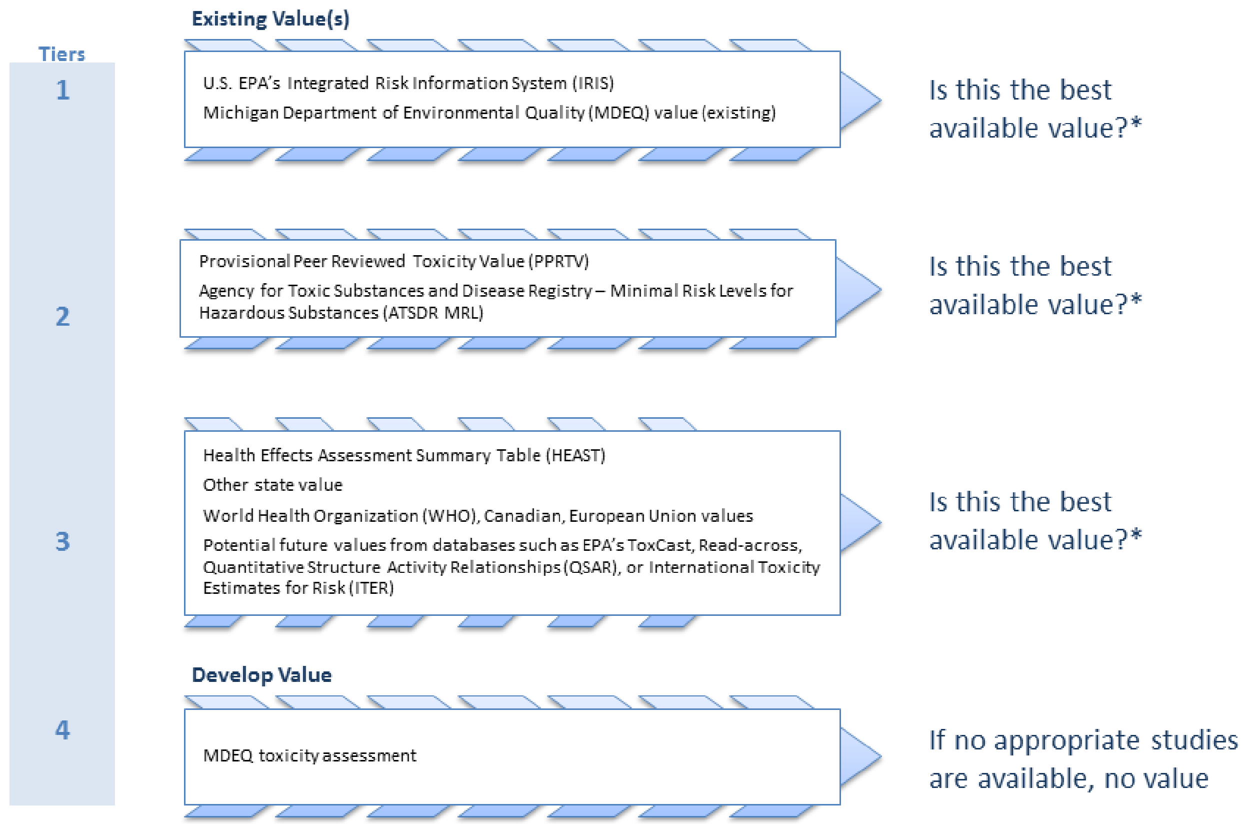
Appendices

- Appendix A: *Chemical/physical Value Decision Framework*
- Appendix B: *Toxicity Value Decision Framework*
- Appendix C: *Four-year Update Cycle*
- Appendix D: *Chemical Update Worksheet*
- Appendix E: *Soil Screening Guidance Background and Rationale for Differing Views*

Appendix A:
Chemical/Physical Value Decision Framework



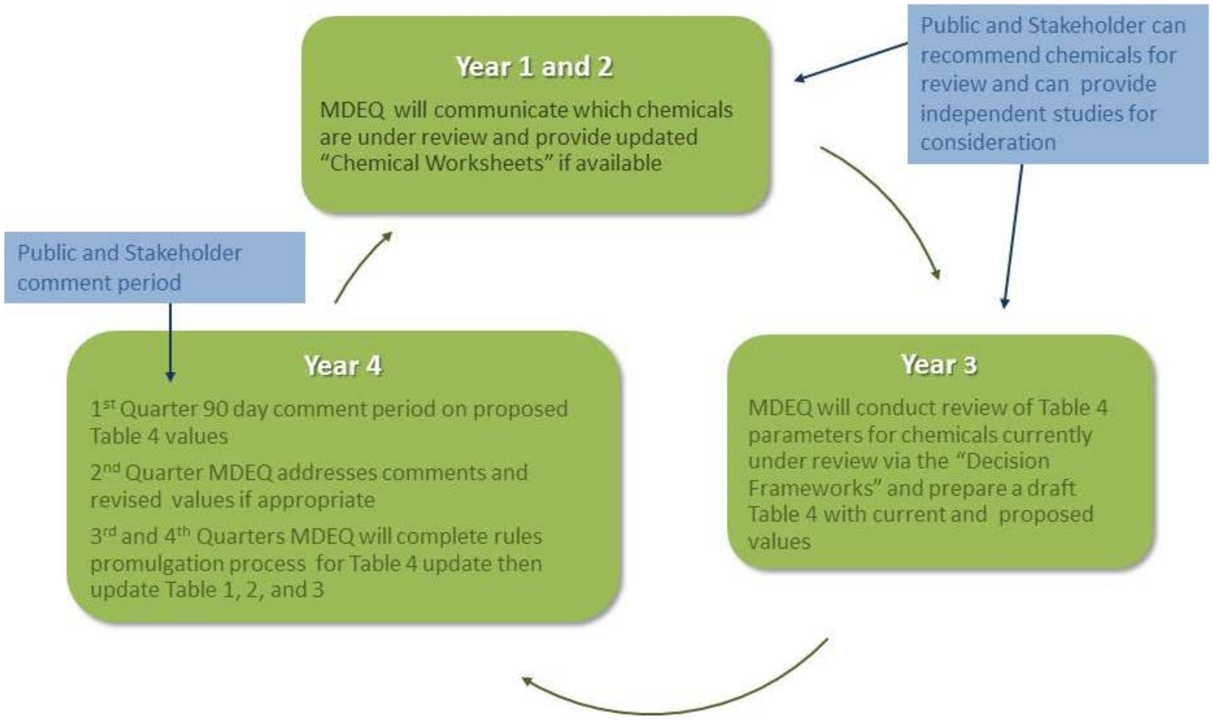
Appendix B:
Toxicity Value Decision Framework



* Values may have to be assessed for best available science (see TAG Recommendation 8)

Appendix C:
Four-year Update Cycle

MDEQ Four-year Update Cycle for Table No. 4



A proposal to update the toxicity and chemical/physical data presented in Table 4 (Toxicological and Chemical/physical Data for Part 201 Generic Cleanup Criteria and Screening Levels) once every four years emerged from the TAG; it would allow for an open submission period (e.g., 3 years) and a petition process for chemicals to be considered for update in years 1, 2, and 3. In year 3, the MDEQ would identify which chemicals would be updated, based upon available information; in year 4, the department would allow a comment period and then move through the legislative rule process. It was noted that the MDEQ has internally discussed annually posting candidates (e.g., 5 to 10 chemicals a year that need to be re-evaluated). The candidate chemicals would come from an open submission period, a petition process for chemicals to be considered, and updated toxicity values that come through IRIS or other significant sources.

The TAG supported the proposal and emphasized the goal should be to ensure the regulated community, Michigan citizens, and the MDEQ are utilizing cleanup criteria that represent best practices, reasonable and realistic conditions, and sound science. In order for this update process to work, the language in the criteria rules would need to be revised to require a mandatory four-year update to Table 4 that, by reference, would cause Table 1 (Groundwater: Residential and Nonresidential Part 201 Generic Cleanup Criteria and Screening Levels), Table 2 (Soil: Residential; Part 201 Generic Cleanup Criteria and Screening Levels), and Table 3 (Nonresidential Part 201 Generic Cleanup Criteria and Screening Levels) to be updated, as well. The intention of the update every four years is to provide current toxicological and chemical/physical parameters. This approach is intended to be a balance between the MDEQ's expectation to update Table 4 in real-time (as the data are made available) and the regulated community's desire to have predictable cleanup criteria. The proposal offers an approach for the MDEQ to communicate what chemicals it will evaluate within a predictable time frame. TAG members noted that while the process indicates that the MDEQ would provide notice every six months, the time period could be different (e.g., 12 months) and would be determined by MDEQ resources.

The Update Process

The proposed update process would occur over the course of four years and would be designed to improve transparency and communication of the chemicals the MDEQ would evaluate during a given cycle.

In year 1, the MDEQ would inform stakeholders that the update process is initiated, share a list of chemicals proposed for update, and provide stakeholders an opportunity to provide input. The MDEQ would solicit input from stakeholders on additional chemicals to review and relevant studies related to those chemicals.

In years 2 and 3, the MDEQ would review the chemical/physical and toxicity values for the proposed subset of the approximately 300 chemicals to evaluate the updated values or data submitted on the chemical.

In year 4, during the first quarter, proposed revisions to the values would be released for comment. In the second quarter, the proposed revisions and comments would be reviewed with stakeholders. In the third and fourth quarters, the revisions would go through the legislative process to complete the update of the criteria.

The TAG discussed if there were other administrative or legislative cycles that should be considered to determine when the four-year update process should begin. Members also discussed developing a mechanism for values to be re-evaluated on an emergency basis. Members agreed that a mechanism would be important and that consideration should be given to how "emergency" is defined. Members suggested that an emergency evaluation could be left to the joint discretion of the directors of the Departments of Community Health and Environmental Quality, when there is an immediate threat to public health.

TAG members discussed instances where ambiguity exists in some definitions (e.g., the definition of *substantial*) and suggested that the legal TAG should concur with language regarding an emergency update to criteria. Members noted that Michigan's Public Health Code may provide examples of language for similar provisions. The group also discussed whether or not a magnitude of change in values should be included in the emergency provision, and whether the language should provide examples of when an emergency action should be taken to help clarify what "emergency" means.

The TAG discussed when the four-year cycle should begin for revisions to the criteria that the MDEQ has had under development since 2009. The TAG noted that the department has a legislative mandate to update the criteria. Members agreed that the TAG should acknowledge that the review process for current updates may present a challenge, but that once new criteria are in place, the proposed four-year update process should be effective.

The group discussed two potential approaches to adopt the updated criteria the MDEQ has been working on since 2009. Under the first approach, proposed updates could begin at year 3 of the four-year cycle. However, the TAG noted that this approach may not meet the mandated time frame to update the criteria.

Under the second approach, the updated criteria could be adopted in a shorter time frame, with a grandfather clause, and a new four-year review cycle would begin at that time. The TAG discussed how sites existing within an approved remedial or corrective action plan (or similar plan) would be addressed when updated criteria are adopted. The goal is to establish a bright line for existing sites with agreed-upon criteria where cleanup activities have occurred, as opposed to *new* sites as criteria are updated into the future. The group also noted that additional consideration would need to be given to smaller *due care* sites using such an approach. The TAG indicated, however, that the review period under this approach may provide a relatively brief time to review and comment on proposed updates.

The TAG identified the following matters that should be considered further by TAG 4 (Legal):

- If the rule establishes a mechanism to update criteria, do updates need to go through the full rule-making process?
- Consider and develop language regarding a provision that would allow for emergency updates to criteria in special circumstances with a clear public health urgency that would include both actual exposure and short-term potential for harm
- The MDEQ should formalize a process to include a provision that would allow a responsible party to apply for site-specific criteria within a specified period of time that would grandfather a site under the former criteria and approved cleanup plan.

The TAG acknowledged that the process used to implement the next update to the criteria may create challenges, but that once new criteria are in place, the proposed four-year update process should be effective. The challenge in updating the process will be in providing adequate time to review and comment on the updates, while adhering to the legislatively mandated time frame to adopt updated criteria. Those in charge of the initial update process should be mindful of the full extent to which criteria can be updated, given MDEQ resources available and the fact that the values have not been updated since 2002.

Documentation

- The MDEQ should provide references for all values listed in Table 4 (e.g., IRIS, MDEQ-derived, ATSDR, ChemIDplus, or other specified references) (Recommendation 2).
- The MDEQ should notify stakeholders and post on its website a list of proposed chemicals and values for update in Table 4 (Recommendation 6).

Communication

- The MDEQ should provide notice via website or e-mail listserv every six months of potential new updates to Table 4. This update will list the chemical(s) affected, and provide a link to the current Chemical Worksheet(s). These updates will not take effect until year four of the update cycle (Recommendation 6).
- Annually, the MDEQ should solicit input from the regulated community and stakeholder groups for chemical(s) the MDEQ should review in a given year, as well as solicit and respond to comments on updates that the MDEQ has proposed that are not yet put into place. Based on current MDEQ staff levels, the MDEQ would likely perform a detailed review of only five to 10 chemicals per year. The MDEQ would provide a response to input received (Recommendation 3).
- The MDEQ should document the basis for selection of proposed updated values, including what values were available and why the identified values were selected, including, but not limited to, rationales for selecting a different toxicity value when an IRIS or Provisional Peer Reviewed Toxicity Value (PPRTV) is available (Recommendation 6).
- Final revised Table 4 values will be documented in chemical update worksheets, which will summarize the selection process for modified values (Recommendation 6).
- Recognizing that the focus of this TAG is generic criteria, when site-specific criteria are being developed, members recommended that the MDEQ provide a form for use in the same format as the

chemical update worksheet, to be filled out by the user. If site-specific criteria are approved, the form will be shared on the MDEQ website. (TAG members discussed the intent of this recommendation, which is to improve transparency by providing information about approved site-specific criteria so others that may have similar site conditions can be aware of the approval of the site-specific criteria.)

Appendix D:

Chemical Update Worksheet

CHEMICAL UPDATE WORKSHEET

Chemical Name:	
CAS #:	
Update Date:	

(A) CHEMICAL/PHYSICAL PROPERTIES

	Part 201 Value	Updated Value	Source/ Reference/Date	Comments/Notes/Issues
Molecular Weight (g/mol)				
Physical State at ambient temp				
Melting Point (˚C)				
Boiling Point (˚C)				
Solubility (ug/L)				
HLC (atm-m^3/mol at 25˚C)				
Log Kow (log P; octanol-water)				
Koc (organic carbon; L/Kg)				
Diffusivity in Air (Di; cm^2/s)				
Diffusivity in Water (Dw; cm^2/s)				
Soil Water Partition Coefficient (Kd; inorganics)				
Flash Point (˚F)				
Lower Explosivity Level (LEL; unitless)				

(B) TOXICITY VALUES/BENCHMARKS

	Part 201 Value	Updated Value	Source/Reference/Date
State Drinking Water Standard (ug/L)			
Secondary Maximum Contaminant Level (ug/L)			
Aesthetic Drinking Water Criterion (ug/L)			
Reference Dose (RfD; mg/kg/day)			
RfD Details			
Oral Cancer Slope Factor (CSF; $(mg/kg\text{-}day)^{-1}$)			
CSF details			
Initial Threshold Screening Level (ITSL; ug/m^3)			
ITSL averaging time			
ITSL details			
Inhalation Unit Risk Factor (IURF; $(ug/m^3)^{-1}$)			
IURF details			
Reproductive Effector? (Y/N)			
Reproductive Toxicity Details			
Developmental Effector? (Y/N)			
Developmental Toxicity Details			
Aesthetic Value or Comments			
Phytotoxicity Value			
Other			

(C) RULE 57 WATER QUALITY VALUES AND GSI CRITERIA

1. Surface Water Assessment Section Rule 57 website
2. Rule 57 table

Current GSI value (µg/L)	
Updated GSI value (µg/L)	
Rule 57 Drinking Water Value (µg/L)	

	Rule 57 Value (µg/L)	**Verification Date**
Human Non-cancer Values- Drinking water source (HNV-drink)		
Human Non-Cancer Values- Non-drinking water sources (HNV-Non-drink)		
Wildlife Value (WV)		
Human Cancer Values for Drinking Water Source (HCV-drink)		
Human Cancer values for non-drinking water source (HCV-Non-drink)		
Final Chronic Value (FCV)		
Aquatic maximum value (AMV)		
Final Acute Value (FAV)		

(D) ANALYTICAL INFORMATION

Target Detection Limit – Soil (µg/kg)	
Target Detection Limit – Water (µg/L)	

Appendix E:
Soil Screening Guidance Background and Rationale for Differing Views

Background

Two differing views emerged among TAG members with respect to using the Soil Screening Guidance (SSG) for the selection of chemical/physical parameters and whether it was appropriately positioned in the Decision Framework (Appendix A). The two views held by TAG members differed and point out an apparent inconsistency between the recommendations of one TAG member to use the SSG and SSG's methodology to select values for physical/chemical parameters and text in the Supplemental Soil Screening Guidance (Supplemental SSG) that states the toxicity values and physical/chemical parameters should be checked for any potential updates before use.

Differing Views

<u>Rationale to support the TAG's prevailing view:</u>

In 1996, the EPA issued the Soil Screening Guidance document (original SSG) which presented, in part, chemical/physical data relevant to the most commonly identified chemicals at National Priorities List (NPL) sites. These data were intended to be used in the development of health protective soil screening levels at NPL sites. In 2002, the EPA issued the Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites document (supplemental SSG), a companion document to the original SSG, which also contained chemical/physical data intended for use in developing health protective soil screening levels.

The methods, models, and data presented in the original (1996) and supplemental (2002) SSG documents were not intended to be used in perpetuity as originally published. The supplemental SSG document itself recommends that users check the most recent versions of the appropriate sources for updated regulatory/health benchmarks (e.g., toxicity values) and chemical/physical properties to confirm that the most current values are being used. Per Appendix C of the supplemental SSG document,

> "All of the sources of the values listed in Exhibits C-1 through C-5 are regularly updated by EPA. In addition, the information in Exhibits C-6 and C-7 was obtained from RAGS, Part E. Therefore, prior to calculating SSLs for a site, regulatory/health benchmarks and chemical properties should be checked against the most recent versions of the appropriate sources to ensure that they are up to date."

Appendix C then directs the reader to check online sources, including the EPA Integrated Risk Information System (IRIS), the National Primary Drinking Water Regulations, Superfund Chemical Data Matrix Report (SCDM), CHEMDAT8, and WATER8; all resources used to populate the toxicity and chemical/physical values in the document.

Since issuance of the 2002 supplemental SSG document, the EPA has continued to advance the science that it uses to develop its health protective soil and water screening levels. This is supported by the following discussions.

- The EPA has continued to conduct health assessments of new and existing chemical substances, which are published in the online IRIS database.

- The EPA revised the National Primary Drinking Waters Standard for inorganic arsenic from 50 parts per billion (ppb) to 10 ppb on January 23, 2006.
- The most current version of SCDM was published online in June 2014. While "Part 2 – Data Selection Methodology" of SCDM does reference the supplemental SSG document for some chemical/physical parameters, it is typically identified as a lower preference data resource. Syracuse Research Corporation's PHYSPROP database (embedded in the EPA's EPI Suite database) and the EPA's EPI Suite database itself are consistently given higher preference as chemical/physical data resources by SCDM. This order of preference and recommendations for use (e.g., measured values preferred over estimated values) are consistent with the chemical/physical decision framework presented in the TAG1 Final Report.
- Per the EPA's WATER9 (version 2.0) model website, the WATER8 and CHEMDAT8 models referenced in the 2002 supplemental SSG have been superseded by WATER9. It is stated on the WATER9 website that "WATER9 is a significant upgrade of features previously obtained in the computer programs WATER8, Chem9, and Chemdat8."
- The May 2014 EPA Regional Screening Level (RSL) Chemical-specific Parameters Supporting Table primarily references the EPA EPI Suite database and WATER9 model as the sources of chemical/physical data used in calculating the RSLs. However, the RSL User's Guide references the soil-water partition coefficient for metals (i.e., Kd) parameter to the supplemental SSG. This is consistent with the approach presented in the TAG1 Final Report chemical/physical decision framework.
- Comparison of measured values in the supplemental SSG to modeled or estimated values in EPI Suite is misleading as measured values can be found in both the SSG and EPI Suite. It should also be noted that the same database, maintained by the Syracuse Research Corporation, is the source for both the supplemental SSG and EPI Suite. Additionally, primary literature citations are available in EPI Suite, but not listed in the supplemental SSG. Use of EPI Suite would allow greater transparency for stakeholders examining the origin of specific chemical parameters.

Rationale to support a TAG member alternative view of the SSG for selection of physical/chemical values

To date, the Part 201 program generally has been using the most scientifically sound, robust, and reputable sources for physical/chemical parameters because it uses the recommended values from EPA's SSG and uses values from the SSG-recommended sources for chemicals that were not specifically listed in the SSG. Physical chemistry values are generally static and therefore not subject to intensive ongoing research in the same way that toxicity values are and as such, the values that are in place now in the generic criteria are up-to-date and correct.

MDEQ's rationale for adopting this EPA guidance was documented in Attachment B of Op Memo No. 18 (August 21, 1998). Although the SSG recommendations were based on a robust and technically sound evaluation, deviations from the recommendations may be justifiable for specific chemicals or parameters on the basis of chemical- or parameter-specific considerations (e.g., an emerging contaminant). MDEQ should have a process for evaluating requests for such deviations, as well as for establishing parameter values when a value is not given in the SSG, cannot be derived by using the methods recommended in the SSG (e.g., deriving Koc values from Kow values), and is not available in the SSG-recommended sources. This process can follow the Generic Criteria Chemical/physical Value Decision Framework and would involve the evaluation of scientific information specific to the parameter in question. The rationale for establishing a value on the basis of this information should be transparent and well documented.

Although the SSG is from 1996 and was updated in 2002, its recommendations for the selection of chemical/physical parameters are still more robust and scientifically sound than any other subsequent EPA guidance because the recommendations were based on an extensive evaluation of many sources of chemical/physical values, addressed the difficult issue of selecting a value from multiple, valid measurements, were subject to extensive public comments, and are well documented (see SSG: Technical Background Document, Part 5: Chemical-Specific Parameters). As such, the SSG values and the recommended hierarchy of sources should continue to be first choice in deriving Part 201 generic criteria, although deviations from the SSG recommendations on a parameter-by-parameter basis may be valid, and certain parameters specific to the dermal route (ABS_{derm} and FA) should be taken from RAGS Part E (Dermal Guidance, 2004) which was also based on a rigorous evaluation (i.e., peer reviewed) and subject to extensive public notice and comments.

The following example (using K_{oc} for benzene) illustrates why the SSG remains the most robust source for selecting default values for physical/chemical parameters, as compared to alternate sources such as EPI Suite or ChemIDPlus:

- EPA recognized that it must address the issue of selecting a single value from among the multiple valid measured values found in the literature (including those in Syracuse Research Corporation databases), which may span a wide range of values for many chemicals.
- EPA recognized that K_{oc} can be difficult to measure, and as a result, measured values are available for a limited list of chemicals, and the measurements for some chemicals are variable (for benzene the range EPA evaluated after removing outliers was from 31 to 100 L/kg).
- EPA recognized that K_{oc} is strongly related to K_{ow}, and measured K_{ow} values are more readily available and can be used to estimate K_{oc} values (Section 5.3.1 of the SSG cites the work of Lyman and DiToro as the basis for using a linear regression of measured values for chemicals of concern at Superfund sites).
- EPA presented two regression equations of log K_{ow} to log K_{oc} for calculating K_{oc} based on measured K_{ow} values that showed good correlation for the chemicals in the different chemical classes associated with each regression equation; and
- These equations were used in SSG to provide a consistent means of addressing variability among the measured K_{oc} values for a given chemical and filling gaps in the K_{oc} dataset for chemicals that lack measured K_{oc} values but have measured K_{ow} values.

The above examples demonstrate that the values contained within the SSG were derived through relevant and accepted methods, are credible, and are based on experimental data. Further, in total the SSG is a comprehensive source as it provides chemical/physical values for numerous chemicals and a procedure for selection of values for chemicals not included in the SSG.

As an alternative to the SSG, the TAG considered using the measured value(s) included in EPI Suite. However, attributing the values contained within EPI Suite to EPI Suite would be incorrect and even misleading, for the following reasons (continuing with the benzene K_{oc} example):

- The K_{oc} of 56.2 L/kg included in EPI Suite is not generated by the prediction algorithms in EPI Suite, which per the software documentation is the sole purpose of the EPI Suite software, and the program provides no documentation on how or why this value was selected.
- As indicated in the EPI Suite documentation, the K_{oc} of 56.2 L/kg is actually a 1991 measured value from the Syracuse Research Corporation (SRC), presumably included in EPI Suite as a point of

reference for judging the values predicted by EPI Suite, and is only one of at least 13 measured K_{oc} values for benzene that EPA included in the development of its recommendations in the SSG.

The TAG further considered using online databases such as ChemIDplus for identifying default values for certain parameters. However, ChemIDplus has limitations that are similar to those associated with attributing measured values to EPI Suite. Specifically, ChemIDplus appears to prefer values from SRC (while providing no basis for selection of these values), which is only one of the many sources EPA included in its evaluation in the SSG, and as such, is less robust and less scientifically sound. Continuing with benzene as an example, the values for various parameters from SRC are cited to studies published between 1979 and 1995 that EPA included in the development of its recommendations in the SSG.

The TAG also considered using prediction methods from EPI Suite. However, the measured and prediction results from EPI Suite are less robust and less scientifically sound than those from the SSG, for the following reasons (continuing with the benzene K_{oc} example):

- EPI Suite predicts two K_{oc} values for benzene (145.8 and 70.51 L/kg) and provides no guidance or recommendation on which value to use.
- The predicted value of 145.8 L/kg is outside the measured range for benzene, as documented in the SSG.
- The other predicted value is apparently estimated using a correlation to K_{ow}, which is similar to the correlation recommended in the SSG, but lacks information on its basis and source (e.g., what chemicals were used in the regression, and how good was the fit).

Response to comments from TAG members not supporting the continued use of SSG as the primary source of chemical/physical values

The main point of the comments from the TAG seems to be pointing out an *apparent* inconsistency between the recommendations to use the SSG and SSG's methodology to select values for chemical/physical parameters and text in the Supplemental SSG that could be interpreted to read that EPA believes that the values for physical/chemical parameters are routinely modified.

The statement from the Supplemental SSG that reads, "All of the sources of the values listed in Exhibits C-1 through C-5 are regularly updated by EPA." does not accurately characterize EPA's actual practice as it relates to chemical/physical parameters. The values in Exhibit C-5 of the Supplemental SSG (toxicity values) are routinely updated as new toxicity studies emerge. But the updating of toxicity values (which is the subject of the first two bullets in Appendix F) is not relevant to the discussion of chemical/physical parameters. The chemical/physical values in Exhibits C-1 through C-4, specifically Koc, solubility, henry's law constant, melting point, Kd, and diffusivities are generally considered static and little or no new research is available for these values. The values in Exhibit C-1 to C-4 of the Supplemental SSG demonstrate this. A comparison of the values in Exhibit C-1 to C4 with those in the 1996 SSG shows that the two sets of values are the same; none of the values for the parameters in Exhibit C-1 to C4 changed between the 1996 SSG and the 2002 Supplemental SSG. Therefore, the EPA statement quoted above applies to the toxicity values in Exhibit C-5 but does not apply to the chemical/physical parameters.

The inaccuracy of the above quoted statement relative to chemical/physical parameters is further demonstrated by investigating the source of the values provided in both EPI Suite and ChemIDPlus. Using the example of benzene from the original proposed text shows that the most recent cited study from either of these sources is from 1995, which predates both the SSG and the Supplemental SSG.

In principle, EPI Suite is a reasonable source where acceptable measured values are not available. However, the text provided above describes the merits of using the SSG approach (with benzene as an example) to illustrate some of the many ways that EPA identified and used acceptable measured values in making its recommendations, which remain valid. EPA's sources of acceptable values included SRCs PHYSPROP database as well as 12 other sources of measured values of Koc for benzene. EPA then used the proven relationship between Kow and Koc to develop a correlation that relies on measured values of Kow to calculate Koc values that honor this physical relationship. Therefore, the SSG approach for deriving Koc relies on literature to derive values based on measured Kow.

While the new methodology document from SCDM does identify that it uses a new approach for selecting Koc values, we were unable to find within the SCDM documentation any rationale for why it now believes the approach for calculating Koc should be modified to prefer the MCI estimation methodology (which existed at the time the SSG was written) over the log Kow method used in the SSG.

Appendix B:

TAG 2 Final Report: Updating Exposure Pathway Assumptions and Data Sources

Final Report:
Part 201: Updating Exposure Pathway Assumptions and Data Sources

October 2014

Prepared for
The Criteria Stakeholder Advisory Group (CSA)

Submitted by
TAG 2: Exposure Pathway Assumptions and Data Sources

In collaboration with
Public Sector Consultants Inc.
Lansing, Michigan
www.pscinc.com

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Introduction

Technical Advisory Group 2 (TAG) met eight times from June to September 2014 to review, discuss, and develop responses and recommendations related to 11 questions that were outlined in the White Paper prepared by Public Sector Consultants Inc. (PSC). Those questions addressed generic exposure pathway assumptions used to derive Part 201 generic criteria.[1] PSC's White Paper served as the framework for the TAG's discussions. This final report to the Criteria Stakeholder Advisory Group (CSA) presents the TAG's discussions, findings, and recommendations.

WHITE PAPER AND REVIEW PROCESS

In reviewing the White Paper, the TAG had several ideas of additional topics to include, as well as questions and suggestions. The TAG suggested inserting a broad overview of the legislative background and intent of the generic Part 201 cleanup criteria and the generic exposure assumptions for residential and for nonresidential land use. Some members also requested more narrative regarding how the current values were established for the purpose of showing why certain choices were made, and to underscore that it should be an informed process. Much of this information is provided in existing Michigan Department of Environmental Quality (MDEQ) Part 201 technical support documents (TSDs). It was determined that the focus should be on future updates and moving forward, rather than focusing on how the current equations and exposure assumptions were developed.

This report is organized into the following sections: summary of TAG recommendations, general background information, the White Paper questions, a summary answer to each of the questions, along with the resulting discussions and recommendations for each of the questions. Detailed discussions are provided in Appendix F. The report presents the White Paper questions in the order they were considered and addressed by the TAG.

TECHNICAL ADVISORY GROUP MEMBERS

Exhibit 1 details the TAG membership:

EXHIBIT 1. TAG Members

Donal Brady	Enviro Solutions
Christine Flaga	Department of Environmental Quality
Kory Groetsch	Department of Community Health
Christene Jones	Barr Engineering
Patricia Koman	University of Michigan
Francis Ramacciotti	ENVIRON
Steve Zayko	PM Environmental

[1] White Paper: Generic Exposure Pathway Assumptions and Data Sources, Public Sector Consultants, May 2014.

WHITE PAPER QUESTIONS

The TAG was asked to review and address the following questions and issues:

Land Uses: Residential and Nonresidential

1. What is the most appropriate receptor to use for residential land use criteria?
2. Should the age-dependent adjustment factors (ADAFs) recommended by the U.S. Environmental Protection Agency (EPA) be used to address early-life exposure to mutagenic carcinogens? The ADAFs would be applied to those substances that have been identified by the EPA to be mutagenic carcinogens (approximately ten substances on the current Part 201 list of hazardous substances and cleanup criteria).
3. What is the most appropriate nonresidential scenario for workers, that is, indoor, outdoor, or a combination of both?
4. In totality, do the pathways, models and cumulative exposure assumptions "take into account best practices from other states, reasonable and realistic conditions, and sound science," as required by Section 20120a(18) of the Natural Resources and Environmental Protection Act (NREPA)? (answered as final question)

Data Sources/References

5. What are the appropriate data sources for the estimates for exposure assumptions such as drinking water ingestion rates, soil ingestion rates, body weights for the selected age groups, relative source contribution factors, and other dermal exposure assumptions?
6. What are the appropriate data sources for, and estimates of, exposure frequency, exposure duration, and averaging time?
7. Where available, should the department utilize data that are representative of Michigan, rather than nationally representative data? If so, which data should be utilized?
8. Should the algorithms, including exposure parameters, be consistent with or based upon federal (i.e., EPA) methodology and data? If yes, are there any circumstances under which deviations from the federal methodology and data should be allowed? If no, what methodology and data should be used?

Numeric Values: Exposure Assumptions

9. Based on the identified receptors, routes of exposure, and data sources, what are reasonable values for the various assumptions? Given the range of exposure assumption values, how should the most reasonable numbers be selected and updated and why?
10. Do probabilistic approaches (e.g., Monte Carlo) have a place in the selection of exposure parameters for generic criteria and, if so, what should that role be?
11. For each pathway calculation recommended, has it been determined to be *reasonable and relevant* and does it make sense in the *real world?*

SUMMARY OF TAG RECOMMENDATIONS

While consensus was not achieved in many instances, the group agreed on several of the White Paper questions.

In general, the TAG recommends using a framework that allows for the identification of exposure values and recommends that the exposure values and algorithms for generic cleanup criteria be periodically reviewed, using a process that is transparent and includes documentation and opportunity for public review and comment. The TAG's proposed decision framework or process represents the best available science, best practices (from the EPA, other federal agencies, and other states and countries), reasonable and realistic conditions, and sound science, as required by Section 20120a(18) of the NREPA. Ideally, the value for each exposure parameter should represent Michigan's population and exposure conditions. However, Michigan-specific exposure parameter values may not exist or may be difficult to calculate due to the characteristics of the data set. The purpose of Appendix D: Decision Framework for Updating the Michigan Part 201 Generic Cleanup Criteria Exposure Assumptions is to assist the MDEQ in the periodic evaluation of existing exposure parameters with respect to the best available science. All determinations, including the determination that no changes are necessary, are to be documented in a technical support document and provided for public review and comment.

Regarding the generic residential receptor for all pathways, the TAG recommends an age-adjusted adult plus child receptor that assumes 30 years of exposure with two age bins. Where appropriate, the generic cleanup criteria should be adjusted on a chemical-specific basis to account for the protection of pregnant women and young children from developmental and reproductive toxicants. The group considered and discussed the option of a child-only receptor as the representative population for the residential population. Some TAG 2 members were concerned about the impacts to the program if a child-only receptor was implemented for development of the generic residential criteria. There was consensus on the technical points that children (aged 0 to 18 years) have different exposures than adults, and that exposures at critical periods of development across their lifetime may be more important. It was also agreed that age-dependent adjustment factors (ADAFs) recommended by the EPA should be used to address early-life exposure from mutagenic carcinogens.

The TAG generally agreed that the basis for the generic nonresidential receptor (indoor or outdoor) should be the receptor with the highest exposure, thereby providing protection for both indoor and outdoor workers. To assist the CSA with making final decisions regarding the most appropriate nonresidential receptor and associated exposure assumptions, this report presents options and background information for those options.

The TAG recommends using Michigan-specific data when they are available, relevant to the exposure scenario, and best meet the data quality objectives (DQOs) outlined in question 5. Along with Michigan-specific data, EPA's exposure factors should also be used as a starting point for exposure assumption estimates. All data sources, including the EPA's, ideally should meet the DQOs proposed herein. Data that are representative of Michigan, when available, are preferred, as long as they are relevant to the exposure scenario, and best meet the DQOs as outlined in Question 5. The consideration of Michigan-specific data is included in the proposed decision framework.

The group achieved consensus around a range for many, but not all, values for nonresidential exposure assumptions, as well as a process for selecting future values for those not identified during the TAG meetings. Given the limited time available to discuss the values, the group was unable to reach consensus on many of the residential exposure factor values. However, two sets of alternative values for residential and nonresidential exposure factors were provided by two separate groups comprised of TAG 2 members. These alternative values are provided in Appendices K, L, and M.

The TAG concluded that probabilistic approaches (e.g., Monte Carlo) can be used to validate the final combination of proposed exposure factors used to calculate generic criteria. Also, while it was agreed that probabilistic approaches can be used to inform the individual exposure factors, using a probabilistic approach to produce the generic cleanup criteria, independent from other factors and considerations, is a process that could not be recommended at this time.

While consensus on a framework or process to arrive at “reasonable and relevant” exposure inputs to pathway-specific calculations was achieved, TAG 2 had insufficient time to evaluate individual pathways for the residential scenario. Some TAG members recommended utilizing EPA and Great Lakes states as benchmarks for the recommended generic exposure assumptions, while others did not.

Report Appendices

In addition to this report containing summary answers, recommendations, and discussion narrative related to each of the White Paper questions considered by the TAG, a series of 13 appendices (A–M) are included. These appendices are offered as supplemental information on a variety of topics related to the White Paper questions. The report narrative makes reference to these appendices throughout the document where relevant to provide additional detail to the report content. TAG members were not precluded from submitting supplemental information, individually or collectively.

Appendix A are the references cited in the report. Appendices B and C are the tables of a range of exposure values— the TAG discussed Appendix B but not Appendix C in the time available. Appendix D and E provide the decision framework and DQOs and criteria review cycle that the TAG is recommending to the Criteria Stakeholder Advisory Group (CSA). Appendix F contains narrative of the TAG discussions and includes items brought to the TAG for discussion. While many discussions may not have resulted in group consensus, the narrative demonstrates the participation of all TAG members and highlights items that some members found important. Appendix G contains exposure assumption considerations for all populations. Appendix H presents an example of a Conceptual Site Model (CSM) brought to the discussion for reference purposes only—this specific CSM was not discussed by the group. Appendix I is the summary work of a TAG member that analyzed a soil temperature dataset available online from Michigan State University Extension to illustrate the use of climate data to inform exposure values. Appendix J was solicited by the TAG and presents scientific studies regarding soil ingestion rates and a summary of EPA/OSWER evaluation of those studies. The discussion in Appendix J is an evaluation of soil ingestion rates conducted in the spirit of the DQO/TSD evaluation process. The requested discussion in Appendix J is an example of when high-end values are used. While the topic of soil ingestion rates were discussed at length, group consensus was not reached. The discussion was brought to the table by the MDEQ out of concern for inconsistencies between two programs within the department. Appendices K and L were provided by three TAG members and present numerical alternatives for nonresidential and residential exposure assumption values with the supporting references and rationale. Appendix M was provided by three other TAG members and present numerical alternatives for nonresidential and residential exposure assumption values with the supporting references and rationale. Appendices K, L, and M were submitted voluntarily and were not discussed by the full TAG.

TAG members that submitted supplemental information for inclusion as appendices are named on the appendix. Some appendices were discussed more than others and some were submitted voluntarily, and their inclusion in this report does not imply that all TAG members were in agreement to the information presented. The goal is to provide as much relevant information as possible to help inform the CSA discussions without giving preference or weight to a specific appendix.

Questions, Answers, and Recommendations

The following section presents each White Paper question, a summary answer to the question posed, recommendations to the CSA, and a summary of the TAG's discussion about the question. Note that several questions were realigned by the TAG, consistent with the information being discussed and the overlap among topics. This report organizes the questions as they were considered and addressed by the TAG.

Question 1

What is the most appropriate receptor to use for residential land use criteria?

Summary Answer: Except for hazardous substances that are developmental or reproductive toxicants (e.g., Footnote DD), the recommended generic receptor is an age-adjusted child plus adult that assumes 30 years of exposure with two age bins. Where appropriate, the criteria equations and exposure inputs should be adjusted on a chemical-specific basis to account for developmental and reproductive toxicants for which the child-only receptor is most appropriate. The group considered and discussed the option of a child-only residential receptor. Some TAG 2 members were concerned about impacts to the cleanup program if a child-only receptor was implemented for development of the generic residential criteria. There was consensus that children can be more susceptible and have different exposures than adults. The TAG agreed that the language in the current Rules should enable the MDEQ to develop criteria that addresses developmental or reproductive toxicants and that this language should be maintained.

Recommendation 1: The recommended generic receptor is an age-adjusted child plus adult that presently assumes exposure across two age bins, except in the case of developmental toxicants.

Recommendation 2: The MDEQ should follow EPA guidance to develop a process to account for those chemicals, or classes of chemicals that have documented developmental or reproductive effects.

Recommendation 3: The MDEQ should maintain language in the current Part 201 rules (R299.49 (DD)) that allows the agency to regulate developmental and reproductive toxicants to protect sensitive subpopulations from these substances on a chemical-specific basis. For developmental and reproductive toxicants, the MDEQ should evaluate if the age-adjusted child plus adult receptor is protective of childhood and early-life-stage exposures on a chemical-specific basis.

Discussion and Background

Currently, the MDEQ uses an adult-only receptor for drinking water, and an adult plus child age-adjusted receptor for direct soil contact for noncarcinogens. The age bins for direct soil contact are birth to six years, and 7 through 30 years; however, the age group of 7 through 30 years is given the same exposure assumptions as the adults. This raised the concern that susceptible and vulnerable populations (for example, children aged 7 to 18 years) are not being as protected as they could be if more ages and developmental stages were considered in the exposure equations (National Academies of Science 2009, National Academies of Science 2014, Firestone et al. 2007, Schwartz et al. 2011).

One TAG member proposed four age bins (0–6; 7–11; 12–18; and 19–31) for direct soil contact and drinking water exposure values. Another TAG member noted that the group had discussed how developmental toxicants should be considered, and whether the proposed age bins would adequately protect against exposure during critical developmental windows. This member suggested that the age-adjusted approach might not be appropriate, because it assumes prolonged exposure rather than exposures at critical developmental points. When there is evidence of developmental toxicity, an age-adjusted receptor cannot be considered protective of childhood or early-life-stage exposure. TAG members agreed that the concern was related to increased sensitivity during certain developmental periods (e.g., embryos, infants, young children) and that the receptor must be associated with the appropriate exposure period and toxicity value(s).

Some TAG members raised the concern that if too many age bins are incorporated into the generic residential equations, the complexity associated with implementation is magnified significantly. One idea raised was to focus the use of additional age bins only on the handful of chemicals known as a concern to children at different ages and developmental stages (for consistency with the toxicity value(s)).

The TAG discussed differences in exposure assumptions associated with the age bins. A member noted that there would be, in some instances, little to no difference in exposure assumptions between the age bins due to the paucity of exposure studies. For example, exposure factor data does not exist for several age bins proposed by TAG members and the data currently available would be need to be used for several age bins. In other words, the differences among Age Bin 1 (birth to six years old) and Age Bin 2 (birth to two years old and two to six years old) may be insignificant. Considering this, some TAG members suggested a simpler approach to have fewer age bins if there are no studies examining certain age categories. Members noted that they had agreed earlier in the meeting to use the EPA values as their starting point for this discussion on age bins.

One member noted additional data or new studies may become available in the future that could affect the age-adjusted categories. Having the framework in place would allow for modification when new information becomes available. TAG members suggested a process could be developed to periodically re-evaluate new information.

The TAG discussed and agreed to recommend generating child- or age-specific criteria for chemicals or groups of chemicals that are documented as developmental toxicants (R299.49 (DD)). The TAG agreed to maintain the MDEQ's authority to protect for the most sensitive health effects, which may include developmental effects, authorized under the current statute and administrative rules. There are currently 26 Part 201 chemicals with toxicity data based on developmental effects that MDEQ identifies with Footnote "DD" in the Criteria Table. TAG members brought up the lack of population-representative data necessary for many of the input values for different age groups of children. The EPA's Exposure Factor Handbook (2011) identifies values such as body weight and skin surface area for different age groups of children. However, soil ingestion rate for different children age groups is not described in this handbook, but is discussed in subsequent peer reviewed literature (Stanek et al. 2012). More information may become available in the future. A TAG member suggested that the MDEQ should consider ways to address data gaps and obtain missing information given the availability of department resources such as external stakeholders being given the opportunity to provide information to the department.

It was noted that MDEQ does not currently have a written or well-defined process on how developmental and environmental toxicants are addressed, or how criteria are generated to protect for that sensitivity. Under statute, the MDEQ does have the authority to do this. The group recommends that the MDEQ create this process.

Question 2

Should the age-dependent adjustment factors (ADAFs) recommended by the EPA be used to address early-life exposure from mutagenic carcinogens? The ADAFs would be applied to those substances that have been identified by the EPA to be mutagenic carcinogens (approximately ten substances on the current Part 201 list of hazardous substances and cleanup criteria).

Summary Answer: Yes—ADAFs should be used to address early-life exposure to mutagenic carcinogens in the development of the Part 201 cleanup criteria.

Recommendation 4: ADAFs for the chemicals recommended by the EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, March 2005 (and most recent updates) should be used to address early-life exposure from mutagenic carcinogens.

Recommendation 5: A periodic review of the list of mutagenic chemicals should be included in the criteria update process to ensure that the MDEQ uses updated information, reflecting the best available science and includes additional mutagenic carcinogens as they are identified by the EPA.

Discussion and Background

TAG 2 received a list of the chemicals identified by MDEQ with a mutagenic mode of action for carcinogenesis. TAG 2 members had concerns about how the chemicals listed as mutagenic carcinogens are determined, specifically when Chromium VI is included in the list. TAG 2 asked TAG 1 to examine the list of mutagenic chemicals and develop criteria for how and why a chemical is on this list. TAG 1 recommended that the list of mutagenic chemicals are those carcinogens with a mutagenic mode of action identified by the EPA, and evaluated by the MDEQ as needed.

There is one chemical (hexavalent chromium – Cr-VI) on the list of mutagenic carcinogens provided to TAG 2 that is not on the EPA's website list of mutagenic carcinogens, but it was included because the EPA calculated the Regional Screening Level (RSL) for Chromium VI based upon a mutagenic mode of action. TAG 1's response gives the MDEQ the ability to add or remove chemicals from the list of mutagenic chemicals. Some TAG 2 members would like more transparency and further explanation when the MDEQ deviates from the EPA's website list. Other TAG 2 members stated that the list of mutagenic carcinogens should have a process for public and stakeholder review that would require a transparent, detailed explanation for a chemical's addition or removal from the MDEQ mutagenic chemical list.

TAG 2 reaffirmed the recommendation that ADAFs should be used for mutagenic carcinogenic chemicals. TAG 2 recommends that the MDEQ routinely use the most up-to-date list of mutagenic carcinogens from the EPA, and that a review of this list of mutagenic carcinogens should be included in the periodic criteria update process.

Question 3

What is the most appropriate nonresidential scenario for workers, that is, indoor, outdoor, or a combination of both?

Summary Answer: The group generally agreed that the basis for generic cleanup criteria for a given exposure pathway for the nonresidential scenario (indoor and outdoor) should be the indoor or the outdoor worker depending on which had the highest intake; thereby providing protection for both indoor and outdoor workers as represented by the reasonable maximum exposure (RME). In the time allowed, however, the group did not achieve consensus and make a final determination or recommendation. To assist the CSA with making a final decision regarding the most appropriate nonresidential receptor and the associated exposure assumptions, this report presents exposure factor options and background information, which are addressed under Question 9.

Recommendation 6: The MDEQ should consider the impact of Part 201 generic criteria on other programs such as drinking water programs. For example, the Michigan Safe Drinking Water Act, or SDWA (1976 PA 399), does not recognize a distinction between residential and other drinking water standards. A chemical-specific drinking water standard, currently established by the SDWA, applies to water for both residential and nonresidential use. TAG 2 members want to communicate these differences between Part 201/213 and the SDWA to the CSA.

Options:

The group noted that there were three primary alternatives for MDEQ consideration:

- Set exposure assumptions for an outdoor worker;
- Set exposure assumptions based on indoor worker; or
- Develop two sets of exposure assumptions: one set for indoor workers and one for outdoor workers, which might require statutory change.

Discussion and Background

The TAG reviewed MDEQ's current process for establishing nonresidential screening levels. The current Part 201 nonresidential soil direct contact receptor is generally based on an outdoor worker previously categorized as an industrial worker. The previous receptor for drinking water was more broadly considered a commercial/industrial worker and was never subcategorized as the soil direct contact criteria were. The receptor for inhalation was assumed to be an indoor worker since the pathway is the migration of vapors from the subsurface into indoor air. Prior to Part 201, there were four commercial receptor (i.e., worker) subcategories for the soil direct contact pathway. These were Commercial I (equivalent to the residential criteria), Commercial II (equivalent to the industrial worker criteria), Commercial III (a worker performing low soil-intensive activities, such as a warehouse operator or someone who works in a plant nursery), and Commercial IV (a worker performing high soil-intensive activities, such as a gardener or groundskeeper). As part of the amendments, the subcategories were combined into a single category to decrease the complexity of the program. Since the health-based values for the industrial worker were protective for the other worker categories, it was selected to represent the nonresidential receptor. Essentially, an outdoor worker was the generic receptor based on the assumption that outdoor workers would receive the greatest exposure to contaminated soil.

In discussing the receptor scenarios, the group discussed restrictive covenants and site-specific criteria. Two TAG members suggested that site-specific or generic criteria could be developed that would allow for a higher level of exposure—if assurances could be provided that the site would be maintained appropriately. These assurances could include a Due Care Plan if the implementation of the plan was reviewed by the MDEQ to ensure proper implementation and ongoing maintenance of the Due Care Plan or a restrictive covenant (for example, paving the affected area of the subject property).

Members discussed the merits and challenges of the need to be protective of the most susceptible workers. A TAG member stated that the generic criteria should protect most workers (the reasonable maximum exposed worker, or an upper end estimate [90 to 95 percent] of the worker population), including those that work outdoors. This member stated that selection of an indoor worker for the soil direct contact pathway would make it difficult for the department to communicate that all (including outdoor workers) are protected by the generic criteria. Implementation of this approach for generic purposes would also be difficult, as properties with outdoor workers would not be represented by the generic criteria and properties with outdoor workers could not implement the generic soil criteria. In addition, if a facility had indoor workers only, they could pursue site-specific criteria.

See Appendix F for detailed discussion.

Question 8

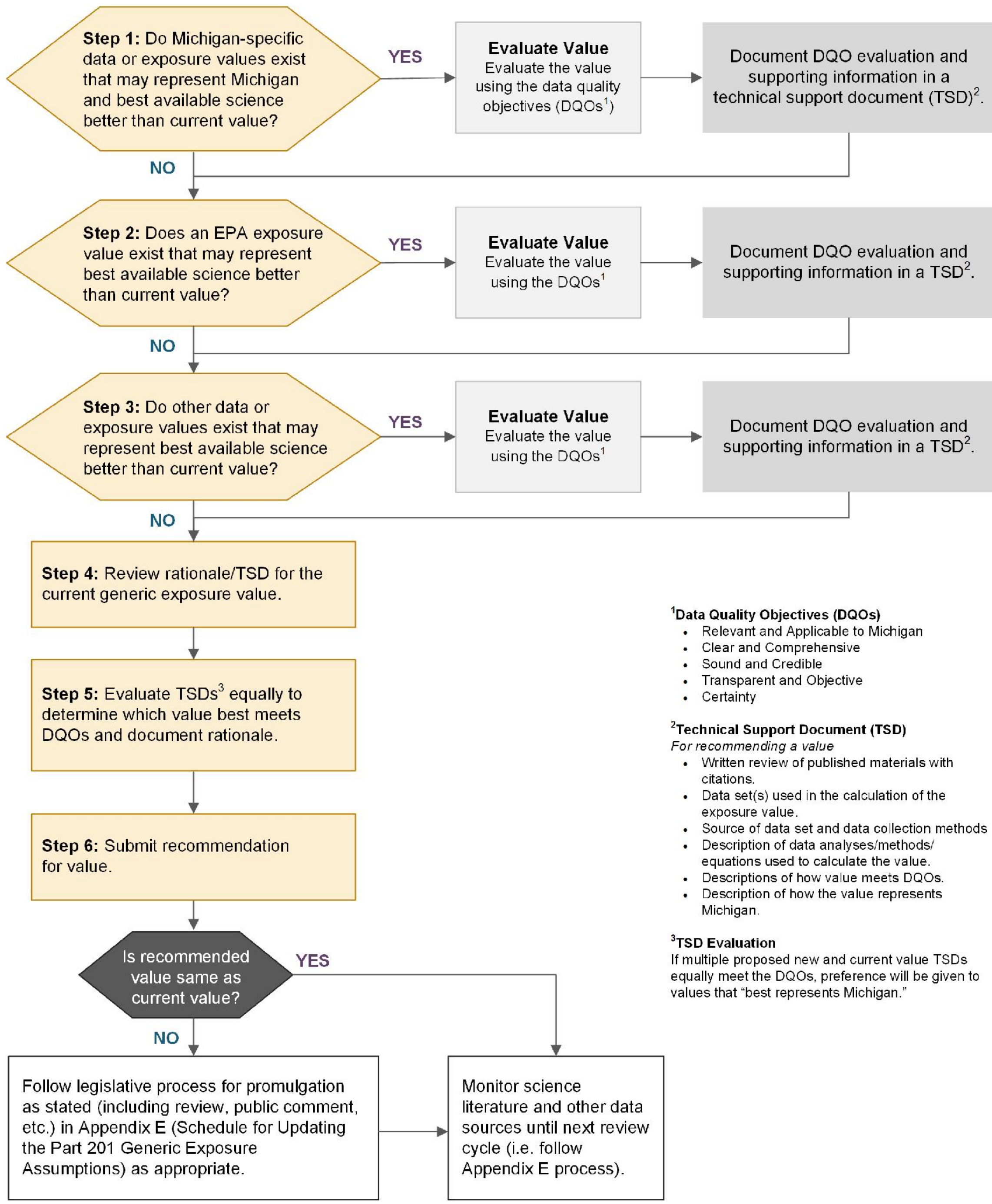
Should the algorithms, including exposure parameters, be consistent with or based upon federal (i.e., EPA) methodology and data? If yes, are there any circumstances under which deviations from the federal methodology and data should be allowed? If no, what methodology and data should be used?

Summary Answer: The TAG recommends using a decision framework to determine the exposure values, and also that those values and associated algorithms for the generic cleanup criteria be periodically reviewed using a process that is transparent and includes documentation and opportunity for public review and comment. This process considers federal methodology, and others, with an emphasis on data quality objectives with flexibility as proposed in the decision framework in Exhibit 2 below (also see Appendix D).

Recommendation 7: For all updated values, the TAG recommends a process and decision framework for selection of the generic exposure assumptions that is transparent and provides opportunities for meaningful public input.

Recommendation 8: The TAG generally supports the use of a regular review process for publicly reviewing and updating algorithms and exposure parameters for generic cleanup criteria.

EXHIBIT 2. Proposed Framework for Determination of Exposure Values



Discussion and Background

The TAG did not discuss the algorithms presented in Appendix A of the White Paper, since the CSA directed TAG 2 to focus their work on the White Paper questions and the generic exposure receptors, sources, and assumptions as well as a process for selecting the values. The TAG agreed that the EPA-recommended exposure values should be considered; however, if Michigan-specific data are available and appropriate and better meet the DQOs, the Michigan-specific data should be used first.

The TAG agreed that it would be good to provide an example of a conceptual site model to evaluate the applicability of generic criteria at a particular site. An example is provided in Appendix H.

The TAG noted that the equations were developed in the late nineties, and were consistent with EPA guidance at the time. The EPA has since made many updates and modifications. For contact with soil, the EPA considers that if soil is exposed, a person is not only ingesting and establishing skin contact, they are also breathing in the particulates and the volatiles. The MDEQ has considered combining these exposure factors, following the EPA's lead, but changes to this algorithm have not yet occurred.

The framework recommends using Michigan-specific data when possible (Question 7) and instructs the MDEQ to evaluate and determine if the existing value best meets the DQOs when compared to other sources. The exposure value or data could come from any source including Michigan, federal agencies, other states, other countries (e.g., Canada), or international entities (e.g., World Health Organization or European Union) as long as it best meets the DQOs. An initial list of sources is provided along with the framework for consideration when determining an exposure value. At this juncture, the list is not intended to be exhaustive. Sources not listed may be considered in the determination of exposure values.

All determinations are to be documented in a TSD and provided for public review and comment.

To ensure that these values stay up to date and represent the best available science, the TAG recommends a process for reviewing and updating the algorithms and exposure parameters for generic cleanup criteria (See Appendix E).

Question 5

What are the appropriate data sources for the estimates for exposure assumptions such as drinking water ingestion rates, soil ingestion rates, body weights for the selected age groups, relative source contribution factors, and other dermal exposure assumptions?

Summary Answer: The TAG supports using Michigan-specific data when available and that best meet the DQOs within the decision framework. The best available information from all sources (e.g., Michigan-specific, EPA, and other data sources) should be considered.

Recommendation 9: The TAG supports the use of data sources for the generic exposure assumptions for reasonable and relevant scenarios that best meet the fundamental data source characteristics, herein referred to as data quality objectives (DQOs).

- **Relevant and Applicable to Michigan:** The extent to which the information is relevant and applicable to Michigan generic criteria development (e.g., representative of Michigan population and conditions, currency of the information, adequacy of the data collection period).
- **Clear and Comprehensive:** The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented.
- **Sound and Credible:** The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application, and are regularly maintained, subject to peer review, and the best available science.
- **Transparent and Objective:** The data are published or publicly available and free from conflicts of interest.

- **Certainty:** The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized, including peer review and agreement of studies.

Recommendation 10: The TAG recommends evaluating Michigan-specific data, EPA sources, and other sources against current generic exposure values to select values that best meet the DQOs and consistent with the decision framework.

Discussion and Background

The TAG discussed establishing a set of data sources that could be used for the generic exposure factors, and that all data sources need to be consistent with DQOs. The data sources discussed are a part of the decision framework (Appendix D). The TAG discussed having a single data source as a starting point for the generic exposure assumptions when Michigan-specific data is unavailable, though consensus was not reached on the preferred source. Thus, the TAG agreed to retain both of the EPA sources—the OSWER Directive and the RSLs, as alternatives discussed.

Question 6

What are the appropriate data sources for, and estimates of, exposure frequency, exposure duration, and averaging time?

Summary Answer: See Question 5. The group made no distinction between data sources for these variables over those considered in Question 5.

Discussion and Background

The TAG reported that this question was very similar to Question 5, and they would use the same starting data sources, data source criteria, and recommended framework to deviate from the starting source.

Question 7

Where available, should the department utilize data that are representative of Michigan, rather than nationally representative data? If so, which data should be utilized?

Summary Answer: Yes—data that is representative of Michigan, when available, are preferred, so long as the data best meet the DQOs outlined in Question 5. The consideration of Michigan-specific data is included in the proposed decision framework.

Recommendation 11: The TAG recommends using Michigan-specific data to generate values for the exposure parameters when it is available and best meets the DQOs.

Discussion and Background

The TAG members agreed that it makes sense to incorporate Michigan-specific factors (for example, Michigan's winter) when selecting values—especially for outdoor exposures. However, Michigan-specific data sources need to best meet the DQOs when compared to other data sources. A TAG member noted that other Region 5 states do not make adjustments of the national values. Other members clarified the differences between the screening levels used by many of these states and the generic cleanup levels used in Michigan.

At this time, certain exposure factors were not derived using Michigan-specific data. For example, the nonresidential ingestion pathway exposure frequency does not account for Michigan weather and is assumed to be 245 days per year for outdoor worker. The nonresidential dermal contact pathway exposure frequency does, however, consider days to account for Michigan winters. This is calculated with the following formula: 365 days per year, less 120 days and 21 days divided by 5 workdays per 7 days = 160 days of exposure per year. The 120 represents winter days where the soil is potentially frozen or covered with snow, which is assumed to eliminate exposure to contaminated soil. The 21 days represents three weeks for vacation and sick time; and the 5/7 accounts for the work week. This leaves 160 days of potential soil dermal contact exposure. A second method for calculating dermal exposure frequency for an outdoor worker is to identify the number of days the worker meets the assumptions for dermal contact, including exposed hands and face and short-sleeve shirts, and 3,470 cm2 of exposure skin surface area. (6 months*4 weeks per month + 2 weeks)*6 = 156 which rounds to 160. There are six months per year when outdoor workers typically wear short sleeves without additional layers for rain and/or cold (May through October). Since each month has more than four weeks, two additional weeks are added to account for 30/31 days per month. This equation assumes that outdoor workers work six days per week and take no time off during Michigan's outdoor working season. This method of calculating dermal exposure frequency for an outdoor worker also indicates 160 days of potential soil dermal exposure is appropriate for Michigan.

As a potential example of Michigan-specific data, a TAG member suggested looking at MSU's Enviro-Weather website (http://www.agweather.geo.msu.edu/mawn/), which has ten years of data on soil temperatures in the two inches of soil at all of the Michigan Weather Monitoring Station locations. An analysis of the data was sent to TAG members and the member suggested that this could be one source used to evaluate the number of winter days in Michigan (i.e., when surface soils are frozen and it is unlikely that inadvertent soil ingestion would occur). This data source needs to go through the decision framework, however, and meet all of the DQOs before being considered. One TAG member pointed out that one drawback of this data source is that it only accounts for frozen days, and does not consider snow cover. Snow cover could also impact ingestion of outdoor soil (dust). For a further review of this data source, see Appendix I.

A TAG member also suggested, as another example of Michigan-specific data, central tendency values for body weight. Five studies (Hayes et. al 2013; Carlson et. al. 2012; USDHHS CDC 2012; Drenowarz et. al. 2012; Yee et. al. 2011) were mentioned that demonstrated that Michigan children and adults are typically 7 percent heavier than the national average. The majority of the TAG members expressed concern with changing the body weight input based on these data. Additionally, the American Medical Association recognizes obesity as a disease. Obese individuals may be more susceptible to the health risks posed by chemical contaminant exposures and some of those chemicals are considered to contribute to the disease (Institute of Medicine 2012, McClean, K. M. et al. 2008, Schwartzman, I. N., & Johnston, R. A. 2003). Thus, while Michigan-specific data was considered, the group did not reach consensus on a modification of this parameter based upon Michigan-specific data.

See Appendix F for detailed discussion.

Question 9

Based on the identified receptors, routes of exposure, and data sources, what are reasonable values for the various assumptions? Given the range of exposure assumption values, how should the most reasonable numbers be selected and updated and why?

Summary Answer: It is the intent of each exposure to be representative of an individual with a reasonable maximum exposure (RME). The RME is achieved by combining high-end or upper-bound and mid-range (central tendency) values. The TAG has consensus on some updated nonresidential values, however, these values have not been formally evaluated through the proposed decision framework with TSD documentation established by the TAG. The TAG developed a decision framework for determining values for the current and future updates. The group discussed and achieved consensus for many values for nonresidential exposure in Table A (Appendix B). Given the limited time available to devote to discussing the residential exposure factors the group was not able to discuss the residential exposure factor values in Table B (Appendix C).

Recommendation 12: As a starting point, use the identified values the TAG presents in Table A, and use the decision framework proposed by the TAG to establish and confirm values for all exposure factors including those recommended by the TAG.

Recommendation 13: The MDEQ should include the basis and percentile for each value in Table A and Table B.

Recommendation 14: To the extent possible, provide a detailed description of each value in a technical support document that includes DQOs, citations, and calculations.

Discussion and Background

While reviewing proposed values for Table A and Table B, a TAG member asked that the values used by MDEQ and EPA be identified as mid-range (average or central tendency) or high-end values. It was noted that this information relates to the RME concept, which is explained in Appendix F. An attendee of the TAG meetings reminded the group of the importance of using high-end values for sensitive parameters, since the Part 201 criteria do not consider exposures to multiple chemicals and multiple pathways at this time. Some TAG members stated that the criteria should consider exposures to multiple chemicals and multiple pathways in the future. Due to the usefulness of knowing if a value is high-end or mid-range, the TAG members agreed that this information should be added to Table A and Table B. The high-end or mid-range designation was largely based on TAG members' best professional judgment, as time constraints did not allow for comprehensive literature reviews or data analysis.

The nonresidential values (or range of values) that the group discussed are soil ingestion rate, exposure duration, body weight, averaging time for cancer, and averaging time for noncancer, all exposure factors for soil dermal contact, all factors for drinking water consumption, and all factors for air inhalation. The group recommended removing adjusted inhalation rate, and using exposure time in the equation instead, which would require a modification to the equation. The group did not agree on the nonresidential soil ingestion exposure frequency value for an outdoor worker. Instead, the group discussed a range of values of 160 to 245.

Members discussed that EPA only calculates one set of drinking water standards (i.e., Maximum Contaminant Limits (MCLs)) that are applied to all municipal drinking water sources in the U.S. This is also true of Michigan's State Drinking Water Standards (SDWS), which supersede the Part 201 drinking water criteria. The fact that the SDWS have only one set of standards for all uses presents a challenge for the DEQ given it regulates two programs with different approaches. In addition, some members felt the public may find it illogical to calculate nonresidential drinking water criteria, because water that met the Part 201 nonresidential drinking water criteria would not necessarily be safe for residents to drink. One member asked if the drinking water fountain that met the Part 201 nonresidential criteria would have a sign making users aware of the drinking limitations.

Table B (Appendix C) presents the range of residential exposure values proposed by each TAG member to allow the TAG to identify certain parameters that would or would not require in-depth discussions. Given the limited time available to devote to discussing the residential exposure assumptions, the group was not able to discuss the residential exposure factor values. The values in this table do not represent a TAG recommendation, since the basis for any number in this table has not been vetted by the TAG at any of the meetings.

Question 10

Do probabilistic approaches (e.g., Monte Carlo) have a place in the selection of exposure parameters for generic criteria and, if so, what should that role be?

Summary Answer: Yes. Probabilistic approaches can be used to validate the final combination of proposed exposure factors used to calculate generic criteria. Also, while the process of using probabilistic approaches can be used to derive individual exposure factors, using a probabilistic approach, independent from other factors and considerations, is a process that could not be recommended at this time as meeting the requirements of 324.20120a.

Discussion and Background

The TAG discussed two potential uses of probabilistic approaches. The first would be to derive individual exposure factors and/or calculating criteria values using data sets for all exposure factors. The second use would be to validate the combination of selected point-estimate exposure factors (final criteria value) with respect to the distribution of all calculated criteria values using all possible input values from the various distributions of each exposure factor. The lack of experimentally determined, data-validated distributions is one primary limiting factor in applying probabilistic approaches.

A TAG member had performed a limited sensitivity analysis for the variables in the equations for the residential direct contact criteria (DCC) for carcinogenic contaminants for demonstration purposes only. The TAG agreed that the process of performing this type of probabilistic method was appropriate to use as a validation for the final exposure factors the MDEQ recommends for use to generate criteria, though some TAG members questioned the sensitivity analysis that was conducted because a detailed methodology was not provided for evaluation.

See Appendix F for detailed discussion.

Question 11

For each pathway calculation recommended, has it been determined to be reasonable and relevant and does it make sense in the real world?

Summary Answer: While consensus on a process to arrive at "reasonable and relevant" pathway calculations was achieved, the TAG had insufficient time to evaluate individual pathways.

Discussion and Background

The group discussed the fact that the CSA would like to see benchmarks for the recommended values. EPA and Region 5 values were included in the White Paper for this purpose. The TAG recommended considering benchmarks based on other Region 5 states, and nearby locations like Ontario, Canada, which may have conditions more similar to Michigan than other states outside of the region. Although other states (e.g., California) may rely on good science, data, and documentation for their values, it was suggested that benchmarking to states outside of Region 5 could become too unwieldy. However, as it relates to the decision framework and the selection of exposure values, information from states and other government agencies (e.g., other countries) can be considered if they are determined to be relevant to Michigan conditions.

The TAG noted that generic exposure assumptions should be protective, but not excessively so, and should be representative of reasonable maximum exposures (RME). Some members suggested they should also protect susceptible populations, whereas another member noted that susceptibility is related to chemical-specific conditions that should be under the purview of TAG 1. The group discussed the uncertainties related to the various generic exposure assumptions.

To better understand if the values are reasonable, relevant, and protective in the real world, the TAG discussed what is meant by "generic cleanup criteria" and the level of required protectiveness. According to The Natural Resources and Environmental Protection Act 451 of 1994, Chapter 7 Remediation, Part 201 Environmental Remediation, Section 324.20120a (1) cleanup criteria, there are four categories: (a) residential, (b) nonresidential, (c) limited residential, and (d) limited nonresidential. None of these terms are explicitly defined in Part 201, nor are the phrases "cleanup criteria" or "generic cleanup criteria." Therefore, a TAG member noted that the characteristics of generic cleanup criteria must be gathered from the combination of a common definition of terms found in a standard dictionary. The context of the use of these terms within applicable sections of Part 201, and the Administrative Rules for Part 201 is lacking.

So far, it is the TAG's understanding that the generic cleanup criteria apply to two categories of land uses —residential and nonresidential—and address individual differences in activities within those land uses. The generic criteria are also intended to limit to a minimal level the risk of human health effects from reasonable maximum exposure. The methodological approach is generic human health risk assessment.

More succinctly, generic cleanup criteria are required to be adequately protective of public health, safety, welfare, and the environment from exposure to hazardous substances.

See Appendix F for detailed discussion.

Question 4

In totality, do the pathways, models, and cumulative exposure assumptions take into account best practices from other states, reasonable and realistic conditions, and sound science," as required by Section 20120a(18) of NREPA?

Summary Answer: While consensus on a decision framework for selection of the generic exposure assumptions for the current exposure pathway equations was achieved, some TAG members believe that time required came at the expense of being able to address this question fully. Several suggestions to update the information base, relying on current scientific literature, practices in other states and available tools, were suggested for future consideration.

Discussion and Background

General Discussion and Additional Option

Throughout the TAG 2 meetings, the group discussed a couple of areas that were not specifically requested by the White Paper, but may be relevant to the MDEQ's communication goals around the Part 201 update process, and were related to the areas TAG 2 was asked to address. The group's discussion about this and their recommendation is provided below.

Option: The MDEQ should increase its efforts on increasing awareness and education among due care site owners and operators regarding compliance requirements.

Discussion and Background

The TAG discussed the nonresidential exposure factors and whether the nonresidential criteria needs to be protective of all workers. One member stated that this is not the intent of the generic criteria, as other worker protections, such as due care requirements, were incorporated into Part 201 (and Part 212). The TAG continued discussing due care obligations for sites not meeting residential criteria. It was noted that owners/operators are responsible for maintaining the site and must account for foreseeable acts (trespass, for example), however, this requirement is not always enforced at this time. A site can reach closure by mitigating either the contaminant levels or the exposure pathway, but exposure assumptions varying from those used in calculating generic criteria typically must be addressed through an institutional control (e.g., deed restriction). The group discussed compliance, monitoring, and enforcement related to due care sites. The MDEQ stated that they do not know to what extent due care obligations are being met. Due care documentation is typically not submitted to the MDEQ by owners/operators unless they are the parties conducting cleanup or seeking brownfield funding. Some MDEQ staff believe there is a significant level of unawareness, which may lead to noncompliance; MDEQ staff also reported that Brownfields Redevelopment sites do require MDEQ oversight and have documentation of their due care.

An MDEQ representative provided a preliminary estimate of 9,700 Part 201 sites and 7,000 Part 213 sites in the state. The MDEQ has approximately 130 field staff that are unable to visit all sites to ensure compliance. It was noted that owner awareness generally increases during property transactions and when baseline environmental assessments (BEAs) are prepared.

Recently, the MDEQ has started to provide educational outreach to entities with due care obligations to make them aware of their legal obligations. The MDEQ stated that larger entities seem to be most likely to understand and implement their due care obligations. A TAG member stated that, as currently implemented, due care obligations do not appear to be equivalent to institutional controls.

Given this information, some TAG members thought that there should be a recommendation to the CSA that the MDEQ should increase its education and outreach activities. Other TAG members felt that although increasing outreach and awareness sounds like a good idea, not enough information was presented to give a true scope of this issue, and recommending increased education and awareness activities is outside of the scope of TAG 2's responsibilities, and therefore should not be a recommendation to the CSA.

Appendices

- Appendix A: Report References
- Appendix B: Table A: December 2013 Nonresidential Exposure Factors' Values (discussed) for Part 201 Generic Cleanup Criteria
- Appendix C: Table B: December 2013 Residential Exposure Factors (not discussed) for Part 201 Generic Cleanup Criteria
- Appendix D: Proposed Decision Framework for Updating the Michigan Part 201 Generic Cleanup Criteria Exposure Assumptions
- Appendix E: Proposed Update Process for Exposure Parameters for Generic Cleanup Criteria
- Appendix F: Detailed TAG Discussions
- Appendix G: Exposure Assumption Considerations for All Populations, Including Those Most Vulnerable
- Appendix H: Conceptual Site Model Example
- Appendix I: Summary of Michigan Daily Surficial Soil Temperatures from 2004 to 2014
- Appendix J: Justification for High-end Soil Ingestion Rate
- Appendix K: Alternatives for Nonresidential Assessment Factors
- Appendix L: Alternatives for Residential Assessment Factors
- Appendix M: Alternative Part 201 Generic Residential and Nonresidential Exposure Assumptions

Appendix A
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Appendix B

Table A: December 2013 Nonresidential Exposure Factors' Values (discussed) for Part 201 Generic Cleanup Criteria

TAG 2's indoor and outdoor worker values and ranges of values were discussed by the whole TAG, but these are not recommendations of the TAG.

			Current Nonresidential Routine*	Basis for Current MDEQ Values	TAG 2 Indoor Worker**	TAG 2 Outdoor Worker**
Soil Ingestion - R299.20						
Ingestion rate	mg-soil/day	**IR**	100	Upper-bound	50	100
Exposure frequency	Days/year	**EF**	245	Upper-bound	245	RANGE: 160–240
Exposure duration	Years	**ED**	21	Upper-bound	21	21
Body weight	kg	**BW**	70	Mid-range	80	80
Averaging time, cancer	Days	**AT_c**	25,550	Upper-bound	365*70 = 25,550	365*70 = 25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	Upper-bound	365*21 = 7,665	365*21 = 7,665
Soil Dermal Contact - R299.20						
Adherence factor	mg-soil/cm^2	**AD**	0.2	Mid-range for skin surface areas and adherence factor for receptors in high-end soil activity	0.07	0.12
Skin surface area	cm^2/day	**SA**	3,300	Mid-range	3,470	3,470
Soil Dermal Contact - R299.20 (cont.)						
Exposure frequency	Days/year	**EF**	160	Mid-range	245	160
Exposure duration	Years	**ED**	21	Mid-range	21	21
Body weight	kg	**BW**	70	Lower-bound	80	80
Averaging time, cancer	Days	**AT_c**	25,550	Lower-bound	365*70 = 25,550	365*70 = 25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	Lower-bound	365*21 = 7,665	365*21 = 7,665
Drinking Water Consumption - R299.10						
Drinking rate	L-water/day	**DR**	1	Adult: upper-bound	RANGE: 1.0–2.5	RANGE: 1.0–2.5
Exposure frequency	Days/year	**EF**	245	Adult: upper-bound	245	245
Exposure duration	Years	**ED**	21	Adult: upper-bound	21	21
Relative source contribution	Unitless	**RSC**	0.2	Noncancer only: upper-bound	RANGE: 0.2–1.0	RANGE: 0.2–1.0
Body weight	kg	**BW**	70	Upper-bound	80	80
Averaging time, cancer	Days	**AT_c**	25,550	Upper-bound	365*70= 25550	365*70= 25550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	Upper-bound	365*21= 7665	365*21= 7665
Air Inhalation - R299.14, R299.24, R299.26						
Adjusted inhalation rate		**AIR**	2.0	Cancer criteria only: lower-bound	REPLACE w/ ET	REPLACE w/ ET
Exposure time	Hours/day	**ET**	10.0	Not used in current MDEQ equation	8	8
Exposure frequency	Days/year	**EF**	245	Upper-bound	245	245
Exposure duration	Years	**ED**	21	Mid-range	21	21
Air Inhalation - R299.14, R299.24, R299.26 (cont.)						
Averaging time, cancer	Days	**AT_c**	25,550	Upper-bound	365*70 = 25,550	365*70 = 25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	Mid-range	365*21 = 7,665	365*21 = 7,665
Averaging time, cancer	Hours	**AT_c**	613,200	Not used in current MDEQ equation	365*70*24 = 613,200	365*70*24 = 613,200
Averaging time, noncancer	Hours	**AT_{nc}**	183,960	Not used in current MDEQ equation	365*24*21 = 183,960	365*24*21 = 183,960

* The current exposure values are from the MDEQ 2013 Cleanup Criteria Requirements for Response Activity (Formerly the Part 201 Generic Cleanup Criteria and Screening Levels) Rules. The basis for these values are found in the MDEQ Op Memo 1 Technical Support Documents (TSD): TSD – Attachment 6 (MDEQ, 2005), TSD – Attachment 7 (MDEQ, 2007), and TSD – Attachment 3 (MDEQ, 2004). These TSDs replaced the TSD OpMemo 18, MDEQ 1998.
** The exposure factors and values for TAG 2 Indoor Worker and TAG 2 Outdoor Worker discussed by TAG 2 are generally from the EPA 2014 OSWER Directive. The May 2014 updated EPA RSL adopted the OSWER values. Michigan-specific values for exposure frequency (EF) and exposure duration (ED) are from the MDEQ 2013 Rules. Averaging time based on a 78-year lifespan was taken from the 2011 Exposure Factor Handbook.

References for Current MDEQ Exposure Values:

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MDEQ. 2007. Technical Support Document – Attachment 7. Part 201 Generic Soil Inhalation Criteria for Ambient Air/Part 213 Tier I Soil Inhalation Risk-based Screening Levels for Ambient Air. July 2007. Available: http://michigan.gov/documents/deq/deq-rrd-OpMemo_1-Attachment6_285488_7.pdf (accessed 10/09/2014)

References for TAG 2 Nonresidential Exposure Values:

MDEQ. 2004. Technical Support Document – Attachment 3. Part 201 Drinking Water Criteria/Part 213 Tier I Drinking Water Risk-based Screening Levels. December 2004. www.michigan.gov/documents/deq/deq-rrd-OpMemo_1-Attachment3DrinkingWaterCriteriaTechnicalSupportDocument_284872_7.pdf (accessed 10/09/2014)

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U.S. EPA. OSWER. 2014. OSWER Directive 9200.1-120 Human Health Evaluation Manual, Supplemental Guidance: Update of Default Exposure Factors.

U.S. EPA Regional Screening Level (RSL). May 2014. Mid-Atlantic Risk Assessment.

Appendix C

Table B: December 2013 Residential Exposure Factors (not discussed) for Part 201 Generic Cleanup Criteria

Individual TAG 2 members presented values for each exposure factor as a starting point for discussion. Due to time constraints, however, there was no discussion about these values. The values and ranges of values do *not* represent TAG recommendations.

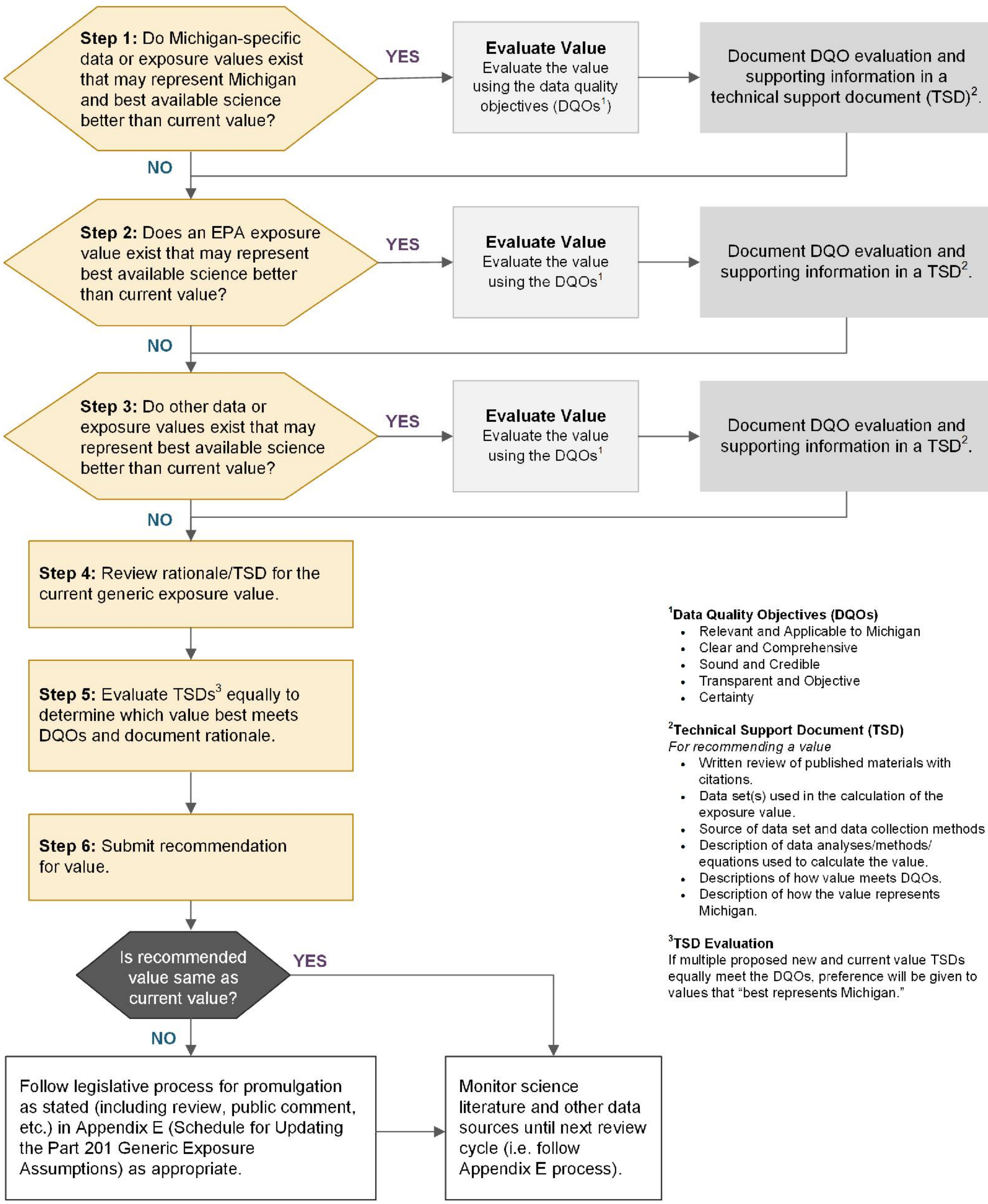
			Current Residential Values			Basis for Current Values	Presented TAG 2 Residential Values	
			Age 1–6	Age 7–31	Resident	MDEQ	Age Bin 1 "Child"	Age Bin 2 "Adult"
Soil Ingestion - R299.20								
Ingestion rate	mg-soil/day	**IR**	200	100		Upper-bound	RANGE: 40–200	RANGE: 50–100
Fraction contacted	Unitless	**FC**	1	1		Unit not in MDEQ Equation	RANGE: 0.83–1.0	RANGE: 0.83–1.0
Exposure frequency	Days/year	**EF**	350	350		Upper-bound	350	350
Exposure duration	Years	**ED**	6	24		Upper-bound	6	RANGE: 20–27
Body weight	kg	**BW**	15	70		Mid-range	RANGE: 14.6–15.0	RANGE: 70–80
Averaging time, cancer	Days	**AT_c**	25,550	25,550		Upper-bound	RANGE: 25,550–28,470	RANGE: 25,550–28,470
Averaging time, noncancer	Days	**AT_{nc}**	10,950	10,950		Upper-bound	RANGE: 9,490–12,045	RANGE: 9,490–12,045
Soil Dermal Contact - R299.20								
Adherence factor	mg-soil/cm^2	**AD**	0.2	0.07		Mid-range	0.2	0.7
Skin surface area	cm^2/day	**SA**	2,670	5,800		Mid-range	RANGE: 2,690–2,900	6,032
Conversion factor	kg/mg	**CF**	0.000001	0.000001			.000001	.000001
Fraction contacted	Unitless	**FC**	1	1		Unit not in MDEQ Equation	RANGE: 0.83–1.0	RANGE: 0.83–1.0
Exposure frequency	Days/year	**EF**	245	245		Upper-bound	RANGE: 230–350	RANGE: 230–350
Exposure duration	Years	**ED**	6	24		Upper-bound	6	RANGE: 20–27
Body weight	kg	**BW**	15	70		Mid-range	15	RANGE: 70–80
Averaging time, cancer	Days	**AT_c**	25,550	25,550		Upper-bound	RANGE: 25,550–28,470	RANGE: 25,550–28,470
Averaging time, noncancer	Days	**AT_{nc}**	10,950	10,950		Upper-bound	RANGE: 9,490–12,045	RANGE: 9,490–12,045
Drinking Water Consumption - R299.10*								
Drinking rate	L-water/day	**DR**			2	Adult: upper-bound	Not available	Not available
Exposure frequency	Days/year	**EF**			350	Upper-bound	Not available	Not available
Exposure duration	Years	**ED**			30	Upper-bound	Not available	Not available
Relative source contribution	Unitless	**RSC**			0.2	N/a	Not available	Not available
Body weight	kg	**BW**			70	Mid-range	Not available	Not available
Drinking Water Consumption - R299.10* (cont.)								
Averaging time,	Days	**AT_c**			25,550	Upper-	Not available	Not available

			Current Residential Values			Basis for Current Values	Presented TAG 2 Residential Values	
			Age 1–6	Age 7–31	Resident	MDEQ	Age Bin 1 "Child"	Age Bin 2 "Adult"
cancer						bound		
Averaging time, noncancer	Days	**AT_{nc}**			10,950	Mid-range	Not available	Not available
Air Inhalation - R299.14, R299.24, R299.26*								
Adjusted inhalation rate		**AIR**			1.0		Not available	Not available
Exposure time	Hours/day	**ET**					Not available	Not available
Exposure frequency	Days/year	**EF**			350	Upper-bound	Not available	Not available
Exposure duration	Years	**ED**			30	Upper-bound	Not available	Not available
Averaging time, cancer	Days	**AT_c**			25,550	Upper-bound	Not available	Not available
Averaging time, noncancer	Days	**AT_{nc}**			10,950	Upper-bound	Not available	Not available
Averaging time, cancer	Hours	**AT_c**				Unit not in MDEQ equation	Not available	Not available
Averaging time, noncancer	Hours	**AT_{nc}**				Unit not in MDEQ equation	Not available	Not available

*Due to differences in how TAG members shared their values for these two sets of exposure factors, (i.e., in age bins or for a resident) these values cannot be included in the table.

Appendix D

Proposed Decision Framework for Updating the Michigan Part 201 Generic Cleanup Criteria Exposure Assumptions



[1] **Data Quality Objectives (DQOs)**

- Relevant and Applicable to Michigan
- Clear and Comprehensive
- Sound and Credible
- Transparent and Objective
- Certainty

[2] **Technical Support Document (TSD)**

For recommending a value

- Written review of published materials with citations.
- Data set(s) used in the calculation of the exposure value.
- Source of data set and data collection methods
- Description of data analyses/methods/ equations used to calculate the value.
- Descriptions of how value meets DQOs.
- Description of how the value represents Michigan.

[3] **TSD Evaluation**

If multiple proposed new and current value TSDs equally meet the DQOs, preference will be given to values that "best represents Michigan."

Data Quality Objective Descriptions

- **Relevant and Applicable to Michigan:** The extent to which the information is relevant and applicable to Michigan generic criteria development (e.g., representative of Michigan population and conditions, currency of the information, adequacy of the data collection period).
- **Clear and Comprehensive:** The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented.
- **Sound and Credible:** The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application, and are regularly maintained, subject to peer review, and the best available science.
- **Transparent and Objective:** The data are published or publicly available and free from conflicts of interest.
- **Certainty:** The extent to which the variability and uncertainty (quantitative and qualitative) in the information or the procedures, measures, methods, or models are evaluated and characterized, including peer review and agreement of studies.

Suggested List of Data Sources to Consider for Value Determination

This list is not intended to either limit or endorse source selection—other sources may be used.

Michigan-specific Sources:

MDCH—Michigan Department of Community Health

MDEQ—Michigan Department of Environmental Quality (meteorological and hydrogeological data)

MDOL—Michigan Department of Labor

MSU, UM, etc.—Michigan State University, University of Michigan, and other university studies/reports on climate (rainfall, snow and frozen days) and hydrogeological data

Open literature—Studies and surveys on Michigan population and hydrogeology

National or Other State Data Sources:

(Sources listed below are intended to include any future updated versions)

EPA Sources—Listed alphabetically:

ADAF—EPA Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, EPA/630/R-03/003F, March 2005. www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm

EFH 2011—EPA Exposure Factors Handbook 2011 Edition (Final). National Center for Environmental Assessment, Office of Research and Development. Washington D.C. Currently available online at http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.

EFH 1997—EPA 1997 Exposure Factors Handbook (1997a). Office of Research and Development, Washington, DC. EPA/600/P-95/002Fa.

OCSPP—EPA Office of Chemical Safety and Pollution Prevention (OCSPP)

OSWER 2014—"Human Health Evaluation Manual, Supplemental Guidance: Update of Default Exposure Factors" (2014). OSWER Directive 9200.1-120. www.epa.gov/oswer/riskassessment/pdf/superfund-hh-exposure/OSWER-Directive-9200-1-120-ExposureFactors.pdf

OSWER 1991—EPA Human health evaluation manual, supplemental guidance: "Standard default exposure factors" (1991a). OSWER Directive 9285.6-03.

RAGS A—EPA 1989 Risk Assessment Guidance for Superfund. Volume I: Human health evaluation manual (Part A) (1989). Interim Final. Office of Emergency and Remedial Response.

RAGS B—EPA Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals) (1991b). Office of Emergency and Remedial Response. EPA/540/R-92/003. December 1991

RAGS E—EPA 2004 Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Final. OSWER 9285.7-02EP. July 2004. Document and website www.epa.gov/oswer/riskassessment/ragse/index.htm

RAGS F—EPA 2009 Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment) Final. OSWER 9285.7-82. January 2009. Document, memo and website. www.epa.gov/oswer/riskassessment/ragsf/index.htm

RSL, latest update—EPA Regional Screening Level, latest edition. http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm

SSG—EPA Soil Screening Guidance: User's Guide (1996a). Office of Emergency and Remedial Response. Washington, DC. www.epa.gov/superfund/health/conmedia/soil/index.htm#user

SSG-TBD—EPA Soil Screening Guidance: Technical Background Document (1996b). Office of Emergency and Remedial Response. Washington, DC. OSWER No. 9355.4-17A www.epa.gov/superfund/health/conmedia/soil/introtbd.htm

SGSS—EPA 2002 Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. OSWER 9355.4-24. December 2002. www.epa.gov/superfund/health/conmedia/soil/index.htm

EPA List of Chemicals with a Mutagenic Mode of Action (MOA) for Carcinogenesis. (accessed 8/2014)

http://www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm

Other National Sources:

ATSDR—Agency for Toxic Substances and Disease Registry www.atsdr.cdc.gov/hac/index.html

Census Bureau—Bureau of Labor Statistics, etc. https://www.census.gov/aboutus/surveys.html

NOAA—National Oceanic and Atmospheric Administration. www.noaa.gov/

NIH—National Institute of Health

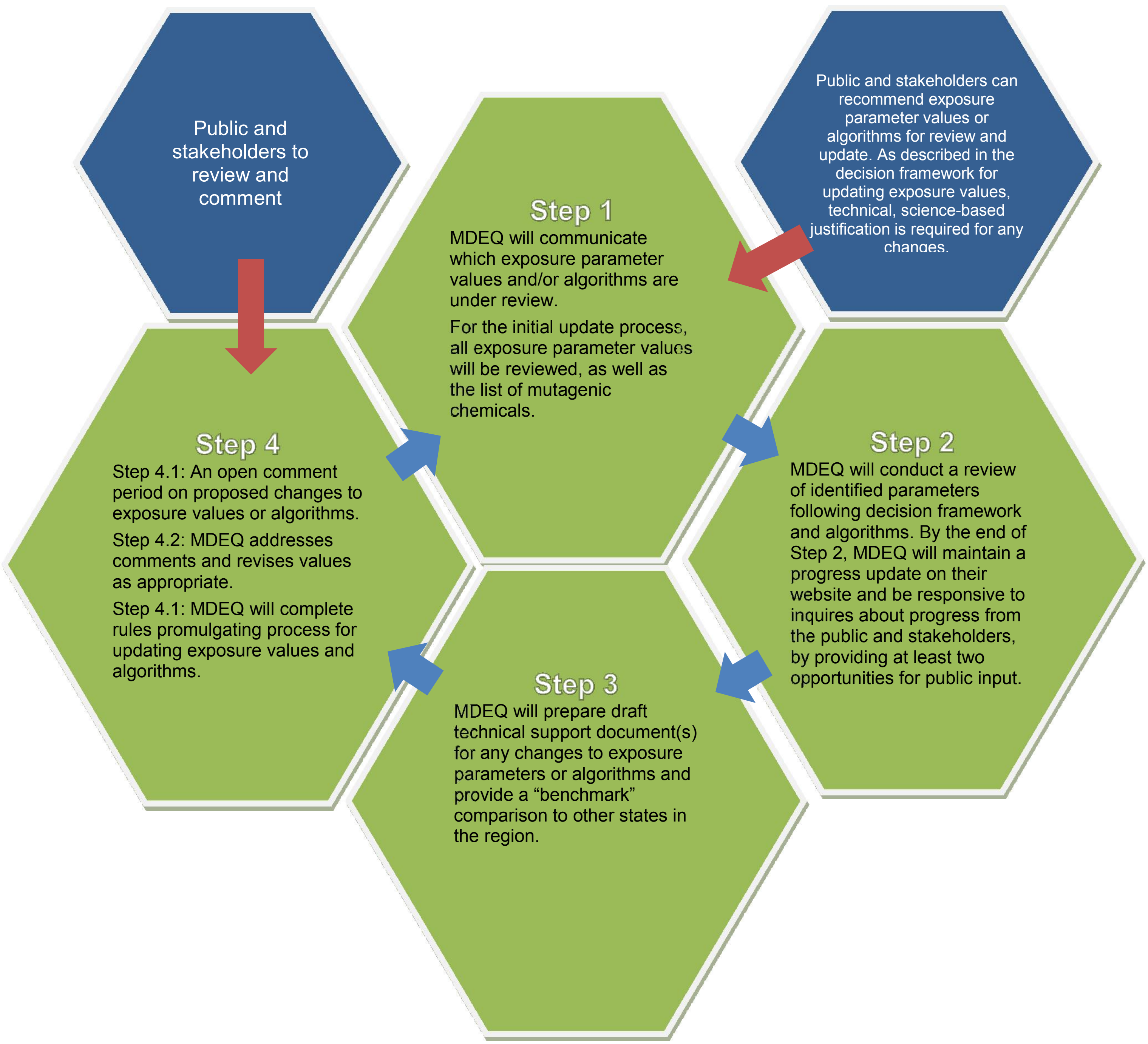
International Data Sources:

WHO—World Health Organization

Joint Research Centre—European Commission

Appendix E

Proposed Update Process for Exposure Parameters for Generic Cleanup Criteria



Appendix F
Detailed TAG Discussions

Question 3

What is the most appropriate nonresidential scenario for workers, that is, indoor, outdoor, or a combination of both?

Several members recommended the receptor be an outdoor worker, because while many employees may work indoors, the more protective approach should be used in instances of uncertainty. One member recommended that the generic, nonresidential receptor should be an indoor worker. Lastly, one member suggested looking at the values for both an indoor worker and an outdoor worker before deciding on the worker scenario. It was noted that a relatively small proportion of workers are represented by the combination of an indoor and outdoor worker, and instead, a distinction could be made in the criteria between indoor and outdoor workers.

In an attempt to agree on a single (nonresidential) worker receptor (i.e., indoor versus outdoor), the group reviewed and discussed the list of the exposure factors in Table A: December 2013 Nonresidential Exposure Factors' Values without first agreeing on a receptor. TAG members provided recommendations and rationale for Table A (Appendix B), and then reviewed these values as group. Many members gave multiple values for each exposure factor because the values differed if the receptor was an indoor worker, an outdoor worker, or a construction worker.

After selecting a set of exposure values for indoor workers and another for outdoor workers, the TAG planned to review the two worker groups to see which had the greater intake. It was believed that this approach would help guide the TAG's decision on choosing one set of values for all nonresidential workers, or for recommending two sets of values, if necessary. Some TAG members believed that if two separate receptor values are recommended—one for indoor workers and one for outdoor workers—legal considerations would need to be made, since adding an additional nonresidential receptor column to Table A could require an amendment to the statute. The TAG also decided against identifying a unique set of values for construction workers, a separate receptor scenario, because the data for construction workers is not as robust for several exposure factors. Additionally, a construction worker's exposure duration would be much less than the outdoor worker in most cases. Therefore, the outdoor worker generic criteria are expected to be protective of the construction worker.

The group discussed the member-recommended values for each exposure factor, with each member offering their rationale for their values. As a group, TAG members provided exposure parameter value(s) for an indoor worker and a separate set of values for an outdoor worker; for some parameters, this was the same value (e.g., body weight). The group's recommended values or range of values, are captured in a version of Table A (discussed further under Question 9).

In discussing the exposure assumption values, many TAG members generally agreed that the recommended exposure factors for residential and nonresidential exposure should be different because of onsite controls, except for drinking water. Different residential and nonresidential exposure factors produce different health-based Part 201 generic drinking water criteria and Part 213 Tier 1 risk-based screening levels (RBSLs) for a given chemical. It was noted that the federal and state drinking water standards apply to all drinking water (i.e., they are not specific for residents and workers). A chemical-specific drinking water standard, currently established by the Michigan Safe Drinking Water Act, or SDWA (1976 PA 399), applies to both residential and nonresidential use. The MDEQ informed the TAG that developing a nonresidential drinking water criterion creates an inconsistency between the drinking water and cleanup programs. TAG 2 members want to communicate this inconsistency between Part

201/213 and the SDWA to the CSA, but they are not recommending specific action items with respect to this issue. At least one member of TAG 2 foresaw difficulty explaining this inconsistency to the public. Three members of TAG 2 brought up situations when nonresidential criteria/RBSLs would not be protective of public health, and the group generally agreed those situations would be best addressed on a chemical-by-chemical, or case-by-case, basis.

Part 201, Section 20120a(5) and Part 213, Section 21304a(4) mandate Part 201 generic drinking water criteria and Part 213 Tier 1 RBSLs default to drinking water standards, national secondary drinking water regulations, or other concentrations determined by the department to be protective of aesthetics. Approximately 73 individual chemical, residential, and nonresidential drinking water criteria/RBSLs default to a drinking water standard, while approximately 18 default to another concentration protective of aesthetics. Consequently, approximately 91 individual chemicals do not have different residential and nonresidential criteria/RBSLs. This list could expand over time. SDWA standards or other concentrations protective of aesthetics have not been established for the remaining 198+ chemicals with criteria/RBSLs. The criteria/RBSLs for the majority of the remaining 198+ chemicals were developed with different residential and nonresidential exposure factors (such as drinking water ingestion rate, body weight, exposure frequency, and exposure duration). Therefore, the residential and nonresidential criteria/RBSLs for the majority of the remaining 198+ chemicals differ.

Given that the TAG did not reach agreement on all values for either an indoor or outdoor worker, they were unable to complete an evaluation of the total exposure assumptions for a worker receptor and thus unable to recommend a single worker receptor for the nonresidential criteria.

Question 5

What are the appropriate data sources for the estimates for exposure assumptions, such as drinking water ingestion rates, soil ingestion rates, body weights for the selected age groups, relative source contribution factors, and other dermal exposure assumptions?

The OSWER Directive was released on February 6, 2014. The purpose of the directive is to update the Interim Final Standard Exposure Factors Guidance (i.e., exposure factor values) from 1991. At PSC's request, a TAG member provided the following summary of the purpose of this OSWER Directive: one use of the standard default exposure factors in the directive is in the "remedial investigation and feasibility study process (e.g., assessing baseline health risks, developing preliminary remediation goals, evaluating risks of remediation alternatives)." The OSWER Directive supplements the original risk assessment guidance (EPA 1989). It also supersedes and replaces certain portions of OSWER Directive 9285.6-003 from March 25, 1991, and updates Risk Assessment Guidance for Superfund, Part E (EPA 2004). Updated information in the Exposure Factors Handbook (EPA 2011) and the Child-Specific Exposure Factors Handbook (EPA 2011) were used to develop some of the OSWER Directive recommendations. The guidance was developed to reduce variability and uncertainty in the exposure assumptions used by regional Superfund staff to characterize exposure to human populations for risk assessments.

The TAG member also provided the following summary of an interpretation of the content and purpose of USEPA's Regional Screening Levels (RSLs). The generic RSLs are based on default exposure parameters and factors that represent reasonable maximum exposure (RME) conditions for chronic exposures, and are based on the methods outlined in the EPA's Risk Assessment Guidance for Superfund, Part B Manual (1991) and Soil Screening Guidance documents (1996 and 2002). All of the exposure parameters used to develop the screening levels are presented in the User's Guide. The RSLs are chemical-specific concentrations of individual contaminants in air, drinking water, and soil that may warrant further investigation or site cleanup. The recent update of the RSLs included the incorporation of the exposure values recommended in the 2014 OSWER Directive; the most recent version of the User's Guide and the RSLs is from May 2014. The EPA typically updates the RSLs twice a year, usually in the spring and fall.

The RSLs have a website with information (www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm). The purpose of this website is to provide tables of the default RSL values and a calculator to assist Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs), risk assessors, and others involved in decision-making concerning CERCLA hazardous waste sites and to determine whether levels of contamination found at the site may warrant further investigation or site cleanup.

The TAG members noted that the RSLs are not designed for a specific region or state, and therefore do not consider Michigan-specific factors. Some members agreed that the state of the science is evolving and beginning to consider baseline (existing) exposures, which do more to consider environmental justice. Baseline exposure is not something that is operationalized yet in Michigan though it has been in California according to a TAG member, and should be noted as important so that when it becomes operational, it can be incorporated into the recommended framework. Additionally, one member noted that the exposure factors data does not take cumulative exposure or vulnerable workers (for example, pregnant workers) fully into consideration.

The group noted that all values, including existing values and newly recommended exposure parameter values, go through a documented review and approval process (as outlined in the framework and update process in Appendix D and E), while at least one other TAG member believed this was the responsibility of TAG 2.

Question 7

Where available, should the department utilize data that are representative of Michigan, rather than nationally representative data? If so, which data should be utilized?

The proposed framework process discussed in response to Question 8 was designed to evaluate data sources proposed for consideration. While data published in peer reviewed literature is preferred, other data sources may be considered for use with caution. Specifically, publically available and analysis should undergo a thorough review by MDEQ as described in the framework. The TSD developed for an unpublished data set, and the statistics applied to the data sets, must be robust enough to undergo the same type of technical and scientific scrutiny that a document considered for publication in a technical, peer-reviewed, journal would undergo.

The Michigan-specific data discussed in Appendix I documents ten years of "surficial soil temperatures" from Michigan Agricultural Experiment Station and MSU Extension to examine soil temperatures in Michigan. A TAG member, with extensive experience designing and using soil temperature probes reviewed the data set and its applicability for use in representing availability of surficial soil to exposure. One member's view was that the data set was inappropriate, as the sensors and data collection methods were designed for collecting agricultural data—not representative of soil accessibility at urban, industrial, nonresidential types of contaminated properties. If the Michigan data set were to be used for evaluation of accessibility, the evaluation would need to consider the entire hourly data set values, the changes in the hourly data values, and the rates of changes of the hourly data sets, rather than a single value from each day. In addition to the data set itself, the evaluation methods and the statistics applied should also be peer reviewed and subjected to the framework by MDEQ against the DQOs including a literature review for other sources (e.g., NOAA). For example, the analysis of the data set in Appendix I indicates that the soils in Ingham County with snow cover were not frozen or inaccessible for a single day between December 1, 2013 and May 1, 2014.

Question 8

Should the algorithms, including exposure parameters, be consistent with or based upon federal (i.e., EPA) methodology and data? If yes, are there any circumstances under which deviations from the federal methodology and data should be allowed? If no, what methodology and data should be used?

The Part 201 generic cleanup criteria are calculated using algorithms promulgated in Part 201 Rules (R299.1-R299.50 December 30, 2013). The algorithms contain variables for exposure parameters, chemical-specific toxicity endpoints, and chemical/physical parameters. Ideally, the value for each exposure parameter should represent Michigan's population and exposure conditions; however, Michigan-specific exposure parameter values may not exist or may be difficult to calculate, due to the characteristics of the data set. The purpose of Appendix D is to assist the MDEQ in periodically evaluating existing exposure parameters with respect to the best available science.

It is assumed that the framework will be used during a periodic review cycle for evaluating and revising (if necessary) existing generic cleanup criteria per 324.20120a of the NREPA. The MDEQ is advised to evaluate and determine if existing exposure parameter value(s) best meet the DQOs. If, during the periodic review cycle, new data are identified, this framework is recommended as the evaluation process. Existing and new exposure values/data will be evaluated in a step-wise fashion starting with Michigan, then the EPA, then other data (other federal agencies, other states, other countries (e.g., Canada), and/or international entities (e.g., World Health Organization or European Union). This list of data sources is not intended to be comprehensive and sources not listed that meet the DQOs can be used in the determination of exposure values.

All determinations, including the determination that no changes are necessary, are to be documented in a technical support document and provided for public review and comment.

Question 9

Based on the identified receptors, routes of exposure, and data sources, what are reasonable values for the various assumptions? Given the range of exposure assumption values, how should the most reasonable numbers be selected and updated and why?

At the request of the TAG, one member provided the following interpretation of reasonable maximum exposure (RME) for the benefit of TAG members with limited experience in exposure assessment. The TAG discussed this interpretation and disagreement emerged on specific details (e.g., whether "high-end" or "pica" constitute RME).

The RME Concept and When and Why High-end Values Are Used

The RME is defined as the highest exposure that is reasonably expected to occur at a site (EPA 1989). EPA guidance (EPA 1992) recommends that risk assessors approach the estimation of the RME by first identifying the most sensitive exposure parameters. The sensitivity of a parameter generally refers to its impact on the exposure estimates, and the sensitivity of the parameter correlates with the degree of variability of the parameter values. Parameters with a high degree of variability in the distribution of parameter values are likely to have a greater impact on the range of risk estimates than those with low variability. Maximum or near-maximum (high-end) values should be used for a few of the sensitive parameters, with central tendency (or average) values used for all other parameters. The high-end estimates are often based on statistically derived 95th or 90th percentiles, and in other cases, on best professional judgment. In general, exposure duration, exposure frequency, and contact rates (ingestion rates and soil adherence factor) are likely to be the most sensitive parameters in an exposure assessment (EPA 1989). Historically, and in line with EPA guidance, the MDEQ has selected mid-range values to represent exposure parameters such as life span, body weight, and surface area. The MDEQ Direct

Contact Technical Support Document (2005) indicates that the MDEQ followed the EPA Guidance on Risk Characterization for Risk Managers and Risk Assessors (1992) and use exposure assumptions, which represent a mix of high-end and mid-range values. A detailed justification of using a high-end soil ingestion value is in Appendix H. The OSWER Directive 9200.1-120 (EPA 2014) specified the exposure assumptions that should be used, and the values indicated a historic mix of upper-bound and mid-range values as shown in the original directive (EPA 1992). For example, high-end values (90th percentile) were used for water ingestion rate, soil ingestion rate, and exposure duration. According to this document, the EPA's Exposure Factor Handbook (2011) is not a Superfund-specific document; therefore, the OSWER-recommended exposure values are based on the "context, needs, and existing health risk assessment policy/guidance for the Superfund Program, such as ensuring that the recommended exposure factors are protective of the reasonable maximum exposure (RME), consistent with the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP)."

At Superfund sites, risk assessment is based on an estimate of the RME expected to occur under both current and future land-use conditions. RMEs are estimated for each pathway in the EPA's Risk Assessment Guidance for Superfund Volume I. Human Health Evaluation Manual Part A (1989). The RME represents an exposure scenario within a realistic range of exposure. The goal of the Superfund program is to protect against high-end, not average, exposures. Under the National Contingency Plan (EPA 1990), the Superfund program protects public health by using the RME approach, which is considered a reasonable risk assessment that addresses the exposure of all segments of the community, and not just the average individual.

The EPA document, *An Examination of EPA Risk Assessment Principles and Practices* (March 2004) indicated that a high-end exposure level is included in risk assessments "to ensure an adequate margin of safety for most of the potentially exposed, susceptible population." Additionally, it accounts for the uncertainty and variability in risk assessments. The high-end levels used are between the 90th and 95th percentile. The use of high-end levels is considered a reasonable approach. The EPA contends that some people will potentially be exposed at greater risk, even when a high-end value is used.

The EPA presents statistical comparison of site media concentrations to criteria as a significant element reducing the conservatism of RME estimates.

The 2004 EPA document also states that in relation to the high-end values, the EPA programs are also presenting central tendency values to show a reasonable range of potential risk in the actual distribution and enable risk managers to evaluate those possible risks. However, the goal of risk assessment is to characterize who or how much is at risk. Certain populations that may be at greater risk than the high-end value used (e.g. children with pica habits) should also be identified, so that risk managers can be informed in their decisions.

Question 10

Do probabilistic approaches (e.g., Monte Carlo) have a place in the selection of exposure parameters for generic criteria and, if so, what should that role be?

The TAG discussed two potential uses of probabilistic approaches. TAG members did not object to either potential use if empirically derived distributions exist for the input parameters. The first use would be to derive individual exposure factors. The second would be to validate that the combination of selected point estimate exposure factors result in an intake that is from the 90th to 98th percentile exposure.

For the first alternative, the TAG recognized that one other state (Ohio) and site-specific risk assessments use probabilistic assessment for this purpose. A TAG member indicated, however, that employing probabilistic approaches for the first purpose (i.e., to derive individual exposure factors) might necessitate a change in the statute. Information was provided to the group in writing (revised Region 5 benchmarks) indicating that Ohio's new 2014 standards are based on point estimates, which replaced previous use of probabilistic assessment.

For the second alternative, the TAG discussed how Monte Carlo analysis could be used to estimate the overall intake/exposure for a route or a key parameter (e.g., exposure frequency or soil ingestion), which would be to validate that the combination of selected point estimate exposure factors result in an intake that is from the 90th to 98th percentile exposure.

For both alternatives, the TAG recognized that availability of empirical distributions, such as those given in the EPA Exposure Factor Handbook, could be the limiting factor for using probabilistic approaches. In the absence of such empirical distributions, distributions based on professional judgment can be constructed, which reflect less availability of information but still use available information (e.g., a triangular distribution based on judgment about the range and mode of the distribution). One TAG member stated that using constructed distributions in probabilistic assessments (e.g., Monte Carlo analysis) should be sufficient, if the same data are also believed to be sufficient for selection of a point estimate. Other TAG members stated that in the absence of an empirical distribution, the true distribution is unknown, and a better approach would be to collect the necessary data to develop the empirical distribution.

The EPA has a guidance document on probabilistic risk assessment, but the MDEQ does not have one at this time. The MDEQ has not used the probabilistic approach before in determining the Part 201 cleanup criteria.

Given that most members of the TAG are unfamiliar with using probabilistic methods (e.g., Monte Carlo) in risk assessment for exposure pathways, the TAG is not recommending using Monte Carlo to generate any data for exposure assumptions at this time. Rather, the TAG reported that Monte Carlo, or another probabilistic approach, could be considered for validation of the selected and agreed-upon data.

A TAG member performed a limited sensitivity analysis for the variables in the equations for the residential direct contact criteria (DCC) for carcinogenic contaminants and also for the variables in the equations for the nonresidential direct contact criteria for carcinogenic contaminants (see discussion for Question 11). As part of the analysis, all possible combinations (2.4 MM) of all variables were evaluated to determine the resultant distribution of DCCs, considering all possible combinations of the input variables evaluated. The resultant DCC multipliers displayed a log-normal distribution. The 95th, 90th, 80th, and 70th percentiles were calculated for the data set and compared with the DCC multipliers resultant from the current inputs, as well as inputs preliminarily agreed upon by the members of TAG 2. Both resultant DCC multipliers were approximately equal to the 80th percentile of the distribution of all possible variable combinations, though some TAG members questioned the validity of the sensitivity analysis that was conducted. The TAG agreed that the process of performing this type of probabilistic method might be appropriate to use as a benchmark for better characterizing the uncertainty in the final exposure factors.

Question 11

For each pathway calculation recommended, has it been determined to be reasonable and relevant and do they make sense in the real world?

The common definitions of Michigan's generic cleanup criteria applicable to Part 201 and Rule 299 are:

- Generic: of, applicable to, or referring to all the members of a genus, class, group, or kind
- Residential: suited for or characterized by private residences

- Nonresidential: not suited for or characterized by private residences

From these three common definitions and Section 324.20120a (1), one can discern that “generic cleanup criteria” are to apply to all members in areas with and without private residences.

R299.3, Rule 3.(1) describes a “protectiveness requirement” for generic cleanup criteria: “All response activities shall be protective of the public health, safety, and welfare and the environment. Applicable generic cleanup criteria established by the department pursuant to section 20120a(1) and site-specific cleanup criteria approved by the department under section 20120a(2) and 20120b of the act and these rules reflect the department’s judgment, at the time the criteria are established or approved by the department, about the numerical criteria required to meet this protectiveness requirement, subject to the provisions of R 299.4(3), R 299.28, and R 299.34(2).”

After establishing what is meant by generic cleanup criteria, the TAG members discussed what level of protectiveness is required by the statute for the generic cleanup criteria.

Section 324.20120a (4) states:

> (4) If a hazardous substance poses a carcinogenic risk to humans, the cleanup criteria derived for cancer risk under this section shall be the 95 percent upper bound on the calculated risk of 1 additional cancer above the background cancer rate per 100,000 individuals using the generic set of exposure assumptions established under subsection (3) for the appropriate category or subcategory. If the hazardous substance poses a risk of an adverse health effect other than cancer, cleanup criteria shall be derived using appropriate human health risk assessment methods for that adverse health effect and the generic set of exposure assumptions established under subsection (3) for the appropriate category or subcategory. A hazard quotient of 1.0 shall be used to derive noncancer cleanup criteria. For the noncarcinogenic effects of a hazardous substance present in soils, the intake shall be assumed to be 100 percent of the protective level, unless compound and site-specific data are available to demonstrate that a different source contribution is appropriate. If a hazardous substance poses a risk of both cancer and one or more adverse health effects other than cancer, cleanup criteria shall be derived under this section for the most sensitive effect.

From Section 324.20120a (4), the risk assessment is for hazardous substances that pose either a carcinogenic or noncarcinogenic effect. The generic cleanup criteria must be protective of the most sensitive effect. The risk assessment is to limit risk to one additional cancer per 100,000 individuals and noncancer risk to a hazard quotient of 1.0. The intent of this language appears to limit the risk of human health effects from exposure to hazardous substances to a minimal level.

The first part of Section 324.20120a (3) says:

> (3) The department shall develop cleanup criteria pursuant to subsection (1) based on generic human health risk assessment assumptions determined by the department to appropriately characterize patterns of human exposure associated with certain land uses. The department shall utilize only reasonable and relevant exposure pathways in determining these assumptions.
>
> Section 324.20120a (3) makes it clear that “generic cleanup criteria” are based on generic human health risk assessment assumptions that are protective of all people. The assumptions are to “appropriately” characterize potential human exposure to hazardous

> substances with certain land use considerations (i.e., residential and nonresidential), where the appropriateness is based on 324.20120a (18):
>
> (18) Not later than December 31, 2013, the department shall evaluate and revise the cleanup criteria derived under this section. The evaluation and any revisions shall incorporate knowledge gained through research and studies in the areas of fate and transport and risk assessment and shall take into account best practices from other states, reasonable and realistic conditions, and sound science.

The final part is to determine if Section 324.20120a provides recommended information sources for the calculation of generic cleanup criteria. In three locations [(5),(9), and (9)(c)], Section 324.20120a cites the EPA as a source for information and methods in developing cleanup criteria. Further, 20120a(18) states that any revisions "shall take into account best practices from other states, reasonable and realistic conditions, and sound science."

Based on Part 201, the intent is for the MDEQ to look to the EPA, other Great Lakes states, and scientific literature to develop generic cleanup criteria that is protective of the public health, safety, welfare, and the environment in residential and nonresidential settings, as the basis of what constitutes "reasonable and relevant" and what "makes sense in the real world."

To help consider if the values are reasonable and relevant, a sensitivity analysis was performed (using a members' own assumptions and without input from other TAG members) by a TAG member for the variables in the residential direct contact criteria (DCC) equations for carcinogens. A limited sensitivity analysis was performed for the variables in the equations for the nonresidential direct contact criteria for carcinogens. Most variables were evaluated using a triangle distribution (minimum value, maximum value, and central value) with ingestion rates (both age groups) and body weight and age 7-30 evaluated with five to nine values that could (very loosely) be considered a normal distribution. The first evaluation utilized the values that would result in a minimum DCC), the current MDEQ values, and the maximum values. The resultant DCC multipliers for chemical-specific inputs were roughly factors of one, two, and ten for the minimum, current, and maximum values.

The second evaluation utilized the minimum values for all (other) input variables while adjusting a single variable to evaluate magnitude of change that a single variable has on the resultant DCC. Soil adherence factors and averaging time had the greatest effect on the resultant DCC. Skin surface areas and body weight had the least effect.

The third evaluation utilized all possible combinations (2.4 MM) of all the variables. The resultant DCC multipliers displayed a log-normal distribution. The 95th, 90th, 80th, and 70th percentiles were calculated for the data set and compared with the DCC multipliers resultant from the current inputs and inputs preliminarily agreed upon by the members of TAG 2. Both resultant DCC multipliers were approximately equal to the 80th percentile of the distribution of all possible variable combinations.

A fourth evaluation was performed using the variables in the equations for the nonresidential direct contact criteria for carcinogenic contaminants. This was done specifically to evaluate two worker scenarios: 1) an outdoor worker with outdoor exposure assumptions (EFi=160 days/year) and ingestion rates (100 mg/d), and 2) an indoor worker with indoor exposure assumptions (EFi=245 days/year) and outdoor ingestion rates (50 mg/d). The resultant DCC multiplier for the outdoor worker was approximately 7 percent less than the resultant DCC multiplier for the indoor worker.

The output from the sensitivity analysis was briefly presented to TAG 2 with minimal discussions and no final agreement on the analysis was reached.

Appendix G
Exposure Assumption Considerations for All Populations, Including Those Most Vulnerable

Submitted by Patricia Koman, as solicited by the TAG

Question 4

In totality, do the pathways, models and cumulative exposure assumptions take into account best practices from other states, reasonable and realistic conditions, and sound science," as required by Section 20120a(18) of NREPA?

Following EPA guidelines, the MDEQ uses a RME process. The RME is defined by the EPA as the highest exposure reasonably expected to occur at a site based on both current and future land-use conditions (EPA 1989, 6-4). RMEs are calculated for each individual pathway, and if a population is exposed via more than one pathway, the combination of exposures across pathways should represent the RME. As described above: "The intent of the RME is to estimate a conservative [health protective] exposure case (i.e., well above the average case) that is still within the range of possible exposures" (EPA 1989). To address RME for the sensitive parameters, the high-end values are used and the central tendency or average values are used for the other parameters (EPA 1992a).

For Michigan's current generic criteria, the MDEQ used exposure assumptions which represent a mix of high-end and mid-range values, using a 90th to 95th percentile for sensitive values, depending on data availability and EPA guidance (MDEQ Direct Contact Technical Support Document 2005). Most parameters, however, are based on average values. A TAG member presented a sensitivity analysis using a probabilistic approach to show which parameters were most likely to impact the exposure (intake) values for residential and nonresidential land use based on OSWER and the TAG member's assumed exposure values. The results indicated that soil dermal adherence factors and averaging time (AT), dependent on exposure duration (ED) for noncarcinogens, were the variables that had the most effect on the resultant criteria. The results also indicated that skin surface areas and body weights had the least effect on the resultant criteria. The analysis made no recommendations about values and was also questioned by other TAG members, since no detailed methodology was provided.

The Michigan generic criteria exposure parameters currently consider exposures from drinking water ingestion only, coming into contact with soil through ingestion and skin contact, and inhaling hazardous substances via ambient and indoor air, generally. Michigan uses a chemical-by-chemical approach in developing generic criteria. In addition, exposure pathways are not aggregated. For example, the ambient air inhalation exposure to soil is not combined with the soil ingestion and dermal contact pathways. Likewise, the dermal contact and inhalation of hazardous substances in the tap water are not addressed together with drinking or ingestion exposure pathway.

Areas for Improvement in Michigan MDEQ Exposure Characterizations

In terms of the state of health-based risk assessment, the MDEQ's criteria could be updated to reflect current EPA guidance (e.g., Regional Screening Levels). One TAG member felt the OSWER Directive, which relies upon generally the same data but selects a 90th percentile in place of a 95th percentile, was more appropriate. Other TAG members thought a 95th percentile was appropriate. Other TAG members thought a 98th percentile was an appropriate upper-end value. (The percentile selected is largely a policy issue, not a technical issue, and depends on the authorizing legislation to guide MDEQ in its selection.)

The current MDEQ generic criteria exposure parameters could be improved to protect exposures of young children, pregnant workers, and the most vulnerable in Michigan communities, as described below.

1) More fully characterize pathways or exposure

Michigan's generic criteria exposure parameters exclude inhalation and skin contact during bathing or showering exposure. The criteria do not consider food raised on a site or impacted by contamination migrating into water resources as an intake pathway (e.g., fish, plants, chickens or eggs from backyard chickens).

2) Incorporate baseline exposures

Michigan's generic criteria do not currently consider "baseline exposures" as chemical exposures that an individual had prior to being exposed to the same chemical from the contaminated environmental source. Baseline exposures are different from the background concentration (naturally occurring concentrations in soil).

Baseline exposures can be important due to the ubiquitous presence of hazardous substances in Michigan. For example, a proximity analysis of MDEQ Leaking Underground Storage Tank (LUST) data shows that a third of Michigan schoolchildren spend their school day 500 meters from a leaking underground storage tank, which typically has released gasoline or diesel fuel or solvents into the soil, groundwater, or air. MDEQ assumes children aged 7–18 years have an adult level of exposure, and these potential exposures at school would not be taken into account in considering exposures to environmental contaminants at Michigan contaminated sites. Based on 2007 school data and 2013 MDEQ data, there are 1,325 public and charter schools across the state that are within 500 meters of a leaking underground storage tank. Almost half (45 percent) of the 547,400 students attending schools proximate to LUSTs are eligible for free and reduced lunches. No information about the volume, extent, direction, or depth of the hazardous substance releases was available from MDEQ. While proximity does not equate to exposures, the proximity of children to these sources points to the need for additional study of their exposures, more cleanup and prevention, and mandatory reporting of releases to the public (Moran et al. 2007; Picone et al. 2012; Santos et al. 2013; Squillace and Moran 2007; Williams et al. 2002; Ala et al. 2006; Baibergenova et al. 2003; Gaffney et al. 2005; Kearney and Kiros 2009; Zota et al. 2011; Yao, et al. 2013).

FIGURE 1. Michigan Public and Charter K–12 Schools within 500 Meters of Open Leaking Underground Storage Tanks (1,325 schools, enrolling 547,400 students)

SOURCES: Schools in 2007 and LUSTs in 2013
www.mcgi.state.mi.us/environmentalmapper

3) Consider more fully the greater exposure (dose) to children that is not effectively addressed by the current age-adjusted averaging.

The generic criteria should assure that the chemical exposure or dose for the child receptor is not greater on a body weight basis than would be acceptable for an adult.

There were differences of opinion within TAG 2 about the policy acceptability of a child receptor. There was consensus on the technical points that children have different susceptibility than adults, and that exposures at critical periods of development across one's life may be more important for some developmental endpoints. Recent studies indicate that children's mental and physical development over their entire lives is adversely altered by early-life susceptibility to lead, mercury, dioxins, PCBs, and a host of other contaminants. Childhood exposures are thus relevant, reasonable concerns and need to be quantified more fully.

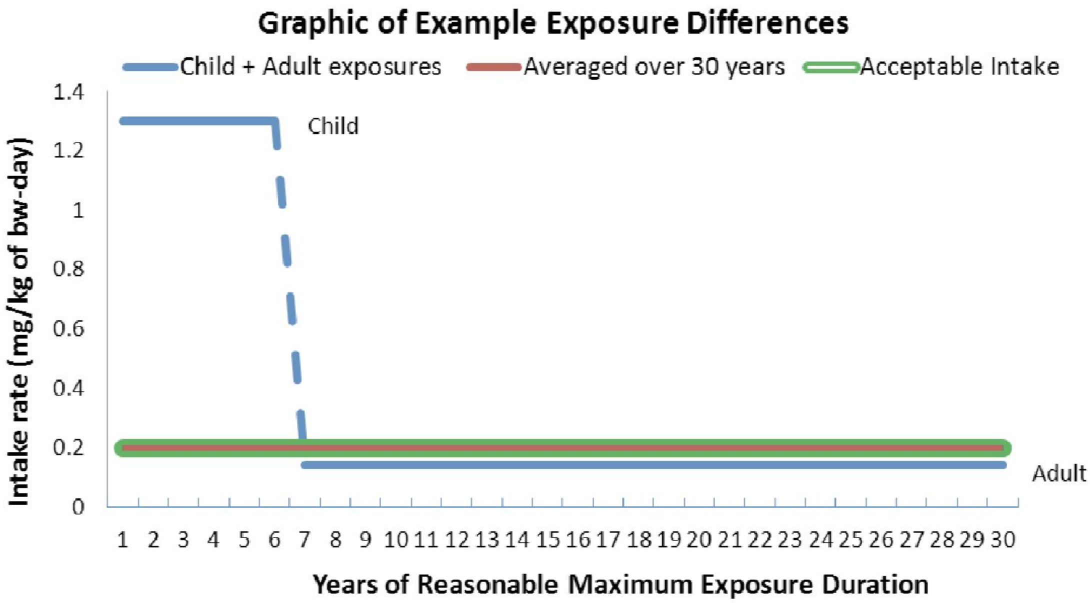
Some members of the TAG supported the use of a child receptor. This will allow MDEQ to better reflect best available scientific information, as required by law, because children are different than adults in ways relevant to their exposures:

- Children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults.
- Children's behavior patterns may make them more susceptible (e.g., breastfeeding, playing on or near ground level, putting hands in mouth, getting dirty, exploring the outdoors).
- Children's neurological, immunological, digestive, reproductive, and other bodily systems are still developing.
- The rapid growth and development of organ systems that takes place during childhood increases the vulnerability of children.
- Children's metabolisms may be more or less capable than adults' of breaking down, inactivating, or activating toxic substances.
- Recent studies indicate that children's mental and physical development over their entire life course is adversely altered by early-life exposure to lead, mercury, dioxins, PCBs, and a host of other contaminants.

In the absence of new studies of soil ingestions among school-aged children, MDEQ's current age-adjusted process assumes an adult exposure to represent that of a seven-year-old, an eight-year-old, a nine-year-old, a teenager, etc. When averaged over 30 years, the average value is dominated by the 24 years of adult exposure, as shown in Figure 2. Thus, the use of age-adjusted criteria is likely to underestimate exposures for preschool and school-age children.

About 25 of 300+ hazardous chemicals have noncancer toxicity endpoints based on developmental toxicity. At the same time, developmental toxicity is covered in the DD footnote.

FIGURE 2. Current MDEQ Age-Adjusted Intake



4) Consider more explicitly the exposures of pregnant and nursing residents and workers.

In considering both residential and nonresidential exposures, the generic criteria should assure that the chemical exposure or dose for pregnant and nursing women are accounted for. Particular windows of exposure may be important to reproductive or developmental toxicants. The American College of Obstetricians and Gynecologists' Committee Opinion (ACOG 2013) states that "the evidence that links exposure to toxic environmental agents and adverse reproductive and developmental health outcomes is sufficiently robust."

With respect to the nonresidential receptor, according to the U.S. Department of Labor, mothers have made up the fastest-growing segment of the U.S. labor force in the previous decade. Approximately 70 percent of employed mothers with children younger than three work full-time. One-third of these mothers return to work within three months after birth, and two-thirds return within six months" (Shealy et al. 2005).

5) Use Michigan Local Public Health or EPA screening tools to understand exposures to other chemical, biological, physical, and psychosocial stressors that contribute to baseline vulnerability in Michigan.

The Michigan-generic criteria do not include exposures to other chemical, biological, physical, and psychological stressors, which are all acknowledged as affecting human health and are potentially addressed in the multiple-stressor, multiple-effect cumulative assessments (NRC 2009). In its report on the state of the science of risk assessment entitled, "Science and Decisions: Advancing Risk Assessment" (NRC 2009), the National Research Council points out that ignoring numerous agents or stressors that affect the same toxic process as the chemical of interest and omitting baseline processes could lead to risk assessments that assume population thresholds exist in circumstances when they may not. Areas with environmental justice concerns are increasingly using cumulative risk methods in settings with vulnerable populations and multiple exposures. Cumulative risk can be defined as the "combination of risks posed by aggregate exposure to multiple agents or stressors in which aggregate exposure is exposure by all routes and pathways and from all sources of each given agent or stressor" (NRC 2009). Exposure characterization is needed for the analysis, characterization, and possible quantification of the combined risks to health or the environment posed by multiple agents or stressors (EPA 2003).

Cumulative risk frameworks are not new. Risk assessment techniques to examine chemical mixtures in the Superfund program date back to the 1980s and Safe Drinking Water Act in 1996. An example can be found in the cumulative risk assessment under the Food Quality Protection Act of organophosphorus pesticides (EPA 2006) and the National Air Toxics Assessment.

O'Neill and colleagues (2003) put forth a theoretical framework for the social patterning of exposure and associated poor health outcomes in the context of air pollution. Three premises underlie this framework: 1) populations of lower socioeconomic status may have greater baseline exposure to contaminants; 2) these populations are more vulnerable to the effects of pollution as a result of poorer health due to material deprivation and psychosocial stress; and 3) the interaction between enhanced exposure and vulnerability results in a more sizeable negative impact on health, as illustrated in Woodruff and colleagues (2007) in Figure 3. In response to the cumulative impacts faced by vulnerable communities, researchers assert that environmental policies should not only focus on exposure to pollutants and their sources, but also on the cumulative impact of exposures and the vulnerabilities of communities comprised by a large number of racial or ethnic minorities and people of low socioeconomic status (Morello-Frosch, et al., 2011).

FIGURE 3. Illustration of Populations With and Without Baseline Exposures and Vulnerability

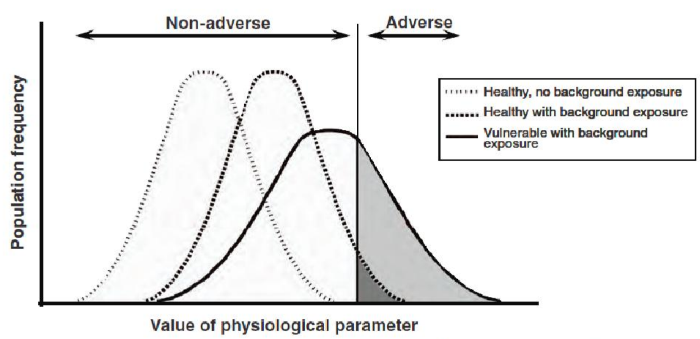


FIGURE 5-2 Value of physiologic parameter for three hypothetical populations, illustrating that population responses depend on a milieu of endogenous and exogenous exposures and on vulnerability of population due to health status and other biologic factors. Source: Adapted from Woodruff et al. 2007. Reprinted with permission; copyright 2007, *Environmental Health Perspectives*.

The EPA and state and local agencies have developed tools, methods, and data that the MDEQ could use to address cumulative risks either explicitly in the generic criteria or site-specific criteria or to target program activities. Building on its Michigan Environmental Mapper, A Michigan GIS-based index or data tool similar to California's Cal Enviro Screen 2.0 could be created (available at http://oehha.ca.gov/ej/ces2.html). If a hazardous pollutant release occurs in a geographic area identified as having these baseline potential exposures to the contaminant, then the MDEQ in calculating the criteria might take this into consideration.

EPA has three tools that are already available and could be used immediately for screening:

- My Environment (www.epa.gov/myenvironment/)
- EJView (www.epa.gov/environmentaljustice/mapping.html)
- NEPA-Assist (www.epa.gov/compliance/nepa/nepassist-mapping.html)

My Environment has publicly available information about TRI releases, Superfund sites, air concentrations, and other factors that could be converted into the density metrics or vulnerability indices. EJView provides screening level information regarding environmental justice or social determinants of health. NEPA-Assist serves in a similar capacity.

For locally available data, some examples for Michigan with searchable maps include:

- Statewide County Health Rankings and Roadmaps: Health factors and health outcomes by county (www.countyhealthrankings.org/app/#/michigan/2013/genesee/county/outcomes/overall/snapshot/by-rank)
- Imagine Flint: Information about housing, vacant properties, land use, schools, transportation (www.imagineflint.com/Documents/MapGallery.aspx)

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Appendix H

Conceptual Site Model Example

Submitted by Francis Ramacciotti, as solicited by the TAG

Exposed Population	Exposure Medium	Exposure Route	Possible Currently?	Possible in Future?	Type of Analysis	Comments
On-site						
Routine workers	Surface soil	Incidental ingestion of and dermal contact with surface soil	Yes	Yes	Quantitative	Potential exposure of routine workers to soil is possible in unpaved areas. Potential indoor exposure is also possible if soil-derived vapors migrate through building foundations.
		Inhalation of soil-derived vapors and airborne particulates (wind erosion) in ambient air	Yes	Yes		
		Inhalation of soil-derived vapors that migrate through building foundations into indoor air	Yes	Yes		
	Subsurface soil	Incidental ingestion of and dermal contact with subsurface soil	No	No	Not applicable	
		Inhalation of soil-derived vapors in ambient air	Yes	Yes	Quantitative	
		Inhalation of soil-derived vapors that migrate through building foundations into indoor air	Yes	Yes	Quantitative	
	Groundwater	Ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for drinking water	No	No	Not applicable	Groundwater is not used at the site for drinking water or other purposes. Potable water is obtained from the municipal drinking water system.
		Incidental ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for purposes other than drinking water	No	No	Not applicable	
		Inhalation of groundwater-derived vapors that migrate through building foundations into indoor air	Yes	Yes	Quantitative	Potential indoor exposure is possible if groundwater-derived vapors migrate through building foundations.
	LNAPL	Inhalation of LNAPL-derived vapors that migrate through building foundations into indoor air	Yes	Yes	Quantitative	LNAPL is in the subsurface at limited areas of the site. Potential indoor exposure is possible if LNAPL-derived vapors migrate through building foundations.
Construction workers	Surface and subsurface soil	Incidental ingestion of and dermal contact with soil; inhalation of soil-derived vapors and airborne particulate in work-space air	Yes	Yes	Quantitative	Exposure of construction workers to soil is possible where soil is exposed during construction-related site preparation activities in support of redevelopment.
	Groundwater	Incidental ingestion of and dermal contact with exposed groundwater; inhalation of vapors from exposed groundwater	No	Yes	Inferred from maintenance workers	Potential exposure to shallow groundwater is possible in excavations that extend into the water table. No such excavations are expected during the redevelopment, according to the current redevelopment plans.
	LNAPL	Incidental ingestion of and dermal contact with exposed LNAPL; inhalation of vapors from exposed LNAPL	No	Yes	Inferred from maintenance workers	LNAPL is present in parts of the site not currently planned for redevelopment. But potential exposure to LNAPL is possible if future excavations extend into the water table at these areas.
	Storm water and sediment	Incidental ingestion of and dermal contact with water and sediment in storm sewers; inhalation of vapors from exposed storm water	No	Yes	Quantitative	Potential exposure is possible if redevelopment activities involve the storm sewer system.

Exposed Population	Exposure Medium	Exposure Route	Possible Currently?	Possible in Future?	Type of Analysis	Comments
On-site (cont.)						
Maintenance workers	Surface and subsurface soil	Incidental ingestion of and dermal contact with soil; inhalation of soil-derived vapors and airborne particulate in work-space air	Yes	Yes	Quantitative	Exposure of construction workers to soil is possible where soil is exposed during construction-related utility maintenance activities.
	Groundwater	Incidental ingestion of and dermal contact with exposed groundwater; inhalation of vapors from exposed groundwater	Yes	Yes	Quantitative	Potential exposure to shallow groundwater and vapors from groundwater within excavation pits that extend into the water table is possible.
	LNAPL	Incidental ingestion of and dermal contact with exposed LNAPL; inhalation of vapors from exposed LNAPL	Yes	Yes	Quantitative	Potential exposure is possible if excavations extend to the water table in the areas where LNAPL is present.
	Storm water and sediment	Incidental ingestion of and dermal contact with water and sediment in storm sewers; inhalation of vapors from exposed storm water	Yes	Yes	Quantitative	Potential exposure is possible during maintenance that requires entry into the storm sewers that service the site.
Trespassers	Surface soil	Incidental ingestion of and dermal contact with surface soil	Yes	Yes	Inferred from routine workers	Potential exposure is possible in areas where surface soil is exposed and not enclosed by fencing.
		Inhalation of soil-derived vapors and airborne particulates (wind erosion) in ambient air	Yes	Yes		
	Subsurface soil	Incidental ingestion of and dermal contact with subsurface soil	No	No	Not applicable	
		Inhalation of soil-derived vapors in ambient air	No	Yes	Inferred from routine workers	
Off-site						
Routine workers	Surface and subsurface soil	Inhalation of soil-derived vapors and airborne particulates in ambient air	Yes	Yes	Inferred from on-site routine workers	Airborne exposures off-site are possible via windblown dust from exposed soil or excavation activities at the site.
	Groundwater	Ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for drinking water	No	Yes	Quantitative	Groundwater is not currently used for drinking water within at least a half mile of the site, and potable water is available from the municipal drinking water system. However, groundwater in the lower aquifer is used in the region as a potable and nonpotable water supply.
		Incidental ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for purposes other than drinking water	No	Yes	Quantitative	
		Inhalation of groundwater-derived vapors that migrate through building foundations into indoor air	Yes	Yes	Quantitative	Potential indoor exposure is possible if groundwater-derived vapors migrate through building foundations.
Maintenance workers	Groundwater	Incidental ingestion of and dermal contact with exposed groundwater; inhalation of vapors from exposed groundwater	Yes	Yes	Quantitative	Potential exposure to shallow groundwater and vapors from groundwater within excavation pits that extend into the water table is possible.
					Inferred from recreational visitors	Potential exposure to lower aquifer groundwater is possible during maintenance of industrial production wells in the vicinity of the site.
	LNAPL	Incidental ingestion of and dermal contact with exposed LNAPL; inhalation of vapors from exposed LNAPL	Yes	Yes	Quantitative	Potential exposure is possible if excavations extend to the water table in the off- site area where LNAPL is present.

Exposed Population	Exposure Medium	Exposure Route	Possible Currently?	Possible in Future?	Type of Analysis	Comments
Off-site (cont.)						
Recreational visitors	Groundwater	Incidental ingestion of and dermal contact with groundwater, and inhalation of groundwater-derived vapors in ambient air	Yes	Yes	Quantitative	Potential exposure to lower aquifer groundwater is possible during recreation at the local recreational area.
	Surface water	Incidental ingestion, dermal contact, and inhalation of vapors	Yes	Yes	Quantitative	Storm sewers and upper aquifer groundwater from the site discharge into the River. The designated uses of the River at the site are for recreation and agricultural and industrial water supply.
Residents	Surface and subsurface soil	Inhalation of soil-derived vapors and airborne particulates in ambient air	Yes	Yes	Inferred from On-Site Routine Workers	Airborne exposures off-site are possible via windblown dust from exposed soil or excavation activities at the site.
	Groundwater	Ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for drinking water	No	Yes	Quantitative	Groundwater is not currently used for drinking water within at least a half mile of the site, and potable water is available from the municipal drinking water system. However, groundwater in the lower aquifer is used in the region as a potable and nonpotable water supply.
		Incidental ingestion of and dermal contact with groundwater and inhalation of groundwater-derived vapors during use of groundwater for purposes other than drinking water	No	Yes	Quantitative	
		Inhalation of groundwater-derived vapors that migrate through building foundations into indoor air	No	Yes	Quantitative	The off-site areas within approximately a half-mile of the site consist of only commercial/industrial land use. Potential residential land use was evaluated in the off-site area where future residential development is plausible.

Appendix I

Summary of Michigan Daily Surficial Soil Temperatures from 2004 to 2014

Submitted by Kory Groetsch and discussed by the TAG

Introduction

People can be exposed to environmental chemical contaminants through soil contact. Soil contamination at Michigan facilities is evaluated relative to cleanup criteria based on generic human health risk assessment. Because Michigan has a temperate climate with four well-defined seasons, it is common during the winter months for the surficial soil to reach freezing temperatures (below 32^{o}F). Frozen soil may result in fewer opportunities for direct contact to occur, reducing exposure frequency. Exposure frequency is a parameter in the direct contact risk assessment algorithm, and could be adjusted for the number of days that Michigan experiences frozen soil.

The objective of this paper is to summarize the past ten years of surficial (i.e., top two inches) soil temperature data collected by *Enviro-Weather*, which is a collaboration coordinated by Michigan State University Extension (www.agweather.geo.msu.edu/mawn).

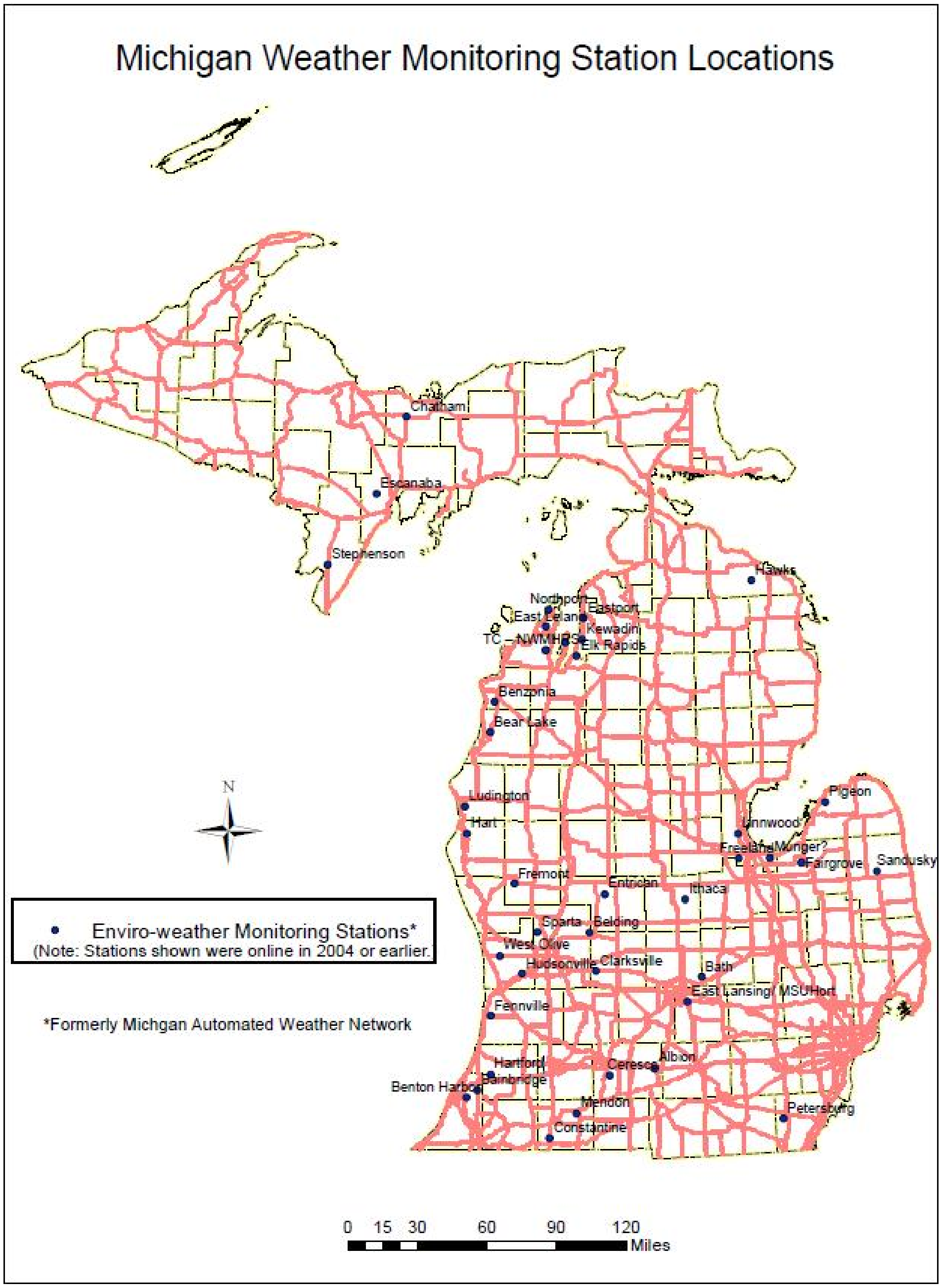
Methods

Minimum and maximum daily soil temperature measurements are reported per location at www.agweather.geo.msu.edu/mawn. To select a location at this website, scroll to the map of Michigan and click on a colored point. For this purpose of determining frozen surficial soil, the maximum daily soil temperature data in the top two inches was downloaded for 40 locations from August 1, 2004, to July 31, 2014, in CSV format for each qualifying station. A station was considered qualified if it began collecting soil temperature data on or before 2004 and had at least ten years of winter data available. A map of the qualifying stations is provided in Figure 1. Forty data sets from 40 locations were imported into Microsoft Excel. Each locational data set had the maximum daily soil temperature measurements for the surficial soil (top two inches) over the ten-year period.

Each locational data set was sorted into annual increments (August 1 to July 31) and from each annual data set the “total number of days that temperature measurements were collected” was recorded. The “number of days the maximum soil temperature was less than 32^{o}F in the top two inches” were counted. Each variable was calculated twice, once using all ten years of data regardless of missing values (i.e. unadjusted), and a second calculation after making the following adjustments:

- If approximately seven or fewer days of missing data occurred during the winter season, and the days before and after the missing days were below 32^{o}F, the missing data were replaced with soil temperatures less than 32ºF. This limits the loss of critical frozen soil days from the annual summary statistics and preserves the use of an annual data set at a given location.
- An annual data set for a location was excluded if as few as five days of missing data occurred during typical frozen soil dates compared to other annual data sets at that location and the soil temperatures before or after the missing days were not below 32^{o}F.
- The year was excluded if a significant number of days were missing during transition periods when the temperature fluctuated between frozen soil and unfrozen soil.

FIGURE 1. Location of Enviro-Weather Monitoring Stations
With Ten Years of Surficial Soil Temperature Data From 2004 to 2014.



For each location across all years, the mean, standard deviation, minimum, 25th percentile, median, 75th percentile, and maximum values were calculated for the "number of days the maximum soil temperature was less than 32°F in the top two inches" for the adjusted and unadjusted data sets. A summary of the mean and median number of days across all locations is also calculated. Results are presented using box-and-whisker plots that display minimum value, 25th percentile, median, 75th percentile, and maximum value for each data set.

Results

Across all locations for the ten-year time frame, the minimum, 25th percentile, median, 75th percentile, and maximum “median number of days the maximum soil temperature was less than 32^oF in the top two inches.” The “mean number of days the soil temperature was less than 32^oF in the top two inches” was between zero and 87 days for unadjusted data sets, and zero to 93 days for adjusted data sets (Table 1). The range for the unadjusted and adjusted median number of days and mean number of days are similar (Figure 2).

TABLE 1.* Number of days where Michigan surficial soil temperature is less than 32^oF across all locations.

	Unadjusted Days		Adjusted Days	
	Median	**Mean**	**Median**	**Mean**
Minimum	0	1	0	0
25^{th} percentile	4	12	4	11
Median	24	29	24	29
75^{th} percentile	58	53	61	53
Maximum	87	80	93	81

* Minimum, 25th percentile, median, 75th percentile, and maximum unadjusted and adjusted medians and means for the number of days

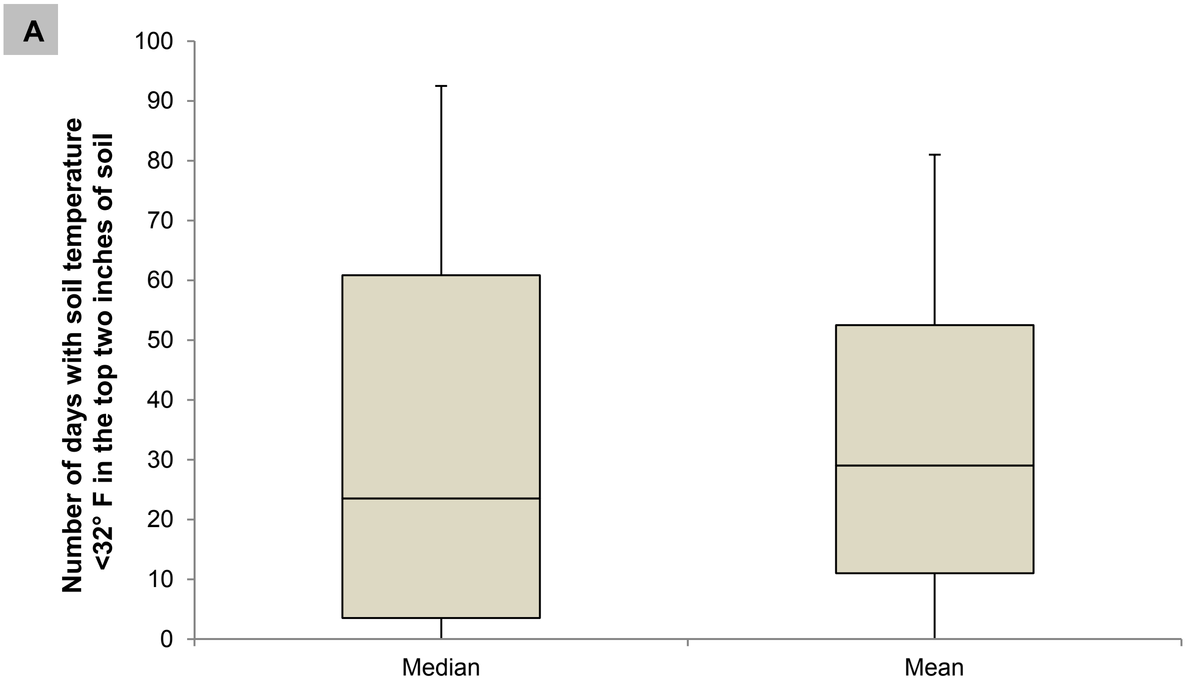
For individual locations, the “number of days the maximum soil temperature was less than 32^oF in the top two inches” were counted and the minimum, 25th percentile, median, 75th percentile, and maximum number of days are summarized in Table 2 (adjusted) and Table 3 (unadjusted). The more southern locations are at the beginning of the tables, and the more northern locations are at the end.

A comparison of these summary statistics using box-and-whisker plots arranged from the most southern locations on the left side of Figure 2 and 3 to the most northern location on the right allow for a visual comparison of variability between years and locations across the range of latitude. Locational variability is significant, with many locations having zero days of frozen soil at the 25th percentile, and some locations having zero days of frozen soil at the 75th percentile.

Conclusions

Robust data sets of Michigan soil temperature, as well as other Michigan weather conditions, exist and may be valuable for determining exposure values for use as parameter in Michigan’s generic cleanup criteria algorithms.

FIGURE 2.* Geographic location



* Medians and means of the number of days with a soil temperature less than 32° F for adjusted (A) and unadjusted (B) top two-inch soil temperature data sets.

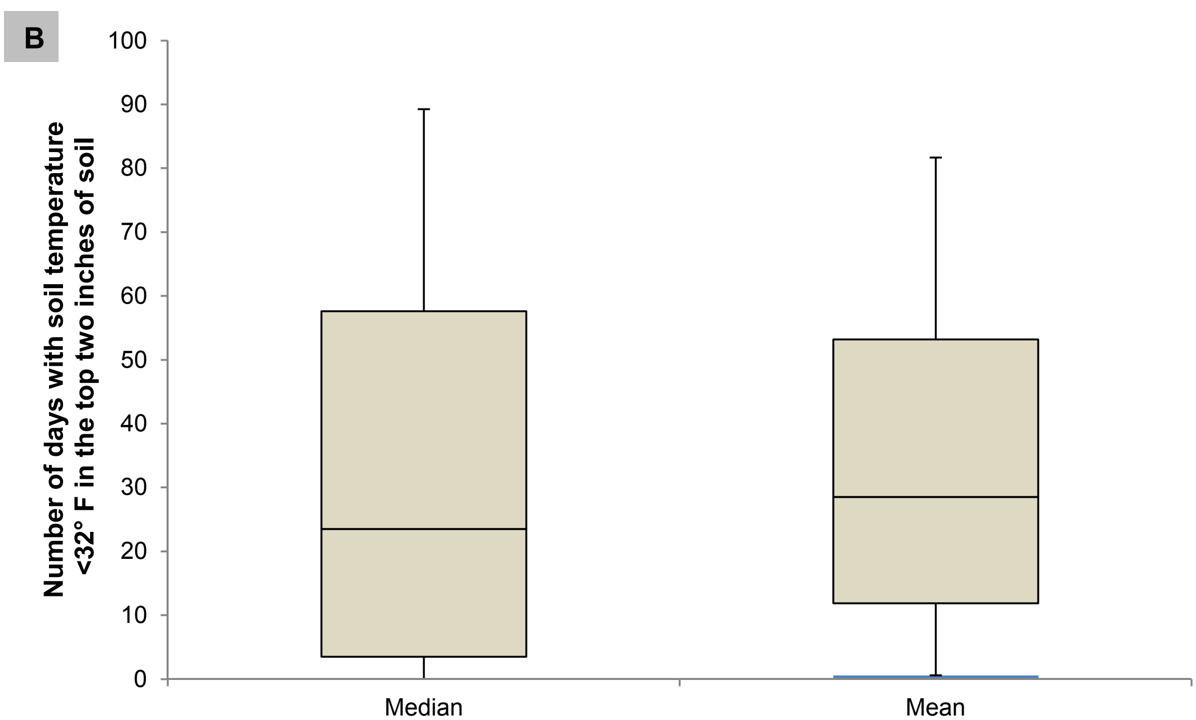


TABLE 2. Number of days the maximum daily surficial soil temperature was less than 32^{o}F.

County	City or Location	Adjusted (Adj.) Mean	Adj. SD	Min.	25th	Adj. Median	75th	Max.	Adj. Number Years
Allegan	Fennville	7	19	0	0	0	1	62	10
Berrien	Bainbridge	21	26	0	8	12	21	82	9
Berrien	Benton Harbor	27	19	0	12	26	42	54	10
Calhoun	Albion	26	21	0	14	16	47	56	9
Calhoun	Ceresco	61	36	4	43	73	87	95	8
Ingham	East Lansing	22	23	0	2	21	32	76	10
Monroe	Petersburg	54	28	4	47	57	64	105	10
St. Joseph	Constantine	8	11	0	0	0	17	26	9
St. Joseph	Mendon	19	15	0	6	19	25	50	10
Van Buren	Hartford	10	13	0	0	4	13	40	10
Bay	Linwood	67	32	11	61	70	82	120	10
Bay	Munger	74	24	25	62	80	89	115	9
Clinton	Bath	52	31	0	38	60	74	88	9
Gratiot	Ithaca	40	21	0	31	39	50	80	9
Ionia	Belding	37	31	0	7	37	58	86	10
Ionia	Clarksville	13	16	0	0	5	22	41	10
Kent	Sparta	11	22	0	1	4	11	71	10
Mason	Ludington	20	23	0	2	14	29	64	8
Montcalm	Entrican	67	27	29	49	64	89	102	10
Newaygo	Fremont	48	25	15	28	42	72	79	9
Newaygo	Pigeon	56	34	0	39	71	77	98	10
Oceana	Hart	8	21	0	0	0	1	63	9
Ottawa	Hudsonville	5	13	0	0	0	2	42	10
Ottawa	West Olive	11	14	0	0	10	13	39	9
Saginaw	Freeland	62	25	27	37	65	77	100	9
Sanilac	Sandusky	44	41	0	0	64	68	108	9
Tuscola	Fairgrove	64	25	15	51	70	79	99	10
Antrim	Elk Rapids	34	33	0	2	30	57	89	10
Antrim	Kewadin	31	30	0	8	22	53	79	10
Antrim	Eastport	13	26	0	0	2	8	71	7
Benzie	Benzonia	19	17	0	6	17	31	48	10
Grand Traverse	Old Mission	45	23	7	34	42	66	75	8
Grand Traverse	Traverse City	37	40	0	6	26	62	117	10
Leelanau	East Leland	3	7	0	0	0	2	22	10
Leelanau	Northport	32	30	0	10	25	56	77	9
Manistee	Bear Lake	0	1	0	0	0	0	2	9
Presque Isle	Hawks	10	26	0	0	0	1	75	8
Alger	Chatham	1	2	0	0	0	0	5	8
Delta	Escanaba	80	28	34	61	87	90	123	10
Menominee	Stephenson	81	43	18	41.5	92.5	113.3	137	8

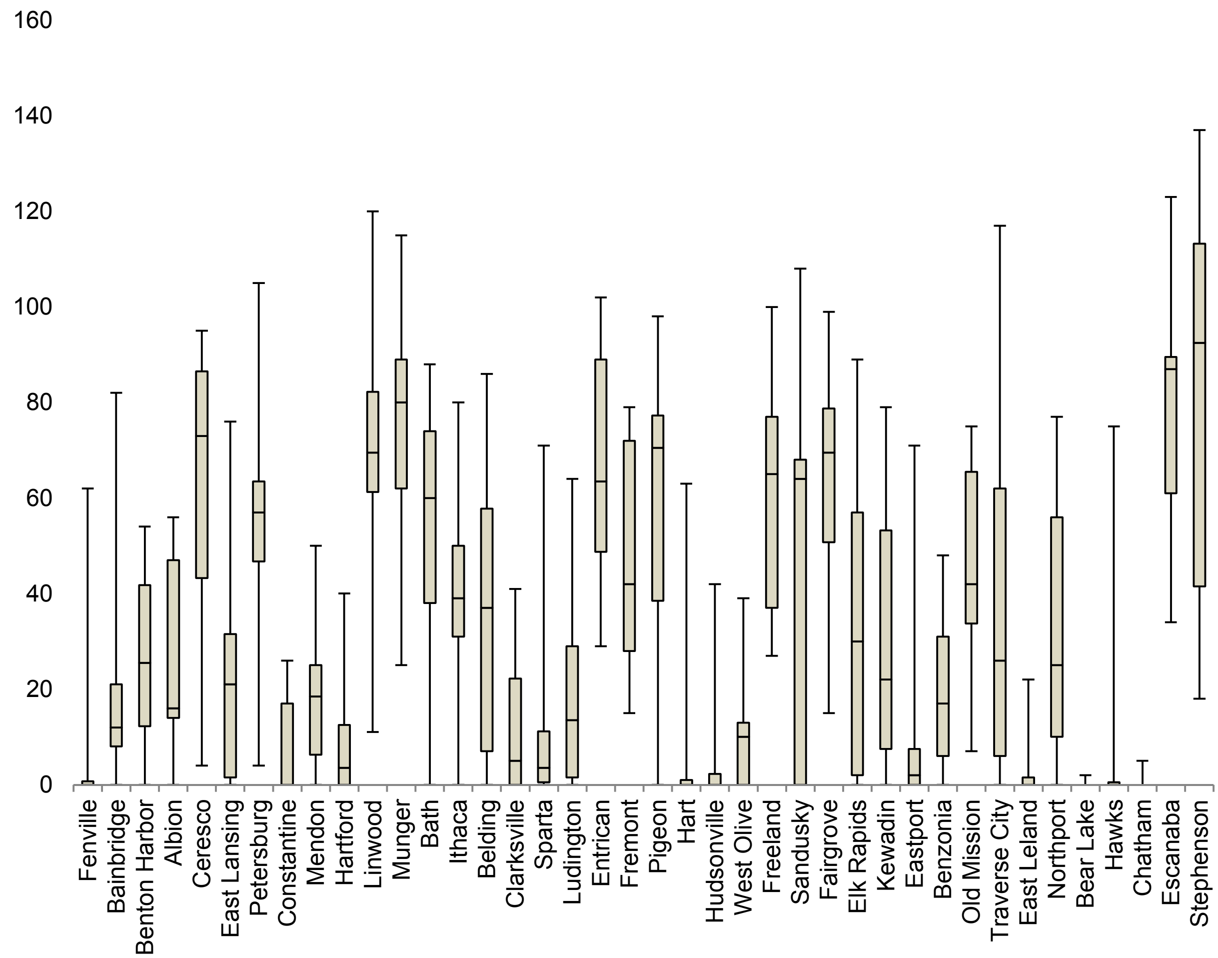
*For each location, the mean, standard deviation, minimum, 25th percentile, median, 75th percentile, maximum for the adjusted count of the number of days.

TABLE 3. Number of days the maximum daily surficial soil temperature was less than 32°F.

County	City or Location	Mean	SD	Min	25%tile	Median	75%tile	Max	Number Years
Allegan	Fennville	7	18	0	0	0	0.75	56	10
Berrien	Bainbridge	22	25	0	9	12	34	82	10
Berrien	Benton Harbor	26	19	0	12	26	38	54	10
Calhoun	Albion	23	22	0	4	15	45	56	10
Calhoun	Ceresco	54	37	0	19	60	84	95	10
Ingham	East Lansing	22	23	0	2	21	32	76	10
Monroe	Petersburg	54	28	4	47	57	64	105	10
St. Joseph	Constantine	9	12	0	0	2	22	26	10
St. Joseph	Mendon	19	15	0	6	19	25	50	10
Van Buren	Hartford	10	13	0	0	4	13	40	10
Bay	Linwood	67	32	11	61	70	82	120	10
Bay	Munger	75	26	25	64	83	90	115	10
Clinton	Bath	47	34	0	17	54	72	88	10
Gratiot	Ithaca	38	21	0	30	38	48	80	10
Ionia	Belding	36	30	0	7	37	58	86	10
Ionia	Clarksville	12	15	0	0	5	22	41	10
Kent	Sparta	11	22	0	1	4	11	71	10
Mason	Ludington	16	22	0	0	6	22	64	10
Montcalm	Entrican	67	27	29	49	64	89	102	10
Newaygo	Fremont	53	28	15	30	55	74	96	10
Newaygo	Pigeon	56	34	0	39	71	77	98	10
Oceana	Hart	7	20	0	0	0	1	63	10
Ottawa	Hudsonville	5	13	0	0	0	2	42	10
Ottawa	West Olive	14	15	0	0	11	24	39	10
Saginaw	Freeland	62	24	27	42	62	75	100	10
Sanilac	Sandusky	47	39	0	4	65	71	108	10
Tuscola	Fairgrove	64	25	15	51	70	79	99	10
Antrim	Elk Rapids	34	33	0	2	30	57	89	10
Antrim	Kewadin	31	30	0	8	22	53	79	10
Antrim	Eastport	9	22	0	0	0	6	71	10
Benzie	Benzonia	19	17	0	6	17	31	48	10
Grand Traverse	Old Mission	45	23	7	34	42	66	75	10
Grand Traverse	Traverse City	37	40	0	6	26	62	117	10
Leelanau	East Leland	3	7	0	0	0	2	22	10
Leelanau	Northport	32	30	0	10	25	56	77	10
Manistee	Bear Lake	1	2	0	0	0	0	7	10
Presque Isle	Hawks	16	32	0	0	0	2	79	10
Alger	Chatham	1	2	0	0	0	0	5	10
Delta	Escanaba	80	28	34	61	87	90	123	10
Menominee	Stephenson	71	45	0	38	83	104	136	10

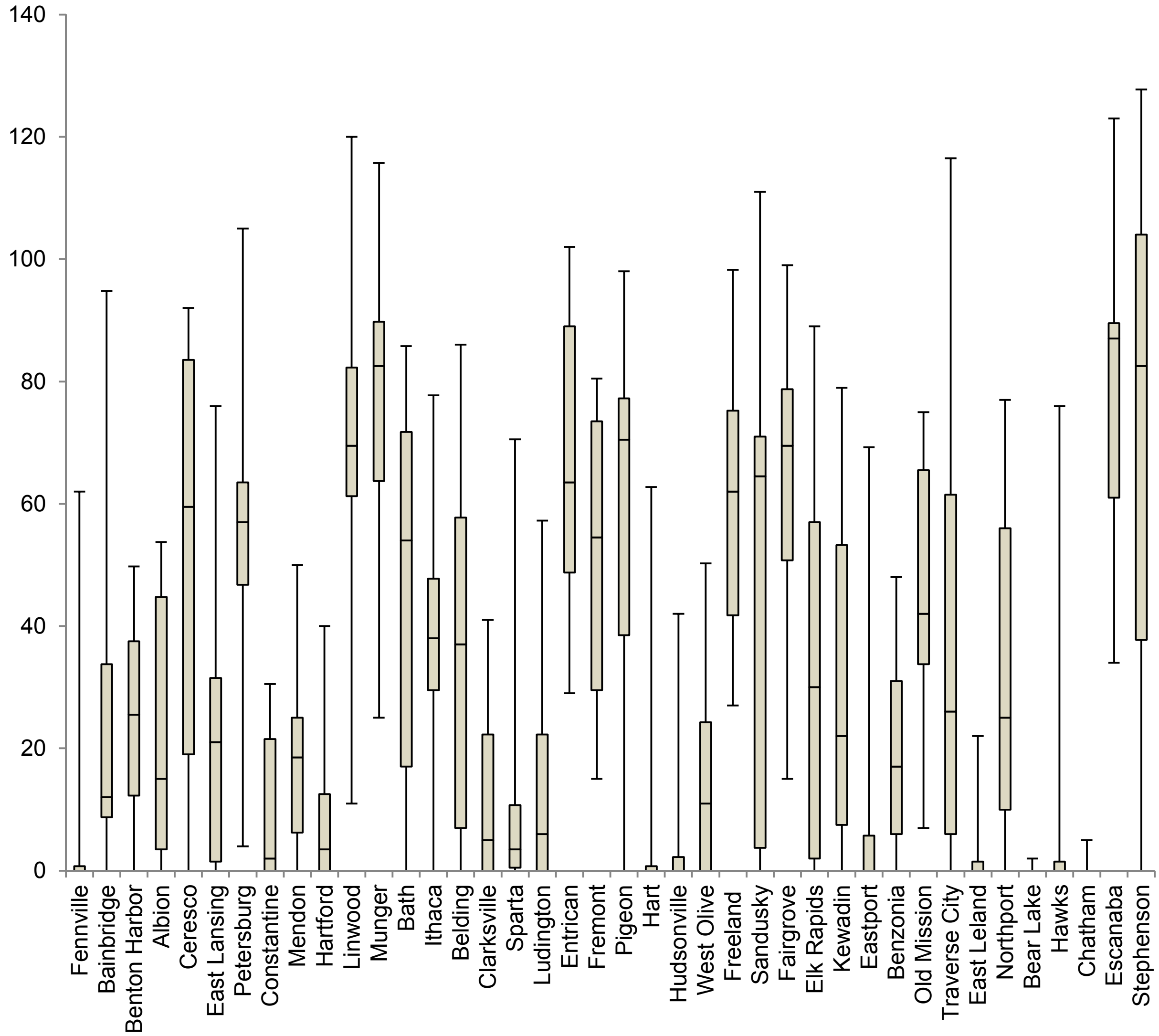
* For each location, the mean, standard deviation, minimum, 25th percentile, median, 75th percentile, maximum for the unadjusted count of the number of days.

FIGURE 3. Number of days the maximum daily surficial soil temperature was less than 32^{o}F.



* For each Michigan location, box-and-whisker plots depicting the minimum, 25th percentile, median, 75th percentile, maximum for the adjusted count of number of days.

FIGURE 4. Number of days the maximum daily surficial soil temperature was less than 32°F.



* For each Michigan location, box-and-whisker plots depicting the minimum, 25th percentile, median, 75th percentile, maximum for the unadjusted count of number of days.

Appendix J

Justification for High-end Soil Ingestion Rate

Submitted by Christine Flaga, as solicited by the TAG

The Part 201 cleanup criteria are health-based values developed by the MDEQ that must incorporate appropriate, reasonable, and relevant exposure pathways and exposure assumptions (20120a(3)). The generic cleanup criteria are intended to apply to most contaminated properties in Michigan and protect most of the population exposed to contamination. It is appropriate and reasonable to ensure that the criteria protect all segments of the population, not just the average individual. The MDEQ has historically followed the EPA's recommendations for exposure assumptions that protect for the reasonable maximum exposure (RME). To represent the RME, the set of generic assumptions must use high-end values (90-99th percentile) for sensitive parameters and central tendency values (mean or 50th percentile) for less sensitive parameters. Since the soil ingestion rate is a sensitive parameter in the direct contact criteria (DCC) calculation, MDEQ elected to use a high end soil ingestion rate value in its current DCC algorithm. Note that even with the use of the high-end value, the calculated risk does not account for children with pica habits and those exhibiting geophagy.

The 2014 OSWER Directive adopted the soil ingestion rate recommended by the 2011 Exposure Factor Handbook (EFH), which is 200 mg/day for children 0–6 years of age. This value represents a 95th percentile value for dust plus soil in Ozkaynak et al. 2011. The same value is the 95th percentile for soil only ingestion rate in two studies: Stanek and Calabrese, 1995 and Ozkaynak et al. 2011. The soil ingestion rate is significantly higher for people 21 or younger who exhibit pica behavior. Moya and Phillips (2014) published an analysis of soil and dust ingestion studies and note that for certain contaminants or for particular age groups, dust ingestion may be a more significant exposure than soil.

One of the TAG members proposed that the meta-analysis presented in Stanek et al. 2012 be used as the basis for the generic soil ingestion rate. One of the EFH authors informed MDEQ in 2012 that they had reviewed the Stanek manuscript. Considering the limitations of this study, they concluded that the EFH-recommended high-end value for the soil ingestion rate appears to be a more reasonable estimate. The limitations included:

1. The study excluded children who may have "higher than normal" ingestion rates. The Stanek study excludes Calabrese et al. 1997 which was targeted at children exhibiting high mouthing behaviors (based on parental observation). The mean soil and dust values for aluminum (Al) and silicon (Si) tracers from the Calabrese et al. 1997 study were 428 mg/day and 386 mg/day, respectively. These values are higher than the 95th percentile values presented by Stanek et al. 2012. The soil ingestion rate should be based on the whole population including those at the high end.
2. The studies selected for the meta-analysis are short-term; therefore may not capture days when the children experience higher than normal ingestion rates, or a day where their ingestion rate is closer to that of a child with pica behavior.
3. Si and Al tracers were the only ones considered in the analysis. Since soil ingestion rates vary widely depending on the tracer used, results for other tracers should have been included.
4. The Stanek study identified several elements of the meta-analysis as influential, describing the impact of each of these elements (see bulleted items below). The impact of each of these elements for the full meta-analysis has decreased the soil ingestion rates predicted by the analysis. Although the influence of each of these individual elements is described to some extent, the impact of some or all of these elements was not evaluated. Moreover, the cumulative impact of two or more of these elements was not provided in the Stanek analysis.

- The Stanek meta-analysis included the Anaconda Study. This study has soil ingestion rate estimates that are clearly lower than the other studies. It may have been influenced by public education efforts of the Superfund program to minimize exposures at the site. These and other aspects of the study are discussed in the last paragraph of Section 4 (bottom of page 441 and top of page 442) of the Stanek paper and states that the significant variation between studies disappears when the Anaconda study is omitted from the analysis. The inclusion of the Anaconda study on the full meta-analysis significantly decreases the soil ingestion rate estimates as shown in the second to the last row of Table II of the Stanek paper.
- The Stanek meta-analysis includes negative soil ingestion rate estimates that are not clearly described. The following is stated at the end of the first paragraph in Section 3.1, page 439 of the Stanek paper: "If estimates of soil ingestion less than zero are set equal to zero, the mean soil ingestion is 31.3 mg/day" as compared to 25.5 from the full analysis. Figure 2 of the paper does not show these negative values used in the meta-analysis, instead truncating those negative values as described on page 440.
- Another critical element of the meta-analysis is the assumption that all of the soil ingestion was from soil, not indoor dust. As described in the first full paragraph on page 443 of the Stanek paper, "Average concentrations of Al and Si in dust are 42-87 percent of the concentrations in soil" indicating that if indoor dust is a significant component of the tracer ingestion rate, the soil and dust ingestion rate may be underestimated by the analysis.
- The meta-analysis excluded 24 subjects and 37 subject weeks of soil ingestion estimates (non-pica) as less reliable estimates. This is described in the beginning of Section 3 on page 439 of the Stanek paper. The last row of Table II shows how excluding this data has also decreased the soil ingestion rate estimates (even without including the child with pica behavior in this evaluation).

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Appendix K

Alternatives for Nonresidential Exposure Assessment Factors

Submitted by Francis Ramacciotti, Donal Brady, and Stephen Zayko

This appendix was not discussed by full TAG.

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Table 1: Summary of Nonresidential Exposure Factors
Table 2: Comparison of Nonresidential Intakes

1 Potentially Exposed Nonresidential Populations

The largest nonresidential population at sites consists of workers who are engaged in routine commercial/industrial activities. These workers are typically engaged in such activities that generally take place either indoors (e.g., manufacturing or sales) or outdoors (e.g., loading/unloading product or grounds keeping). Both types of workers are individually considered in the exposure assessment for the calculation of the generic criteria. A combined exposure scenario (i.e., spending some time indoors and some outdoors) is not considered, as such exposures would not be higher than those for workers who always work either indoors or outdoors. The potential exposures evaluated for each of these receptors are discussed below.

1.1 Routine Indoor Workers

The largest nonresidential receptor population considered in the calculation of generic criteria consists of workers who are engaged in routine commercial/industrial activities that take place only indoors. Potential routes of exposure to surface soil that is a component of indoor dust would include incidental ingestion and dermal contact.

These workers also could be exposed via inhalation of constituents from the subsurface soil or shallow groundwater if constituents were to volatilize and migrate through cracks in the building foundation into indoor air.

Exposure of routine workers via potable groundwater use may also be possible.

1.2 Routine Outdoor Workers

Another nonresidential receptor population considered in the calculation of generic criteria consists of workers who are engaged in routine commercial/industrial activities that take place only outdoors. Such workers could be performing routine activities (e.g., loading/unloading product) or these workers could be conducting occasional (limited size and duration) subsurface maintenance or construction activities or performing other grounds keeping type functions. Workers under this scenario could be exposed to surface and subsurface soil in paved and unpaved areas of the Facility. Potential routes of exposure to surface and subsurface soil during such activities would include incidental ingestion, dermal contact, and inhalation of soil vapor and airborne particulates.

Exposure of routine workers via potable groundwater use may also be possible.

2 Estimation of Nonresidential Intakes

The exposure factors for evaluating the generic nonresidential exposure scenarios summarized above are discussed in this section. In this risk assessment, standard default exposure factors recommended by EPA for estimating RME were used where available and appropriate for the calculation of generic criteria for use in Michigan. Where standard default exposure factors are not available or appropriate for an exposure scenario, the evaluation was conducted using similarly conservative exposure factors that are based on Michigan-specific considerations and professional judgment, as discussed below.

2.1 Routine Indoor Workers

Potential exposure of routine indoor workers to soil is conservatively evaluated using the standard default exposure factors that EPA (1991a, 2014) recommends for estimating reasonable maximum exposure (RME). According to EPA, the standard default exposure factors are conservative assumptions about the magnitude, frequency, and duration of exposures, which, in combination, are intended to provide estimates of exposures that are higher than actual exposures to a large portion (90% to 99%) of a potentially exposed population.

Certain exposure factors (e.g., exposure frequency) could reasonably be modified on a generic basis to reflect the number of days in a single workplace for workers in Michigan. Such a modification could be based on labor statistics from either Michigan or Federal agencies.

2.1.1 Soil Incidental Ingestion Rate

A soil ingestion rate of 50 milligrams per day (mg/day) is used for routine indoor workers, who as discussed in Section 1.1 are engaged in commercial/industrial activities that take place only indoors. EPA has recommended the use of this value for evaluating high-end routine worker exposures to soil (EPA 1991a).

2.1.2 Soil Dermal Contact Rate and Absorption

The dermal contact rate is the product of the exposed skin surface area and the soil to skin adherence factor. The exposed skin area of 3,470 cm^2 and the soil to skin adherence factor of 0.07 milligrams per centimeters squared (mg/cm^2) are the EPA recommended skin area and adherence factor for evaluating high-end contact with soil by workers (EPA 2014). These factors are those recommended by EPA for outdoor workers. EPA does not recommend either a skin surface area or adherence factor for indoor workers, which could be interpreted as dermal exposure is not reasonably possible for indoor workers.

The absorbed dose from dermal contact with soil is estimated by multiplying the dermal contact rate by EPA-recommended absorption factors for absorption from soil (EPA 2004b).

2.1.3 Groundwater Ingestion Rate

A drinking rate of 2.5 Liters per day is EPA's recommended value for adults (EPA 2014). It is conservatively assumed that 1.25 Liters of water per day is ingested while at work and that this water consists entirely of groundwater from a particular site. The drinking water criteria algorithm currently incorporates a relative source contribution of 0.2 to conservatively account for exposures, other than ingestion of groundwater, a receptor may experience. The applicability of the 0.2 relative source contribution is dependent on the drinking water criteria algorithm remaining as is and not accounting for other exposures.

2.1.4 Exposure Time

Routine indoor workers are assumed to be at a site and inhale vapors in indoor air from site-related sources for 8 hours per day, the EPA-recommended value for full-time workers (EPA 2009a, 2014). EPA's (2014) basis for value is a standard 8 hour work day; however, the data in the Exposure Factors Handbook (EPA 2011) suggests a more appropriate average worker exposure time would be less than 8 hours. The Exposure Factor Handbook presents a mean time spent indoors at work (doers only), for the 18 to 64 year old worker population of 6.8 hours/day.

2.1.5 Exposure Frequency and Duration

Routine indoor workers are assumed to be at a site for 245 days per year for 21 years. This combination of exposure frequency and exposure duration is expected to be conservative for the amount of time that workers are actually exposed to soil during indoor activities.

EPA has recommended the use of a high end exposure frequency of 250 days per year (EPA 1991a, 2014). An additional 5 days as sick leave or vacation time away from the workplace is used to give an exposure frequency of 245 days routine indoor worker exposures.

An evaluation of the data on the number of hours worked by the average American and the number of hours worked each day, results in an exposure frequency of approximately 227 days/year for indoor workers. According to data (Feenstra 2013) obtained from the Federal Reserve Economic Data website, the average annual hours worked for those engaged in employment in the US is 2011 was 1,704 hours.

Data collected in 2009 to 2013 for the American Time Use Survey by the USDL, Bureau of Labor Statistics (USDL 2014), demonstrated participants (or doers) worked at their main job an average of 7.5 hours per day. Average annual hours worked (1,704 hours) divided by the average hours worked per day (7.5 hours/day), provides and average number of days worked per year of 227 days. This value derived from data is an alternative to anecdotal exposure frequency recommended by the EPA.

EPA has recommended the use of a high end exposure duration of 25 years (EPA 1991a, 2014). The Department's historic use of 21 years as the exposure duration (ED) for a worker is based on 1991 statistics from the United States Department of Labor (EPA 1991b). However, since the United States Department of Labor Statistics did not detail the distribution for employees working greater than 19 years at one location, 25 years was assumed to be a 95th percentile estimate by the EPA. The 90th percentile was estimated to be 21 years. Although an ED of 21 years differs from EPA's recommendation of 25 years, an ED of 21 years is derived from more recent data. In addition, use of an ED of 21 years follows EPA guidance which recommends using a combination of exposure assumptions which represent 50th, 90th, and 95th percentiles (MDEQ 1998).

2.1.6 Body Weight

The body weight of 80 kilograms (kg) is the standard EPA-recommended body weight for assessing exposure to adults (EPA 2014).

On average the body mass of the population in Michigan (Hayes 2013, Suton 2013, Carlson 2012, Drenowatz 2012, Yee 2011) is 7% larger than that of the United States (USDHHS 2012), which could result in a larger (up to 7%) skin surface area as well as body weight.

2.1.7 Averaging Time

The averaging time for evaluating cancer risk is equal to a lifetime of 70 years and the averaging time for evaluating noncancer risk is equal to the exposure duration (EPA 1989, 2014).

Data from EPA (2011) also shows that the typical lifetime has increased to 78 years, which could be incorporated into the averaging time for evaluating cancer risk.

Although it is recognized that the use of the default exposure factors, rather than site-specific factors (e.g., a fraction contacted term <1), results in overestimation of RME risks at many sites, this approach is conservatively used to calculate generic criteria.

2.2 Routine Outdoor Workers

Potential exposure of routine outdoor workers to soil is conservatively evaluated using the standard default exposure factors that EPA (1991a, 2014) recommends for estimating reasonable maximum exposure (RME). According to EPA, the standard default exposure factors are conservative assumptions about the magnitude, frequency, and duration of exposures, which, in combination, are intended to provide estimates of exposures that are higher than actual exposures to a large portion (90% to 99%) of a potentially exposed population.

2.2.1 Soil Incidental Ingestion Rate

A soil ingestion rate of 100 milligrams per day (mg/day) is used for routine outdoor workers, who as discussed in Section 1.2 are engaged in commercial/industrial activities that take place only outdoors. EPA historically recommend (1991) a soil ingestion rate (IR) of 50 mg/day for workers for evaluating high-end routine workers exposures to soil without differentiating between whether the worker population spend most/all of its time either outdoors or indoors. Subsequent to publishing this document, EPA recommended that risk assessors segregate the worker population at commercial/industrial facilities into "indoor" and "outdoor" workers and then use a soil ingestion rate of 100 mg/day for the outdoor workers, which is twice EPA's standard default ingestion rate of 50 mg/day for commercial/industrial settings.

This recommendation for a two-fold increase from the ingestion rate that EPA had been using since 1991 for estimating the reasonable maximum exposure (RME) for workers is not based on any new data on soil ingestion rates. Rather, it is apparently based on EPA's belief that outdoor workers always work the entire day in areas with bare soil, and a factor of two appropriately accounts for their increased soil contact (Section 4.1.3 of EPA 2002). Therefore, using an IR of 100 mg/day is a conservative generic rate for soil ingestion of outdoor workers.

2.2.2 Soil Dermal Contact Rate and Absorption

The dermal contact rate is the product of the exposed skin surface area and the soil to skin adherence factor. The exposed skin area of 3,470 cm^2 and the soil to skin adherence factor of 0.12 milligrams per centimeters squared (mg/cm^2) are the EPA recommended skin area and adherence factor for evaluating high-end contact with soil by workers in outdoor settings (EPA 2014). The absorbed dose from dermal contact with soil is estimated by multiplying the dermal contact rate by EPA-recommended absorption factors for absorption from soil (EPA 2004b).

2.2.3 Groundwater Ingestion Rate

A drinking rate of 2.5 Liters per day is EPA's recommended value for adults (EPA 2014). It is conservatively assumed that 1.25 Liters of water per day is ingested while at work and that this water consists entirely of groundwater from a particular site.

2.2.4 Exposure Time

Routine outdoor workers are assumed to be at a site and inhale vapors and particulates from site-related sources for 8 hours per day, the EPA-recommended value for full-time workers (EPA 2009a, 2014). EPA's (2014) basis for value is a standard 8 hour work day. The Exposure Factors Handbook (EPA 2011) does not present data for the outdoor worker scenario. However, as previously stated, data collected in 2009 to 2013 for the American Time Use Survey by the USDL, Bureau of Labor Statistics (USDL 2014), demonstrated participants (or doers) worked at their main job an average of 7.5 hours per day.

2.2.5 Exposure Frequency and Duration

Routine outdoor workers are assumed to be at a site for 245 days per year for 21 years. However, the ability of these workers to contact soil is limited by the unique climate in Michigan and as a result the exposure frequency for incidental soil ingestion and dermal contact is assumed to be 160 days per year. This combination of exposure frequency and exposure duration is expected to be conservative for the amount of time that workers are actually exposed to soil during outdoor activities.

EPA has recommended the use of a high end exposure frequency of 250 days per year (EPA 1991a, 2014). The exposure frequency of 160 days per year was derived assuming that four months of winter would preclude an individual from coming into contact with soil. NOAA (2010) has compiled and evaluated 30-years of data for various climatic factors that show that most cities in Michigan have normal mean temperatures less than or equal to freezing for four months of the year (i.e., January, February, March, and December). During these months it is assumed that snow and or ice are covering most of the exposed soil and that outdoor workers cover the majority of their exposed skin while performing outdoor activities. Rain and other inclement weather factors were not considered because it is assumed that this type of worker must still perform outdoor duties. Allowing for three weeks off per year for vacations/sick leave and adjusting for a standard five day work week yields a maximum number of 160 days per year of potential exposure (i.e., 365 - 120 - 21 x 5/7 = 160).

MDEQ had previously evaluated these data and determined that a reasonable maximum exposure frequency for outdoor worker contact with bare soil at a site was 112 days/year.

EPA has recommended the use of a high end exposure duration of 25 years (EPA 1991a, 2014). The Department's historic use of 21 years as the exposure duration (ED) for a worker is based on 1991 statistics from the United States Department of Labor (EPA 1991b). However, since the United States Department of Labor Statistics did not detail the distribution for employees working greater than 19 years at one location, 25 years was assumed to be a 95th percentile estimate by the EPA. The 90th percentile was estimated to be 21 years. Although an ED of 21 years differs from EPA's recommendation of 25 years, an ED of 21 years is derived from more recent data. In addition, use of an ED of 21 years follows EPA guidance which recommends using a combination of exposure assumptions which represent 50th, 90th, and 95th percentiles (MDEQ 1998).

2.2.6 Body Weight

The body weight of 80 kilograms (kg) is the standard EPA-recommended body weight for assessing exposure to adults (EPA 2014).

On average the body mass of the population in Michigan (Hayes 2013, Suton 2013, Carlson 2012, Drenowatz 2012, Yee 2011) is 7% larger than that of the United States (USDHHS 2012), which could result in a larger (up to 7%) skin surface area as well as body weight.

2.2.7 Averaging Time

The averaging time for evaluating cancer risk is equal to a lifetime of 70 years and the averaging time for evaluating noncancer risk is equal to the exposure duration (EPA 1989, 2014).

Data from EPA (2011) also shows that the typical lifetime has increased to 78 years, which could be incorporated into the averaging time for evaluating cancer risk.

Although it is recognized that the use of the default exposure factors, rather than site-specific factors (e.g., a fraction contacted term <1), results in overestimation of RME risks at many sites, this approach is conservatively used to calculate generic criteria.

3 Selection of Representative Nonresidential Receptor

As shown in the attached Table (page K-8), the cancer and noncancer intakes for routine outdoor workers are the same as or slightly higher than those for the routine indoor worker. Therefore, the exposure scenario and associated exposure factors discussed above for routine outdoor workers are recommended as a conservative surrogate for all nonresidential workers.

The intakes for the recommended exposure scenario are similar to or generally less than a factor of two times less conservative than those used by MDEQ in its current Rules (MDEQ 2013).

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5 Table of Alternatives

			Dec 2013 NonRes	Alt 1 - Indoor Worker	Alt 1 - Outdoor Worker	Basis
Soil Ingestion - R299.20						
Ingestion rate	mg-soil/day	**IR**	100	50	100	High
Absorption efficiency - ingestion	unitless	**AE_i**				
Exposure frequency	days/year	**EF**	245	245	160	High
Expoure duration	years	**ED**	21	21	21	High
Body weight	kg	**BW**	70	80	80	Mid
Averaging time, cancer	days	**AT_c**	25,550	25,550	25,550	--
Averaging time, noncancer	days	**AT_{nc}**	7,665	7,665	7,665	--
Intake, cancer	kg-soil/kg/day		2.88E-07	1.26E-07	1.64E-07	
Intake, noncancer	kg-soil/kg/day		9.59E-07	4.20E-07	5.48E-07	
Soil Dermal Contact - R299.20						
Adherence factor	mg-soil/cm^2	**AD**	0.2	0.07	0.12	Mid
Skin surface area	cm^2/day	**SA**	3,300	3,470	3,470	Mid
Absorption efficiency - dermal	unitless	**AE_d**				
Exposure frequency	days/year	**EF**	160	245	160	High
Expoure duration	years	**ED**	21	21	21	High
Body weight	kg	**BW**	70	80	80	Mid
Averaging time, cancer	days	**AT_c**	25,550	25,550	25,550	--
Averaging time, noncancer	days	**AT_{nc}**	7,665	7,665	7,665	--
Intake, cancer	kg-soil/kg/day		1.24E-06	6.11E-07	6.84E-07	
Intake, noncancer	kg-soil/kg/day		4.13E-06	2.04E-06	2.28E-06	
Drinking Water Consumption - R299.10						
Drinking rate	L-water/day	**DR**	1	1.25	1.25	Mid
Exposure frequency	days/year	**EF**	245	245	245	High
Expoure duration	years	**ED**	21	21	21	High
Relative Source Contribution - ncarc	unitless	**RSC**	0.2	0.2	0.2	--
Body weight	kg	**BW**	70	80	80	Mid
Averaging time, cancer	days	**AT_c**	25,550	25,550	25,550	--
Averaging time, noncancer	days	**AT_{nc}**	7,665	7,665	7,665	--
Intake, cancer	L-water/kg/day		2.88E-03	3.15E-03	3.15E-03	
Intake, noncancer	L-water/kg/day		4.79E-02	5.24E-02	5.24E-02	
Air Inhalation - R299.14, R299.24, R299.26						
Adjusted inhalation rate		**AIR**	2.0			
Exposure time	hours/day	**ET**		8	8	High
Exposure frequency	days/year	**EF**	245	245	245	High
Expoure duration	years	**ED**	21	21	21	High
Averaging time, cancer	days	**AT_c**	25,550			
Averaging time, noncancer	days	**AT_{nc}**	7,665			
Averaging time, cancer	hours	**AT_c**		613,200	613,200	--
Averaging time, noncancer	hours	**AT_{nc}**		183,960	183,960	--
EC, cancer	unitless		1.01E-01	6.71E-02	6.71E-02	
EC, noncancer	unitless		6.71E-01	2.24E-01	2.24E-01	

Appendix L

Alternatives for Residential Exposure Assessment Factors

Submitted by Francis Ramacciotti, Donal Brady, and Stephen Zayko

This appendix was not discussed by the full TAG.

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1 Potentially Exposed Residential Populations

Residents are typically engaged in activities that generally take place either indoors or outdoors. Both activities of residents are considered in the exposure assessment for the calculation of the generic criteria. Both types of residents are individually considered in the exposure assessment for the calculation of the generic criteria. A combined exposure scenario (i.e., spending some time indoors and some outdoors) is not considered, as such exposures would not be higher than those for residents who are always either indoors or outdoors. The potential exposures evaluated for each of these receptors are discussed below.

1.1 Outdoor Residents

One residential receptor population considered in the calculation of generic criteria consists of individuals who are engaged in activities that take place only outdoors. Such individuals could be performing routine activities (e.g., walking) or playing or performing other outdoor activities. Individuals under this scenario could be exposed to surface and subsurface soil in paved and unpaved areas of a residential property. Potential routes of exposure to surface and subsurface soil during such activities would include incidental ingestion, dermal contact, and inhalation of soil vapor and airborne particulates.

Exposure via potable groundwater use may also be possible.

1.2 Routine Indoor Residents

The larger residential receptor population considered in the calculation of generic criteria consists of individuals who are engaged in routine activities that take place only indoors. Potential routes of exposure to surface soil that is a component of indoor dust would include incidental ingestion and dermal contact.

These individuals also could be exposed via inhalation of constituents from the subsurface soil or shallow groundwater if constituents were to volatilize and migrate through cracks in the building foundation into indoor air.

Exposure via potable groundwater use may also be possible.

2 Estimation of Residential Intakes

The exposure factors for evaluating the generic residential exposure scenarios summarized above are discussed in this section. In this evaluation, standard default exposure factors recommended by United States Environmental Protection Agency (EPA) for estimating reasonable maximum exposure (RME) were used where available and appropriate for the calculation of generic criteria for use in Michigan. Where standard default exposure factors are not available or appropriate for an exposure scenario, the evaluation was conducted using similarly conservative exposure factors that are based on Michigan-specific data considerations, and professional judgment, as discussed below.

2.1 Routine Outdoor Individuals

Potential exposure of outdoor residents to soil is conservatively evaluated using the standard default exposure factors that EPA (1991a, 2014) recommends for estimating reasonable maximum exposure (RME). According to EPA, the standard default exposure factors are conservative assumptions about the magnitude, frequency, and duration of exposures, which, in combination, are intended to provide estimates of exposures that are higher than actual exposures to a large portion (90% to 99%) of a potentially exposed population.

Certain exposure factors (e.g., exposure frequency) could reasonably be modified on a generic basis to reflect the number of days at a single home for individuals in Michigan. Such a modification could be based on statistics from either Michigan or Federal agencies.

2.1.1 Soil Incidental Ingestion Rate

The soil ingestion rates of 200 and 100 mg/day are EPA's standard default values for evaluating RME in residential settings for children (from birth to age 6) and adults (ages 6 years and older), respectively (EPA 1991a). However, more recent publications on incidental soil ingestion rate suggest that high-end incidental soil ingestion rates for children (up to the age of 8 years old) would be no higher than 100 mg/day (Stanek 2012). EPA appears to have not evaluated these data in its most recent recommendations (EPA 2014). Therefore, using an IR of 100 mg/day is a conservative generic rate for children's soil ingestion while they are outdoors and according to the authors (who also authored the papers EPA used as the basis for its 200 mg/day) this is the "most reliable description of soil ingestion to date among children". There were no new data available for adult's soil ingestion, but it would be expected that this rate would be no higher than that for children.

2.1.2 Soil Dermal Contact Rate and Absorption

The dermal contact rate is the product of the exposed skin surface area and the soil-to-skin adherence factor. The exposed skin surface area of 2,690 and 6,032 cm^2/day and soil-to-skin adherence factor of 0.2 and 0.07 mg/cm^2 are the EPA's recommended values for evaluating high-end contact with soil by children and adults, respectively (EPA 2004b, 2014). The absorbed dose from dermal contact with soil is estimated by multiplying the dermal contact rate by EPA-recommended absorption factors for absorption from soil (EPA 2004b).

As discussed in Section 2.1.6, the population in Michigan is on average 7% larger than that of the United States, which could result in a larger (up to 7%) skin surface area.

2.1.3 Groundwater Ingestion Rate

A drinking rate of 2.5 Liters per day is EPA's recommended value for adults (EPA 2014). The drinking water criteria algorithm currently incorporates a relative source contribution of 0.2 to conservatively account for exposures, other than ingestion of groundwater, a receptor may experience. The applicability of the 0.2 relative source contribution is dependent on the drinking water criteria algorithm remaining as is and not accounting for other exposures.

2.1.4 Exposure Time

Residents are assumed to be at home and inhale vapors and particulates while outdoors for 24 hours per day (or 1,440 minutes per day), which is a conservative (high-end) estimate (EPA 2009a, 2014) for the time spent outdoors at a single residence. The conservatism in this value is evident in that it is assumed that individuals would sleep indoors, which would limit an extreme upper-bound exposure to time 16 hours per day. Further, EPA exposure factors handbook (2011) suggests the average and 90th percentile values for time spent outside at home (doers only) are 2.3 and 5.3 hours, respectively.

Recent studies in children's behavior (Rideout 2010, Juster 2004, and Hofferth 2000) indicate that youth today spend less than 2 hours per day in physical activity, a 30% to 40% decrease from the 1980s to early 2000s, and more than 7.5 hours per day as media time (nearly 300% increase during same time period).

2.1.5 Exposure Frequency and Duration

Residents are assumed to be outside and at home for 350 days per year for 26 years, which are EPA's standard default values for evaluating RME in residential settings. However, the ability of these individuals to contact soil is limited by the unique climate in Michigan and as a result the exposure frequency for incidental soil ingestion and dermal contact is assumed to be 235 days per year. This combination of exposure frequency and exposure duration is expected to be conservative for the amount of time that residents are actually exposed to soil during outdoor activities.

EPA has recommended the use of a high end exposure frequency of 350 days per year (EPA 1991a, 2014). The exposure frequency of 235 days per year was derived assuming that four months of winter would preclude an individual from coming into contact with soil. NOAA (2010) has compiled various climatic data that shows most cities in Michigan have normal mean temperatures less than or equal to freezing for four months of the year (i.e., January, February, March, and December). During these months it is assumed that snow and or ice are covering most of the exposed soil and that residents cover the majority of their exposed skin while outdoors[2]. Rain and other inclement weather factors were not considered because it is assumed that residents may still be outdoors during these events. Allowing for 10 nonwinter vacation and holiday days away from home (standard 14 days of vacation prorated to exclude winter vacation) yields a maximum number of 235 days per year of potential exposure (i.e., 365 - 120 - 10 = 235).

EPA has recommended the use of a high end exposure duration of 26 years (EPA 2014) for residential receptor populations.

2.1.6 Body Weight

Body weights of 15 kg and 80 kg for the child and adult, respectively, are the standard EPA-recommended body weights for assessing exposure to children and adults (EPA 2014) for residential receptors.

On average the body mass of the population in Michigan (Hayes 2013, Suton 2013, Carlson 2012, Drenowatz 2012, Yee 2011) is 7% larger than that of the United States (USDHHS 2012), which could result in a larger (up to 7%) skin surface area as well as body weight.

2.1.7 Averaging Time

The averaging time for evaluating cancer risk is equal to a lifetime of 70 years and the averaging time for evaluating noncancer risk is equal to the exposure duration (EPA 1989, 2014).

Data from EPA (2011) also shows that the typical lifetime has increased to 78 years, which could be incorporated into the averaging time for evaluating cancer risk.

Although it is recognized that the use of the default exposure factors, rather than site-specific factors (e.g., a fraction contacted term <1), results in overestimation of RME risks at many sites, this approach is conservatively used to calculate generic criteria.

2.2 Routine Indoor Individuals

Potential exposure of indoor residents to soil is conservatively evaluated using the standard default exposure factors that EPA (1991a, 2014) recommends for estimating reasonable maximum exposure (RME). According to EPA, the standard default exposure factors are conservative assumptions about the magnitude, frequency, and duration of exposures, which, in combination, are intended to provide estimates of exposures that are higher than actual exposures to a large portion (90% to 99%) of a potentially exposed population.

Certain exposure factors (e.g., exposure frequency) could reasonably be modified on a generic basis to reflect the number of days in a single home for individuals in Michigan. Such a modification could be based on statistics from either Michigan or Federal agencies.

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[2] Exposed areas of soil not covered by snow and/or ice are more likely to freeze and thus become inaccessible when the air temperature is less than 32 F.

2.2.1 Soil Incidental Ingestion Rate

The soil ingestion rates of 200 and 100 mg/day are EPA's standard default values for evaluating RME in residential settings for children (from birth to age 6) and adults (ages 6 years and older), respectively (EPA 1991a). However, more recent publications on incidental soil ingestion rate suggest that high-end incidental soil ingestion rates for children (up to the age of 8 years old) would be no higher than 100 mg/day (Stanek 2012). EPA appears to have not evaluated these data in its most recent recommendations (EPA 2014). Therefore, using an IR of 100 mg/day is a conservative generic rate for children's soil ingestion while they are outdoors and according to the authors (who also authored the papers EPA used as the basis for its 200 mg/day) this is the "most reliable description of soil ingestion to date among children". There were no new data available for adult's soil ingestion, but it would be expected that this rate would be no higher than that for children.

These soil ingestion rates are conservatively assumed to apply to ingestion of soil that is tracked indoors as the source studies do not differentiate between individuals who spend most of their time indoors.

2.2.2 Soil Dermal Contact Rate and Absorption

The dermal contact rate is the product of the exposed skin surface area and the soil-to-skin adherence factor. The exposed skin surface area of 2,690 and 6,032 cm^2/day and soil-to-skin adherence factor of 0.2 and 0.07 mg/cm^2 are the EPA's recommended values for evaluating high-end outdoor contact with soil by children and adults, respectively (EPA 2004b, 2014).EPA recommends an indoor adherence factor of 0.01 mg/cm^2 for children, but suggests a value of 0.07 mg/cm^2 is appropriate for indoor adults (EPA 2004a). Because it is typically believed that children have higher contact rates than adults, the value outdoor value of 0.2 mg/cm^2 is used in this evaluation.

The absorbed dose from dermal contact with soil is estimated by multiplying the dermal contact rate by EPA-recommended absorption factors for absorption from soil (EPA 2004b).

As discussed in Section 2.2.7, the population in Michigan is on average 7% larger than that of the United States, which could result in a larger (up to 7%) skin surface area.

2.2.3 Soil Fraction Contacted

A fraction contacted (FC) term of 0.5 is used to account for the fraction of indoor dust that is outdoor soil. This assumes that the incidental ingestion and dermal contact rates do not change from outdoors to indoors, but that soil tracked into a house accounts for up to half of the indoor dust. Literature sources suggest that an FC of 0.5 to characterize the amount of soil versus dust indoors is conservative (Brattin and Griffin 2011). This use of the FC term serves the same basic purpose as the fraction ingested term the EPA introduced in Section 6.6 of RAGS Part A (EPA 1989).

2.2.4 Groundwater Ingestion Rate

A drinking rate of 2.5 Liters per day is EPA's recommended value for adults (EPA 2014). The drinking water criteria algorithm currently incorporates a relative source contribution of 0.2 to conservatively account for exposures, other than ingestion of groundwater, a receptor may experience. The applicability of the 0.2 relative source contribution is dependent on the drinking water criteria algorithm remaining as is and not accounting for other exposures.

2.2.5 Exposure Time

Residents are assumed to be at home and inhale indoor vapors for 24 hours per day (or 1,440 minutes per day), which is a conservative estimate (EPA 2009a, 2014) for the time spent indoors at a single residence. EPA's exposure factors handbook (2011) suggests the average time spent inside a home (doers only), but not necessarily the same home, is between 16.7 and 20.2 hours, depending on the age group(s) considered.

2.2.6 Exposure Frequency and Duration

Residents are assumed to be at inside the home for 350 days per year for 26 years, which are EPA's standard default values for evaluating RME in residential settings. EPA has recommended the use of a high end exposure frequency of 350 days per year (EPA 1991a, 2014). EPA has recommended the use of a high end exposure duration of 26 years (EPA 2014).

2.2.7 Body Weight

Body weights of 15 kg and 80 kg for the child and adult, respectively, are the standard EPA-recommended body weights for assessing exposure to children and adults (EPA 2014).

On average the body mass of the population in Michigan (Hayes 2013, Suton 2013, Carlson 2012, Drenowatz 2012, Yee 2011) is 7% larger than that of the United States (USDHHS 2012), which could result in a larger (up to 7%) skin surface area as well as body weight.

2.2.8 Averaging Time

The averaging time for evaluating cancer risk is equal to a lifetime of 70 years and the averaging time for evaluating noncancer risk is equal to the exposure duration (EPA 1989, 2014).

Data from EPA (2011) also shows that the typical lifetime has increased to 78 years, which could be incorporated into the averaging time for evaluating cancer risk.

Although it is recognized that the use of the default exposure factors, rather than site-specific factors (e.g., a fraction contacted at a specific location <1), results in overestimation of RME risks at many sites, this approach is conservatively used to calculate generic criteria.

3 Selection of Representative Residential Receptor

As shown in Section 5, the cancer and noncancer intakes for outdoor residents are the same as or slightly higher than those for the indoor resident. Therefore, the exposure scenario and associated exposure factors discussed above for outdoor residents are recommended as an alternative that is a conservative surrogate for all residents.

The intakes for this recommended alternative exposure scenario are similar to or generally less than a factor of two times less conservative than those used by MDEQ in its current Rules (MDEQ 2013).

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5 Table of Alternatives

			Residential			Alt 1 - Outdoor Resident			Alt 1 - Indoor Resident			
			Age 1–6	Age 7–31	Resident	Age 1–6	Age 7–27	Resident	Age 1–6	Age 7–27	Resident	Basis
Soil Ingestion - R299.20												
Ingestion rate	mg-soil/day	**IR**	200	100		100	100		100	100		High
Absorption efficiency - ingestion	unitless	**AE_i**										
Fraction contacted	unitless	**FC**	1.0	1.0		1.00	1.00		0.50	0.50		High
Exposure frequency	days/year	**EF**	350	350		234	234		350	350		High
Exposure duration	years	**ED**	6	24		6	20		6	20		High
Body weight	kg	**BW**	15	70		15	80		15	80		Mid
Averaging time, cancer	days	**AT_c**	25,550	25,550		28,470	28,470		28,470	28,470		--
Averaging time, noncancer	days	**AT_{nc}**	10,950	10,950		9,490	9,490		9,490	9,490		--
Intake, cancer	kg-soil/kg/day		1.10E-06	4.70E-07	**1.57E-06**	3.29E-07	2.05E-07	**5.34E-07**	2.46E-07	1.54E-07	**4.00E-07**	
Intake, noncancer	kg-soil/kg/day		2.56E-06	1.10E-06	**3.65E-06**	9.86E-07	6.16E-07	**1.60E-06**	7.38E-07	4.61E-07	**1.20E-06**	
Soil Dermal Contact - R299.20												
Adherence factor	mg-soil/cm^2	**AD**	0.2	0.07		0.2	0.07		0.2	0.07		Mid
Skin surface area	cm^2/day	**SA**	2,670	5,800		2,690	6,032		2,690	6,032		Mid
Absorption efficiency - dermal	unitless	**AE_d**										
Fraction contacted	unitless	**FC**	1.0	1.0		1.00	1.00		0.50	0.50		High
Exposure frequency	days/year	**EF**	245	245		234	234		350	350		High
Exposure duration	years	**ED**	6	24		6	20		6	20		High
Body weight	kg	**BW**	15	70		15	80		15	80		Mid
Averaging time, cancer	days	**AT_c**	25,550	25,550		28,470	28,470		28,470	28,470		--
Averaging time, noncancer	days	**AT_{nc}**	10,950	10,950		9,490	9,490		9,490	9,490		--
Intake, cancer	kg-soil/kg/day		2.05E-06	1.33E-06	**3.38E-06**	1.77E-06	8.68E-07	**2.64E-06**	1.32E-06	6.49E-07	**1.97E-06**	
Intake, noncancer	kg-soil/kg/day		4.78E-06	3.11E-06	**7.89E-06**	5.31E-06	2.60E-06	**7.91E-06**	3.97E-06	1.95E-06	**5.91E-06**	
Drinking Water Consumption - R299.10												
Drinking rate	L-water/day	**DR**			2			2.5			2.5	High
Exposure frequency	days/year	**EF**			350			350			350	High
Expoure duration	years	**ED**			30			26			26	High
Relative source contribution	unitless	**RSC**			0.2			0.2			0.2	--
Body weight	kg	**BW**			70			80			80	Mid
Averaging time, cancer	days	**AT_c**			25,550			28,470			28,470	--
Averaging time, noncancer	days	**AT_{nc}**			10,950			9,490			9,490	--
Intake, cancer	L-water/kg/day				1.17E-02			9.99E-03			9.99E-03	
Intake, noncancer	L-water/kg/day				1.37E-01			1.50E-01			1.50E-01	

			Residential			Alt 1 - Outdoor Resident			Alt 1 - Indoor Resident			
			Age 1–6	**Age 7–31**	**Resident**	**Age 1–6**	**Age 7–27**	**Resident**	**Age 1–6**	**Age 7–27**	**Resident**	**Basis**
Air Inhalation - R299.14, R299.24, R299.26												
Adjusted inhalation rate		**AIR**			1.0							
Exposure time	hours/day	**ET**						24			24	High
Exposure frequency	days/year	**EF**			350			350			350	High
Exposure duration	years	**ED**			30			26			26	High
Averaging time, cancer	days	**AT_c**			25,550							
Averaging time, noncancer	days	**AT_{nc}**			10,950							
Averaging Time, cancer	hours	**AT_c**						683,280			683,280	--
Averaging time, noncancer	hours	**AT_{nc}**						227,760			227,760	--
EC, cancer	unitless				4.11E-01			3.20E-01			3.20E-01	
EC, noncancer	unitless				9.59E-01			9.59E-01			9.59E-01	

Appendix M

Alternative Part 201 Generic Residential and Nonresidential Exposure Assumptions

Written by:
Christine Flaga, Michigan Department of Environmental Quality
Trish Koman, School of Public Health, University of Michigan
Kory Groetsch, Michigan Department of Community Health

October 3, 2014

This document was written by the authors noted on the cover page and does not represent the opinion of the full Technical Advisory Group No. 2 (TAG). This report was submitted voluntarily specifically to represent an alternative to a similar document written by Francis Ramaciotti, Donal Brady, and Steve Zayko. The information in this appendix was not formally evaluated against the data quality objectives (DQOs) recommended by TAG 2 nor discussed by the full TAG.

Part 201 Generic Cleanup Criteria

The Part 201 generic cleanup criteria are intended to represent most exposure conditions at Michigan Part 201 facilities and protect people, including sensitive individuals, from unacceptable exposure at those facilities. An unacceptable exposure is one that could result in adverse health effects to individuals either now or in the future. Consistent with U.S. EPA risk assessment guidance, the generic criteria attempt to achieve this intent by using a reasonable maximum exposure (RME) scenario. The RME is defined as the highest exposure that is reasonably expected to occur at a site (EPA 1989). EPA guidance (EPA 1992b) recommends that risk assessors approach the estimation of the RME by first identifying the most sensitive exposure parameters i.e., those that have the greatest impact on the risk or cleanup values and have a high degree of variability in the distribution of the parameter values. Maximum or near-maximum values should be used for a few of the sensitive parameters, with central tendency or average values used for all other parameters. The high-end estimates are sometimes based on statistically derived 98th, 95th or 90th percentiles, and in other cases, on best professional judgment. In general, exposure duration, exposure frequency, and contact rates (e.g., ingestion rates and soil adherence factor) are likely to be the most sensitive parameters in an exposure assessment (EPA 1989). Historically, and in line with EPA guidance, the MDEQ has selected mid-range values to represent exposure parameters such as life span, body weight, and skin surface area (MDEQ, 2004). Exposure duration, exposure frequency, soil ingestion rate and soil adherence factors are represented by high end values.

The four main Part 201 human exposure pathways are drinking water, soil direct contact, ambient air (soil volatile and particulate inhalation), and vapor intrusion (soil and groundwater volatilization to indoor air inhalation) (MDEQ, 2004). The current drinking water pathway only addresses the ingestion of contaminated drinking water. Soil direct contact addresses both dermal and ingestion exposure to contaminated soil. The ambient air criteria address volatile and particulate exposures from the soil into the outdoor air and the vapor intrusion criteria address indoor exposures resulting from vapors migrating from the subsurface (soil and groundwater).

Generic Nonresidential Criteria

The 2010 amendments to Part 201 collapsed the industrial and commercial soil direct contact subcategories into one nonresidential category (MDEQ, 2013). The nonresidential soil direct contact criteria are based on the industrial receptor in place prior to the 2010 amendments. This receptor was represented as an outdoor worker. Prior to the 2010 amendments there were two generic commercial subcategories of land uses and receptors different from the residential and industrial land uses (MDEQ, 2005). The first was a commercial subcategory III worker whose outdoor activities were of a low soil intensive nature (e.g., gas stations, auto dealerships, etc.). The commercial subcategory IV worker was a worker who performed high soil intensive activities such as those performed by a grounds keeper. The industrial worker represented the worker with the greatest exposure. The 2010 Part 201 amendments required that the industrial worker represent the nonresidential receptor such that all other nonresidential workers are protected.

The concept of indoor versus outdoor receptors is most relevant for the nonresidential soil direct contact criteria although the pathway addresses direct contact with contaminated soil and the outdoor worker receives the greatest exposure to soil. Since the vapor intrusion pathway is specific to vapors migrating to indoor air, the vapor intrusion criteria are only relevant to indoor receptors. Likewise, the ambient air criteria are relevant only to outdoor receptors. Historically, the drinking water criteria, which only address exposure to contaminated drinking water, apply to all residential and nonresidential receptors and are not related to indoor or outdoor exposures.

EPA Regional Screening Levels (RSLs)

The nonresidential soil contact screening levels presented in the RSL tables are based on a composite worker (U.S. EPA, 2014). The screening level combines soil ingestion, dermal contact, and inhalation of soil volatiles and particulates. The composite worker RSLs for soil ingestion and dermal contact are more conservative than the Part 201 nonresidential criteria since EPA uses an exposure frequency of 250 days per year for both soil ingestion and dermal contact compared to 245 days for ingestion and 160 days for dermal contact under Part 201. Although they are not presented in the RSL tables, EPA provides the ability to calculate outdoor worker, indoor worker, and construction worker screening levels using their on-line calculator.

Recommended Alternative Nonresidential Exposure Assumptions

We recommend that the generic nonresidential receptor for soil direct contact be an outdoor worker using a combination of EPA recommended values and current Part 201 exposure assumptions. Since the current exposure frequency (EF) for dermal and ingestion represents an attempt to represent Michigan weather, we suggest they be maintained until a more thorough evaluation of appropriate Michigan-specific meteorological data can be evaluated and interpreted for dermal and ingestion exposures.

We recommend that the nonresidential receptor for the drinking water pathway is a generic worker with no distinction between outdoor and indoor activities. The updated EPA water ingestion rate for adults is 2.5 liters/day. We recommend half of this value for the nonresidential receptor to represent the less than 24 hour exposure time at work.

The generic nonresidential receptor for the other pathways should be the worker most relevant to the pathway. The soil ambient air pathway addresses exposures to volatiles and particulates from contaminated soil into the outdoor air. The most exposed nonresidential receptor is one working in the outdoor environment. The most exposed nonresidential receptor for the vapor intrusion pathway is one who works indoors. See Table 1 for the alternate generic nonresidential exposure assumptions. They are based on a combination of current Part 201 and EPA recommended exposure values.

Recommended Alternative Residential Exposure Assumptions

At this time, we recommend that the residential receptor be a child plus adult age-adjusted receptor as agreed to unanimously by TAG 2. We recommend a child-only receptor be used to develop criteria for developmental and reproductive toxicants. We further recommend that a child only receptor be considered for future updates to the cleanup criteria as is recommended by EPA and implemented by the other Region V states. See Table 2 for recommended alternate residential generic exposure assumptions.

ISSUES FOR FUTURE CONSIDERATION

The following issues were not discussed in depth during the TAG 2 meetings and should be considered in future updates to the Part 201 Cleanup Criteria:

- Child only residential receptor
- Effects of exposure to multiple contaminants including additivity
- Effects of multiple exposure pathways
- Baseline exposures
- Susceptible populations
- EPA and State benchmarks

TABLE 1. Alternative Values for the Nonresidential Generic Exposure Assumptions and Current Part 201 and EPA Values

Exposure Factors			Part 201 Nonresidential Generic Exposure Assumptions	USEPA RSL or OSWER Directive Nonresidential Exposure Assumptions	Alternative Nonresidential Exposure Assumptions Outdoor worker
Soil Ingestion - R299.20					
Ingestion rate	mg-soil/day	**IR**	100	100	100
Exposure frequency	Days/year	**EF**	245	225	245
Exposure duration	Years	**ED**	21	25	25
Body weight	kg	**BW**	70	80	80
Averaging time, cancer	Days	**AT_c**	25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	9,125	9,125
Soil Dermal Contact - R299.20					
Adherence factor	mg-soil/cm^2	**AD**	0.2	0.12	0.12
Skin surface area	cm^2/day	**SA**	3,300	3,470	3,470
Exposure frequency	Days/year	**EF**	160	250	160
Exposure duration	Years	**ED**	21	25	25
Body weight	kg	**BW**	70	80	80
Averaging time, cancer	Days	**AT_c**	25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	9,125	9,125
Drinking Water Consumption - R299.10					
Drinking rate	L-water/day	**DR**	1	–	1.25
Exposure frequency	Days/year	**EF**	245	–	245
Exposure duration	Years	**ED**	21	–	25
Relative source contribution	Unitless	**RSC**	0.2	–	0.2
Body weight	kg	**BW**	70	–	80
Averaging time, cancer	Days	**AT_c**	25,550	–	25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	–	9,125
Air Inhalation - R299.14, R299.24, R299.26					
Adjusted inhalation rate		**AIR**	2.0	–	1
Exposure time	Hours/day	**ET**	**NA**	8.0	8
Exposure frequency	Days/year	**EF**	245	250	245
Exposure duration	Years	**ED**	21	25	25
Averaging time, cancer	Days	**AT_c**	25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**	7,665	9,125	9,125
Averaging time, cancer	Hours	**AT_c**	–	–	–
Averaging time, noncancer	Hours	**AT_{nc}**	–	–	–

TABLE 2. Alternative Generic Residential Exposure Assumptions and Current Part 201 and EPA Values

			Part 201 (December 2013) Residential Values			**USEPA RSL or OSWER Directive* Values**	**Alternative Set of Exposure Factors / Values for**	
Exposure Factors			**Age 1-6**	**Age 7-30**	**Resident**	**Age 1-6; 7-26**	**an adult**	**a child**
Soil Ingestion - R299.20							**Age 7–26**	**Age 1–6**
Ingestion rate	mg–soil/day	**IR**	200	100		200; 100	100	200
Fraction contacted	Unitless	**FC**	This is not an exposure parameter in current Part 201 criteria calculations.			–		
Exposure frequency	Days/year	**EF**	350	350		350	350	350
Exposure duration	Years	**ED**	6	24		6; 20	20	6
Body weight	kg	**BW**	15	70		15; 80	80	15
Averaging time, cancer	Days	**AT_c**	25,550	25,550		25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**	10,950	10,950		2,190	9,490	9,490
Soil Dermal Contact – R299.20							**Age 7–26**	**Age 1–6**
Adherence factor	mg–soil/cm^2	**AD**	0.2	0.07		0.2	0.07	0.2
Skin surface area	cm^2/day	**SA**	2,670	5,800		2,670	6,032	2,690
Conversion factor	kg/mg	**CF**	1E–06	1E–06		1E–06	1E–06	1E–06
Fraction contacted	Unitless	**FC**	This is not an exposure parameter in current Part 201 criteria calculations.			This is not an OSWER exposure parameter.		
Exposure frequency	Days/year	**EF**	245	245		350	245	245
Exposure duration	Years	**ED**	6	24		6	24	6
Body weight	kg	**BW**	15	70		15; 80	80	15
Averaging time, cancer	Days	**AT_c**	25,550	25,550		25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**	10,950	10,950		2,190	9,490	2,190
Drinking Water Consumption – R299.10							**Age 7–26**	**Age 1–6**
Drinking rate	L–water/day	**DR**			2	0.78	2.5	0.78
Exposure frequency	Days/year	**EF**			350	350	350	350
Exposure duration	Years	**ED**			30	6	26	6
Relative source contribution	Unitless	**RSC**			0.2	–	0.2	0.2
Body weight	kg	**BW**			70	15	80	15
Averaging time, cancer	Days	**AT_c**			25,550	25,550	25,550	25,550
Averaging time, noncancer	Days	**AT_{nc}**			10,950	2,190	9,490	2,190
Air Inhalation – R299.14, R299.24, R299.26							**Not Age Specific**	
Adjusted inhalation rate		**N/A**			1.0	–	N/A	–
Exposure time	Hours/day	**N/A**	This is not an exposure parameter in current Part 201 criteria calculations.			24	N/A	–
Exposure frequency	Days/year	**350**			350	350	350	–
Exposure duration	Years	**26**			30	6	26	–
Averaging time, cancer	Days	**25,550**			25,550	25,550	25,550	–
Averaging time, noncancer	Days	**2,190**			10,950	2,190	9,490	–
Averaging time, cancer	Hours	**AT_c**			–	–	–	–
Averaging time, noncancer	Hours	**AT_{nc}**			–	–	–	–

*The EPA RSLs are based on a child resident. The OSWER Directive provides recommended values for adults and children.

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Appendix C:
TAG 3 Final Report: Updating Part 201 Vapor Intrusion Criteria

Final Report:
Updating Part 201 Vapor Intrusion Criteria

September 10, 2014
(Addendum published November 7, 2014)

Prepared for
The Criteria Stakeholder Advisory Group (CSA)

Submitted by
TAG 3: Vapor Intrusion
Stuart Batterman, University of Michigan School of Public Health
Christina Bush, Michigan Department of Community Health
Jeffrey Crum, Hamp, Mathews & Associates, Inc.
Carrie Geyer, Michigan Department of Environmental Quality
Tom O'Connell, Environmental Resources Management
Steve Song, ENVIRON
Tom Szocinski, AKT Peerless
Matt Williams, Michigan Department of Environmental Quality

In collaboration with
Public Sector Consultants Inc.
Lansing, Michigan
www.pscinc.com

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Glossary

Capillary fringe	Subsurface layer in which groundwater seeps up from a water table by capillary action to fill pores
CHC	Chlorinated hydrocarbons
COC	Contaminants of concern
CSA	Criteria Stakeholder Advisory Group
CSM	Conceptual site model
D	Mean particle diameter
DP	Soil/building differential pressure
ED	Exposure duration
EF	Exposure frequency
ER	Indoor air exchange rate
ET	Exposure time
F_{oc}	Soil organic carbon weight fraction
H_B	Enclosed space height
J&E	Johnson & Ettinger (model)
K_S	Soil-saturated hydraulic conductivity
L_B	Enclosed space floor length
Lcrack	Enclosed space floor thickness
L_F	Distance below grade to bottom of enclosed space floor
L_T	Source/building separation
M	van Genuchten shape parameter
MDEQ	Michigan Department of Environmental Quality
$n^{A \text{ (or V)}}$	Soil total porosity
PHC	Petroleum hydrocarbons
PU	Property use
q^r	Residual soil water content
q_w^A	Soil-water-filled porosity
r_b^A	Soil dry, bulk density (dry weight of the soil)
TAG	Technical Advisory Group
Ts	System temperature (soil and groundwater temperature)
VI	Vapor intrusion
W	Floor/wall seam crack width
W_B	Enclosed space floor width
η	Crack ratio

Introduction

Vapor intrusion is defined as the migration of volatile contaminants from the subsurface into overlying buildings. Volatile contaminants from buried wastes and/or contaminated groundwater or soil can migrate through subsurface soils and into indoor air spaces, posing a risk to people's health.

The Michigan Department of Environmental Quality (MDEQ) officially recognized the vapor intrusion pathway in 1998, and formally promulgated generic criteria for vapor intrusion under Part 201 of Michigan's Natural Resources and Environmental Protection Act in 2002, which "governs the cleanup and redevelopment of contaminated properties in Michigan. Part 201 addresses liabilities associated with owning and operating contaminated properties in Michigan while simultaneously encouraging their redevelopment and reuse" (State Bar of Michigan, 2012).

Groundwater and/or soil concentrations of volatile organic compounds are currently used to determine whether the risk of these contaminants in indoor air is acceptable. An exceedance of the generic criteria in one or more samples at a location is sufficient to require remedial measures under Part 201. In 2010, the Michigan Legislature amended Part 201 to, among other things, require the MDEQ to update the cleanup criteria rules to take into account recent scientific information. As part of a 2014 stakeholder process, a Criteria Stakeholder Advisory Group (CSA) was established to make recommended changes to the Part 201 cleanup criteria. Four separate Technical Advisory Groups (TAGs) were formed to address specific, technical elements of the revised cleanup criteria. TAG 3, Vapor Intrusion, was tasked with evaluating the current criteria and process for evaluating vapor intrusion risks in Michigan under Part 201, and making recommendations regarding potential changes.

The vapor intrusion TAG met four times between July and September to review and discuss the vapor intrusion investigation process under Part 201. As the facilitator of the entire CSA and TAG processes, Public Sector Consultants provided the TAG with a draft white paper on vapor intrusion regulatory issues. The white paper included five questions for the TAG to address in their deliberations:

1. Should Michigan move completely to a tiered, multiple lines of evidence approach similar to that used by other Great Lakes states? If so, how should values be developed and evaluated in each tier and what inputs could be based on Michigan-specific considerations?
2. If Michigan continues to utilize its current generic criteria, what approaches are acceptable for generating vapor intrusion criteria?
3. Should soil gas (the collection of gaseous elements or vapor that occupy that small pore spaces in soil) or soil-contamination levels, or a combination of both, be used in evaluating vapor intrusion risk?
4. Should there be separate values for petroleum hydrocarbons versus chlorinated solvent compounds?
5. What recommendations could be considered for vapor intrusion investigations on undeveloped/vacant properties?

In answer to these questions, the TAG recommends that the vapor intrusion criteria and guidance under Part 201 be revised to use a tiered approach for investigating whether or not there is a complete vapor intrusion pathway and the risk to people.

This tiered approach would allow for a progression of inquiry, site assessment, and decisions in which parties (such as property owners, potential purchasers, financial institutions, or technical consultants for these parties) evaluate whether the subsurface contamination poses an unacceptable exposure and/or health risk for existing or future buildings. The approach is intended to address only those risks associated with the inhalation pathway from subsurface vapors. It is not intended to address risks associated with inhalation of contaminants from indoor or outdoor sources, or risks associated with other exposure pathways, including ingestion and dermal absorption.

Overview of the Recommended Approach for the Vapor Intrusion Investigation Process

The recommended approach developed by TAG 3 for evaluating the vapor intrusion pathway consists of the following elements:

Develop Conceptual Site Model

Develop CSM to describe site history and conditions, identify factors that affect the potential for vapor intrusion

Tiered Analysis of Vapor Intrusion Pathway

Increasing Complexity of Analysis

Tier I Analysis: Initial Screening
Comparison to initial screening levels based on a worst-case scenario. Tier 1 analysis will determine whether any further investigation of the VI pathway is necessary.

Tier 2 Analysis: Incorporation of Geologic-Based Information
Comparison to criteria that identifies a source of vapors by incorporating some site-specific (geologic) information (as opposed to land use or building information). Two options are available for developing and incorporating site and soil information. Tier 2 criteria are used to make a “facility” determination under Part 201.

Tier 3 Analysis: Incorporation of Land Use and Building-Specific Information or Alternate Methods
Comparison to criteria that incorporate land use assumptions (e.g., nonresidential use), specific building parameters (e.g., air exchange rate), as well as more detailed site analysis (e.g., finite contamination source and actual site-specific (geological) information. In addition, a Tier 3 analysis can utilize alternative models/approaches. A Tier 3 analysis determines whether remediation or building/use restrictions are required for closure and/or due care obligations. In cases where an alternate method is used in Tier 3 that only uses site/geologic-specific parameters (that is, it assumes residential use), the Tier 3 analysis may also be used to determine facility status.

Response Actions

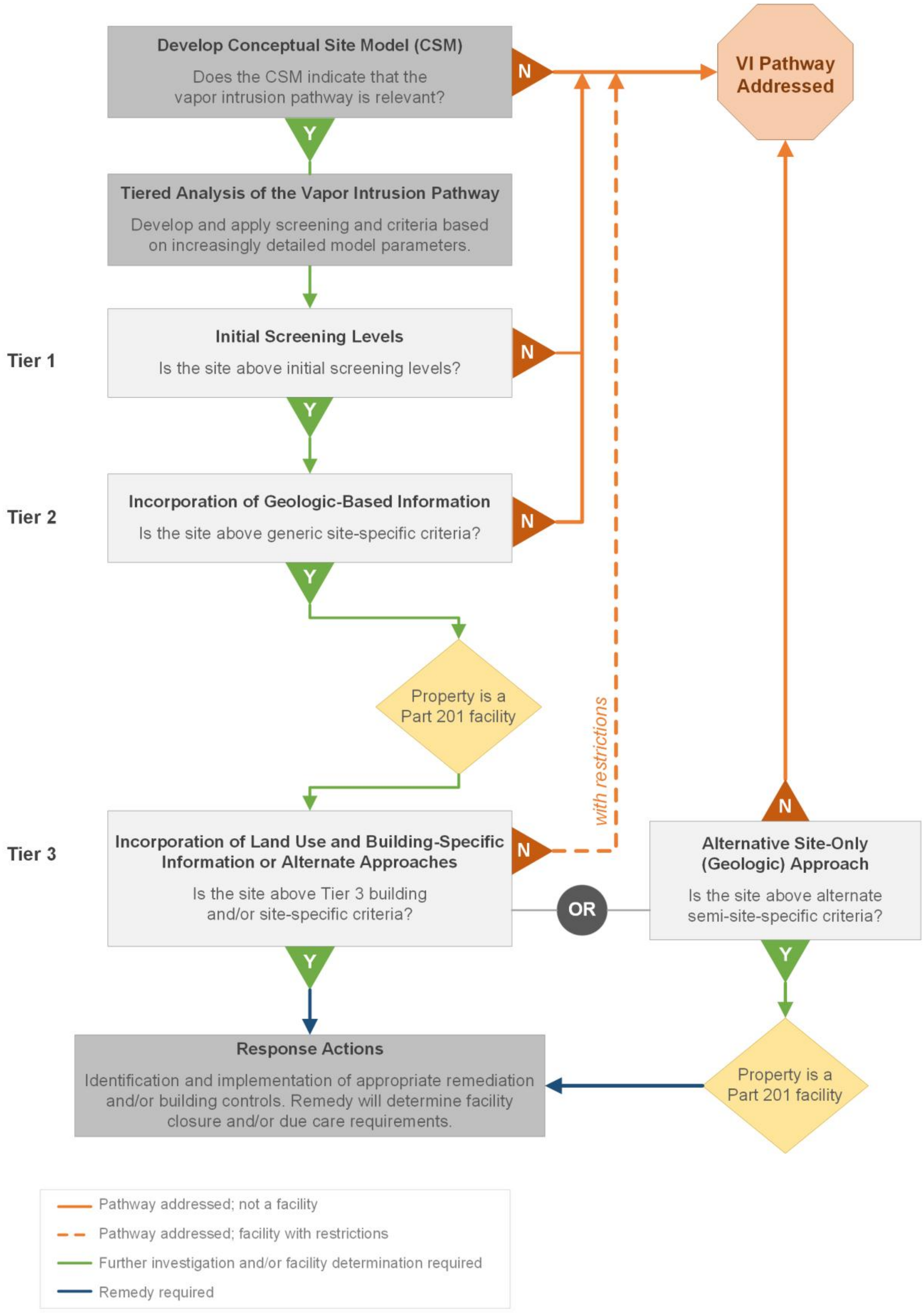
Identification and implementation of appropriate remediation strategies and/or institutional and building controls. The response actions will determine facility closure and/or due care requirements.

Exhibit 1 illustrates the recommended vapor intrusion investigation approach. The process is intended to be a relatively simple, step-by-step approach that uses a modified Johnson & Ettinger (J&E) model to develop generic screening levels and criteria. At each tier, the analysis (and the model) is refined to be more detailed and site-specific. While conceptually the tiered approach is step-by-step or sequential, parties can skip tiers as appropriate to the conditions at a site and/or the circumstances of an investigation. For example, a property owner may skip directly to Tier 3 in order to conduct a more detailed site-specific analysis to evaluate a structure for potential due care obligations. In addition, even though facility status[1] is determined through a Tier 2 analysis, values developed in a Tier 3 alternative approach that require no land use or resource restrictions and allow for unrestricted residential use may be utilized to evaluate whether the site is a facility.

The following sections provide further details on the process and outcomes for each of the different tiers.

1 A "facility" is defined by Michigan's cleanup programs as "any area, place, or property where a hazardous substance in excess of the established state cleanup standard for residential property has been released, deposited, disposed of, or otherwise comes to be located" (MDEQ April, 2013).

EXHIBIT 1. Overview of the Vapor Intrusion Investigation Approach



DEVELOPING A CONCEPTUAL SITE MODEL (CSM)

A critical first step in investigating vapor intrusion (and other) pathways is the development of a CSM. Parties should develop a CSM using appropriate, current standards (such as ASTM E1689 - 95(2014)). The CSM should characterize the site and describe the potential for vapor intrusion risk at the site from sources of pollutants on or near the property.

The CSM is dynamic and will evolve over the course of the investigation as additional information is collected to support more site-specific analyses. For the vapor intrusion assessment, the CSM should:

- Document the historical presence of volatile chemicals at the site
- Identify the type and location of receptors, which includes the identification of current or future structures
- Describe the physical characteristics of the vapor transport media (soil, soil gas, and/or groundwater)
- Use any existing environmental assessments to identify confirmed or suspected sources that may cause a human health risk via the vapor intrusion pathway
- Facilitate the determination of whether immediate action is needed to abate imminent and substantial threats to human health

Based on the CSM, parties should evaluate whether or not there is a potential for a risk from the vapor intrusion pathway. Unless a property owner requests it as part of a response activity plan, a CSM does not need to be submitted to the MDEQ for approval.

If the CSM indicates there is no reasonable potential for risk from the vapor intrusion or the volatilization-to-indoor air pathway, then no further investigation is required; however, if the CSM indicates there is a potential risk, the investigation should proceed to Tier 1—or skip directly to Tiers 2 or 3, or remedy if a party chooses. The CSM assists in developing the sampling plan and the determination of the appropriate media to evaluate. As the process proceeds and the CSM is updated, it should ensure that the data collected are relevant to the analysis and adequate to characterize the nature and extent of the contamination.

TIERED ANALYSIS OF THE VAPOR INTRUSION PATHWAY

Tier 1: Apply Initial Screening Levels

A. Process

Groundwater, soil, and soil gas samples are collected and compared to the initial screening levels (as informed by the CSM). These values are intended to be used for situations where little site detail or information is available. Initial screening levels are intended only to identify the presence of a potentially significant vapor source, not whether there is, or could be, a risk of vapor intrusion.[2] These screening levels are designed to be protective for all vapor intrusion scenarios, except for sites that have crawl spaces or where groundwater is entering (or could potentially enter) into a basement. The latter scenario could result in volatilization from contaminated water that has entered the building, and should be considered a separate pathway. The analysis of this pathway is beyond the scope of this document (see Appendix A for a discussion of remaining, unresolved issues).

[2] These values are not intended to establish facility status, and because facility status is yet not determined, the obligations established under Part 201 and Part 213 are not required at this point.

Groundwater Generic Screening Levels

Screening levels for groundwater were developed based on a residential land use that will have, or currently has, a structure with a basement on it. Though this is conservative for many situations, TAG members deemed it appropriate as a screening level for all sites, and allows application to any type of land use without the need for institutional controls. Later tiers of the vapor intrusion investigation will take into account uses of a property that may or may not involve restrictions. Based on a typical basement construction (two meters below ground), and an anticipated height of the capillary fringe that ranges from 0.2 m to 1 m (depending on soil type); the initial screening level for groundwater assumes a depth to groundwater at the site that is at least three meters (≥ 3 meters). Assuming that depth ensures that intrusion from groundwater into a structure is not reasonably expected to occur.

It is assumed that properties that have a depth to groundwater less than three meters (< 3 meters) have the potential for the direct volatilization of contaminants in water to the indoor air because a basement scenario cannot be precluded without appropriate restrictions. As previously stated, the analysis of this pathway is beyond the scope of this document

The groundwater vapor intrusion screening levels are calculated using a Johnson and Ettinger (J&E) model[3], and the assumptions listed in Exhibit 2. For properties where the contaminants of concern (COCs) include only petroleum hydrocarbons (PHCs) and no chlorinated hydrocarbons (CHCs), regardless of whether it is a release regulated under Part 201 or Part 213, the MDEQ should incorporate the use of a J&E model that accounts for biodegradation of PHCs.

Soil Gas Generic Screening Levels

Soil gas screening levels are based on slab-on-grade construction, which is more conservative than a basement scenario (which uses a larger indoor air mixing height). The soil gas screening levels are calculated using a J&E model and the assumptions listed in Exhibit 3.

Bulk Soil Generic Screening Levels

Similar to other Tier 1 values, soil screening levels are developed under a worst-case scenario where the receptor is assumed to be a resident and the soil type is assumed to be sand. The contaminant mass in this tier is assumed to be infinite (i.e., undefined and potentially covering the entire site) because at this stage in the site analysis, investigators are generally not able to fully define the extent or characterize the contaminant mass. For this combination of assumptions, the calculated soil screening levels may be near or below detection limits. As a consequence, soil data may be more effectively evaluated under Tier 3 analysis where accounting for finite mass may play an important role in characterizing the potential for VI to occur. The bulk soil screening levels are calculated using an infinite source J&E model and the assumptions listed in Exhibit 3 (combined soil/soil gas assumptions).

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[3] In order to assist the regulated community, the MDEQ should provide an online calculator or other method similar to the model available from the USEPA at: www.epa.gov/athens/learn2model/part-two/onsite/JnE_lite.html

EXHIBIT 2. Tier 1 Groundwater Screening Level Assumptions

	Variables		Tier 1: Values and Rationale Model = J&E (assuming no biodegradation)	
Use	PU	Type of property use	Res	Most conservative property use
Building Variables	ED	Exposure duration	TBD	Determined by TAG 2
Building Variables	EF	Exposure frequency	TBD	Determined by TAG 2
Building Variables	ET	Exposure time	TBD	Determined by TAG 2
Building Variables	L_T	Source/building separation	L_{WT} - L_F	The distance between water table and foundation
Building Variables	L_{crack}	Enclosed space floor thickness	10 cm	EPA default
Building Variables	L_F	Distance below grade to bottom of enclosed space floor	200 cm	EPA default for basement construction.
Building Variables	ER	Indoor air exchange rate	.25/hour	Based on EPA's draft vapor intrusion guidance (U.S. EPA 2002)
Building Variables	L_B	Enclosed space floor length	10 m	Based on other state and federal models. Dimensions are consistent with the MDEQ's own original research on buildings in the Midwest. Assumes residential because property use is utilized for facility determinations.
Building Variables	W_B	Enclosed space floor width	10 m	Based on other state and federal models. Dimensions are consistent with the MDEQ's own original research on buildings in the Midwest. Assumes residential because property use is utilized for facility determinations.
Building Variables	H_B	Enclosed space height	3.66 m	Assumes basement construction - most conservative for this environmental medium
Building Variables	W	Floor/wall seam crack width	0.1 cm	EPA default
Building Variables	η	Crack ratio	0.00038	EPA default
Building Variables		Crack soil type	Sand	Assumes same as site soil type
Building Variables		moisture content of crack soil	Sand value above the capillary fringe	Default based on site soil type
Building Variables	f_{oc}	Soil organic carbon weight fraction	N/A	
Building Variables	DP	Soil/building differential pressure	4 Pa	EPA default, varies between 0–20 Pa
Site/Physical Variables	CHC/PHC	Type of COC	Both	Assumes no biodegradation
Site/Physical Variables	L_{WT}	Depth below grade to water table	>3 meters	Assumes no direct contact between groundwater and building. Based on shallow water table in many parts of Michigan, this scenario is premised on depth to groundwater greater than three meters (≥3 meters)
Site/Physical Variables	Ts	System temperature (soil and groundwater temp)	10°C	Average soil temp for Michigan
Site/Physical Variables	r_b^A	Soil dry, bulk density	Sand	Soil properties for sand should come from the 2004 Users Guide for Evaluating Subsurface Vapor Intrusion into Buildings (Table 10) (EQM 2004). Additional choices from Table 10 are available with appropriate site-specific data for grain size analysis to establish soil type.
Site/Physical Variables	$n^{A\ (or\ V)}$	Soil total porosity		
Site/Physical Variables	q_w^A	Soil-water-filled porosity		
Site/Physical Variables	q_r	Residual soil water content		
Site/Physical Variables	M	Van Genuchten shape parameter		
Site/Physical Variables	K_S	Soil-saturated hydraulic conductivity		
Site/Physical Variables	D	Mean particle diameter		

EXHIBIT 3. Tier 1 Soil/Soil Gas Screening Level Assumptions

	Variables		Tier 1: Values and Rationale Model = J&E (assumes no biodegradation)	
Use	PU	Type of property use	Res	Most conservative property use
Building Variables	ED	Exposure Duration	TBD	Determined by TAG 2
	EF	Exposure Frequency	TBD	Determined by TAG 2
	ET	Exposure time	TBD	Determined by TAG 2
	L_T	Source/building separation	1 cm	Minimum distance that the equation needs to operate
	L_{crack}	Enclosed space floor thickness	10 cm	EPA default
	L_F	Distance below grade to bottom of enclosed space floor	200 cm	EPA default for basement construction
	ER	Indoor air exchange rate	.25/hour	Based on EPA's 2002 vapor intrusion guidance (U.S. EPA 2002)
	L_B	Enclosed space floor length	10 m	Based on other state and federal models. Dimensions are consistent with the MDEQ's own original research on buildings in the Midwest. Assumes residential because property use is utilized for facility determinations.
	W_B	Enclosed space floor width	10 m	Based on other state and federal models. Dimensions are consistent with the MDEQ's own original research on buildings in the Midwest. Assumes residential because property use is utilized for facility determinations.
	H_B	Enclosed space height	2.44 m	Assumes mixing into 8' building space (slab on grade). Most conservative for this environmental media
	W	Floor/wall seam crack width	0.1 cm	EPA default
	η	Crack ratio	0.00038	EPA default
		Crack soil type	Sand	Assumes same as site soil type
		moisture content of crack soil	Sand value above the capillary fringe	Default based on site soil type
	f_{oc}	Soil organic carbon weight fraction	0.002	EPA default
	DP	Soil/building differential pressure	4 Pa	EPA default, varies between 0 - 20 Pa
Site/Physical Variables	CHC/PHC	Type of COC	Both	Assumes no biodegradation
	Ts	System temperature (soil and groundwater temp)	10°C	Average soil temp for Michigan
	r_b^A	Soil dry, bulk density	Sand	Soil properties for sand should come from the 2004 Users Guide for Evaluating Subsurface Vapor Intrusion into Buildings (Table 10) (EQM 2004). Additional choices from Table 10 are available with appropriate site-specific data for grain size analysis to establish soil type.
	$n^{A\ (or\ V)}$	Soil total porosity		
	q_w^A	Soil-water-filled porosity		
	q_r	Residual soil water content		
	M	Van Genuchten shape parameter		
	K_S	Soil-saturated hydraulic conductivity		
	D	Mean particle diameter		

B. Possible Outcomes/Decisions from Tier 1

To determine possible outcomes from Tier 1, parties should answer the following question for both residential and nonresidential properties (current or future):

Is the site above Tier 1 screening levels?	**No**	A potentially significant source of vapors is not present, therefore the VI pathway is addressed, and no further investigation or response action required.
	Yes	A potentially significant source of vapors may be present that poses the potential for VI under reasonable worst-case conditions (for example, unrestricted site use). Parties may proceed to Tier 2 analyses, perform Tier 3 analyses, and/or implement a response action (remedy).

Tier 2: Incorporation of Geologic-Based Information

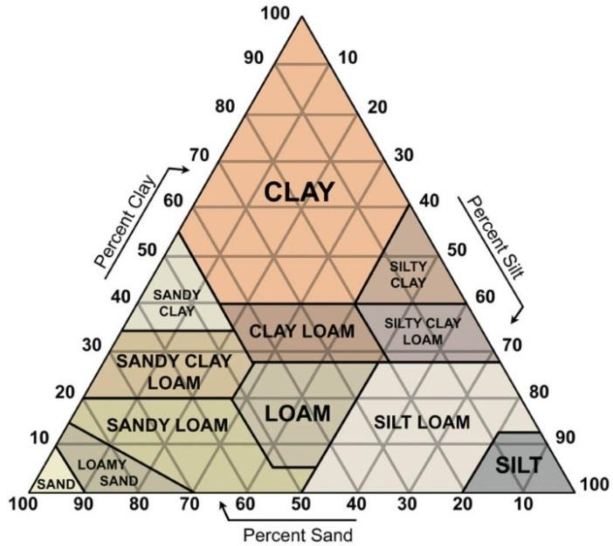
A. Process

In the Tier 2 analysis, the J&E model assumptions and parameters are refined to allow incorporation of information on the site-specific geological and physical site conditions, such as soil type or depth to groundwater. Building parameters cannot be modified in Tier 2 analyses because of the need for site/use restrictions to ensure such assumptions remain valid, which cannot be implemented until the facility status has been determined under this step. As such, Tier 2 criteria are based on residential use of the property.

The approach in Tier 2 allows for two different options for developing and incorporating site-specific information:

- **Option A**: Based on visual field observations, a soil type is selected from one of the following four types: sand, loamy/sand, sandy/loam, and loam. That choice of soil type assigns the associated values of: soil dry, bulk density, total porosity, soil-water-filled porosity, residual soil water content, Van Genuchten shape parameters, soil-saturated hydraulic conductivity, and mean particle diameter from Table 10 of the 2004 Users Guide for Evaluating Subsurface Vapor Intrusion into Buildings (EQM. 2004).
- **Option B:** The soil type is established based on standard soil grain-size analysis (or gradation test) that effectively characterizes the percentage of sand, silt, and clay. From these percentages, the soil type can be assigned through the use of USDA Soil Triangle Chart (see Exhibit 4). Using the soil classification, the associated values are assigned from values established in Table 10 of the User's Guide (EQM 2004).

EXHIBIT 4. USDA Soil Triangle Chart



SOURCE: U.S. Department of Agriculture, Natural Resources Conservation Service.

Exhibits 5 and 6 list the values utilized in calculating the physical/geological site-specific criteria for groundwater and soil/soil gas. The exhibits identify parameters that can be modified, highlighted in bold.

As with Tier 1 screening levels, Tier 2 criteria for groundwater are only applicable to sites with a depth to groundwater of three meters or more (≥ 3 meters) because any shallower depth is assumed to have existing or potential groundwater intrusion into the basement of the structure (groundwater intrusion pathway). For sites with depth to groundwater less than three meters (< 3 meters), facility status will be determined by evaluating all other relevant exposure pathways, potentially including both vapor intrusion and groundwater intrusion pathways.[4]

[4] See Appendix A: Recommended Additional Work to Address Remaining Issues for further discussion on how to address groundwater criteria for properties with depth to groundwater less than three meters (< 3 meters).

EXHIBIT 5. Tier 2 Groundwater Site-Specific (Geological) Assumptions

	Variables		Tier 2 Values and Rationale Models = 1) J&E for PHC, 2) J&E for CHC	
Use	PU	Type of property use	Res	Most conservative property use
Building Variables	ED	Exposure duration	TBD	Determined by TAG 2
	EF	Exposure frequency	TBD	Determined by TAG 2
	ET	Exposure time	TBD	Determined by TAG 2
	L_T	Source/building separation	L_{WT} - L_F	Carried forward from Tier 1
	L_{crack}	Enclosed space floor thickness	10 cm	Carried forward from Tier 1
	L_F	Distance below grade to bottom of enclosed space floor	200 cm	Carried forward from Tier 1
	ER	Indoor air exchange rate	.25/hour	Carried forward from Tier 1
	L_B	Enclosed space floor length	10 m	Carried forward from Tier 1
	W_B	Enclosed space floor width	10 m	Carried forward from Tier 1
	H_B	Enclosed space height	3.66 m	Carried forward from Tier 1
	W	Floor/wall seam crack width	0.1 cm	Carried forward from Tier 1
	η	Crack ratio	0.00038	Carried forward from Tier 1
		Crack soil type	Same as site soil type	Assumes same as site soil type selected below
		moisture content of crack soil	Sand value above the capillary fringe	Crack soil generally has lower moisture content than native soils at the site (designed for drainage), so value is based on more conservative soil choice (sand)
	f_{oc}	Soil organic carbon weight fraction	0.002	Carried forward from Tier 1
	DP	Soil/building differential pressure	4 Pa	Carried forward from Tier 1
Site/Physical Variables	CHC/PHC	Type of COC	**CHC or PHC**	May apply biodegradation model (to be developed) if PHCs are the contaminant of concern
	L_{WT}	Depth below grade to water table	**Default, actual or estimate**	Value may be replaced by actual site data, default to three meters or more (≥3 meters), or use estimated depth
	Ts	System temperature (soil and groundwater temp)	**Actual or average**	Value may be replaced by actual site data or default to soil and/or groundwater temperature estimate based on identified Michigan county-specific input values (drop-down menu by county)
	r_b^A	Soil dry, bulk density	**Sand, loamy/sand, sandy/loam, loam; OR alternate**	**Option A:** Based on visible field observations, a soil type is selected from one of four basic categories that include: sand, loamy/sand, sandy/loam, loam. **Option B:** Soil type is established based on soil sieve analysis (or gradation test) that effectively identifies the percentage of sand, silt, and clay. Soil properties for selected Option A or B soil choice should come from Table 10, Users Guide for Evaluating Subsurface Vapor Intrusion into Buildings (EQM 2004)
	$n^{A\ (or\ V)}$	Soil total porosity		
	q_w^A	Soil-water-filled porosity		
	q_r	Residual soil water content		
	M	Van Genuchten shape parameter		
	K_S	Soil-saturated hydraulic conductivity		
	D	Mean particle diameter		

EXHIBIT 6. Tier 2 Soil Gas/Soil Site-Specific (Geological) Assumptions

	Variables		Tier 2 Values and Rationale Models = 1) J&E for PHC, 2) J&E for CHC	
Use	PU	Type of property use	Res	Most conservative property use
Building Variables	ED	Exposure Duration	TBD	Determined by TAG 2
	EF	Exposure Frequency	TBD	Determined by TAG 2
	ET	Exposure time	TBD	Determined by TAG 2
	L_T	Source/building separation	1 cm	Carried forward from Tier 1
	L_{crack}	Enclosed space floor thickness	10 cm	Carried forward from Tier 1
	L_F	Distance below grade to bottom of enclosed space floor	200 cm	Carried forward from Tier 1
	ER	Indoor air exchange rate	.25/hour	Carried forward from Tier 1
	L_B	Enclosed space floor length	10 m	Carried forward from Tier 1
	W_B	Enclosed space floor width	10 m	Carried forward from Tier 1
	H_B	Enclosed space height	2.44 m	Carried forward from Tier 1
	W	Floor/wall seam crack width	0.1 cm	Carried forward from Tier 1
	η	Crack ratio	0.00038	Carried forward from Tier 1
		Crack soil type	Same as site soil type	Assumes same as site soil type selected below
		moisture content of crack soil	Sand value above the capillary fringe	Crack soil generally has lower moisture content than native soils at the site (designed for drainage), so value is based on more conservative soil choice (sand)
	f_{oc}	Soil organic carbon weight fraction	0.002	Carried forward from Tier 1
	DP	Soil/building differential pressure	4 Pa	Carried forward from Tier 1
Site/Physical Variables	CHC/PHC	Type of COC	**CHC or PHC**	May apply biodegradation model (to be developed) if PHCs are the contaminants of concern
	Ts	System temperature (soil and groundwater temp)	**Actual or average**	Value may be replaced by actual site data, default to ≥3 meters or use estimated depth
	r_b^A	Soil dry, bulk density	**Sand, loamy/sand, sandy/loam, loam; OR alternate**	**Option A:** Based on visible field observations, a soil type is selected from one of four basic categories that include: sand, loamy/sand, sandy/loam, loam. **Option B:** soil type is established based on soil sieve analysis (or gradation test) that effectively identifies the percentage of sand, silt, and clay. Soil properties for selected Option A or B soil choice should come from Table 10 of the User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings (EQM 2004).
	$n^{A\ (or\ v)}$	Soil total porosity		
	q_w^A	Soil-water-filled porosity		
	q_r	Residual soil water content		
	M	Van Genuchten shape parameter		
	K_S	Soil-saturated hydraulic conductivity		
	D	Mean particle diameter		

B. Possible Outcomes/Decisions from Tier 2

Properties containing volatile contaminant concentrations exceeding Tier 2 criteria are determined to be a facility under Part 201, unless values developed through a Tier 3 analysis results in no use or resource use restrictions (e.g., unrestricted residential). To determine possible outcomes from Tier 2, parties should answer the following question:

Is the site above Tier 2 criteria for residential use?	**No**	No further investigation is required and the property is not a facility under Part 201. There are no restrictions on the property.
	Yes	Property is considered a facility under Parts 201 and 213. Parties should proceed to Tier 3 to further evaluate vapor intrusion risks or skip directly to response actions.

Tier 3: Incorporation of Land Use and/or Building-Specific Information or Alternative Methods

A. Process

Tier 3 analyzes the risk of vapor intrusion by incorporating information on land use, the building, and/or other site conditions into the modeled criteria. Tier 3 analyses may also use alternative methods to evaluate the vapor intrusion risk. These two options for evaluating vapor intrusion risk are:

- **Option A:** The Tier 2 J&E model can be refined to develop site-specific criteria that account for actual or planned land use (nonresidential vs. residential), building-related variables (e.g., basement versus slab-on-grade), actual geological conditions (e.g., stratigraphy), and/or any additional variables that may be relevant to the investigation. This option still allows parties to use the (MDEQ-modified) online J&E calculator for developing site-specific criteria, but also includes a potential vapor risk evaluation for current or future buildings that incorporates the building's location within the contaminated site, the type of construction, and other site-specific variables. This option also allows for modifications of depth to groundwater less than three meters (< 3 meters) where groundwater may be shallow and structure may be planned or present. Because Option A analyses incorporate building-specific variable, land use restrictions will be required to ensure that the vapor intrusion risk is acceptable.
- **Option B:** This options allows for use of an alternative method or model for assessing vapor intrusion risk that utilizes only site-specific (geologic) variables or a combination of site- and building-specific variables. The approach must be scientifically sound and supported by adequate site information. Option B also allows the use of different models and evaluation techniques, as well as calculations that account for the mass of contaminants located on a property. Though there are many suboptions under Option B, it is recommended that the MDEQ develop a calculator that provides soil criteria based on finite mass for use when the extent of contamination can be defined. Appendix A provides some initial thoughts on calculating finite mass balance. If Option B values are developed using only site-specific (geologic) variables and assume unrestricted residential use, the analysis can be used to make a determination about whether the site is considered a facility under Part 201.

Exhibits 7 and 8 list the applicable Option A (J&E model) variables for groundwater and soil/soil gas. The building-specific values that can be modified, as well as the site-specific variables from Tier 2, are highlighted in bold. Option B may use values different from those in Exhibits 7 and 8, and may include additional variables and associated values based on the alternative approach selected by property owners or other related parties.

Again, for properties where contaminants consist of only PHCs and no chlorinated contaminants, regardless of whether it is a release regulated under Part 201 or Part 213, a J&E model that includes an attenuation factor that accounts for biodegradation may be utilized, as long as there is a separation between the structure and the source of the contamination.

EXHIBIT 7. Tier 3 Groundwater Assumptions for Option A

	Variables		Tier 3 Values and Rationale Models = 1) J&E for PHC, 2) J&E for CHC or 3) Alternative	
Use	PU	Type of property use	**Res or nonres**	Actual property use
Building Variables	ED	Exposure duration	TBD	Determined by TAG 2
	EF	Exposure frequency	TBD	Determined by TAG 2
	ET	Exposure time	TBD	Determined by TAG 2
	L_T	Source/building separation	**Actual or default**	Value may be replaced by actual site data or default to slab on grade (10 cm) and basement (200 cm) values for a current, planned or proposed structure
	L_{crack}	Enclosed space floor thickness	**Res or nonres default**	Default = 10 cm for residential, 15 cm for nonresidential use based on EPA standards
	L_F	Distance below grade to bottom of enclosed space floor	**Res or nonres default**	Default values for slab on grade (10 cm) and basement (200 cm)
	ER	Indoor air exchange rate	**.25/hour or select from table of values for nonres**	Based on EPA's vapor intrusion guidance (U.S. EPA 2002) or table of values for nonresidential use which are based on ASHRAE Standard 62.1
	L_B	Enclosed space floor length	**Res or nonres default**	Default = 10 m for residential, 20 m for nonresidential
	W_B	Enclosed space floor width	**Res or nonres default**	Default = 10 m for residential, 20 m for nonresidential
	H_B	Enclosed space height	**Res or nonres default**	Based on research showing average residential height = 2.66 meters, average commercial height = 3.33 meters
	W	Floor/wall seam crack width	0.1 cm	Carried forward from Tiers 1 and 2
	η	Crack ratio	0.00038	Carried forward from Tiers 1 and 2
		Crack soil type	**Actual or site soil type**	Value may be replaced by actual site data or default to site soil type selected
		moisture content of crack soil	**Actual or selected soil type value above the capillary fringe**	Value may be replaced by actual site data or default to moisture content based on site soil type selected
	f_{oc}	Soil organic carbon weight fraction	**.002 or actual**	Value may be replace by actual site data or default to the values established in Tier 2 (.002)
	DP	Soil/building differential pressure	4 Pa	Carried forward from Tiers 1 and 2
Site/Physical Variables	CHC/PHC	Type of COC	**CHC/PHC**	Carried forward from Tier 2
	L_{WT}	Depth below grade to water table	**Default, actual or estimate**	Carried forward from Tier 2
	Ts	System temperature (soil and groundwater temp)	**Actual or average**	Carried forward from Tier 2
	r_b^A	Soil dry, bulk density	**Sand, loamy/sand, sandy/loam, loam; OR alternate**	Carried forward from Tier 2
	$n^{A\ (or\ V)}$	Soil total porosity		
	q_w^A	Soil-water-filled porosity		
	q_r	Residual soil water content		
	M	Van Genuchten shape parameter		
	K_S	Soil-saturated hydraulic conductivity		
	D	Mean particle diameter		

EXHIBIT 8. Tier 3 Soil/Soil Gas Variable Assumptions for Option A

	Variables		Tier 3 Values and Rationale Models = 1) J&E for PHC, 2) J&E for CHC	
Use	PU	Type of property use	**Res or nonres**	Actual property use
Building Variables	ED	Exposure Duration	TBD	Determined by TAG 2
	EF	Exposure Frequency	TBD	Determined by TAG 2
	ET	Exposure time	TBD	Determined by TAG 2
	L_T	Source/building separation	**Actual or default**	Value may be replaced by actual site data or default to slab on grade (10 cm) and basement (200 cm) values for a current, planned, or proposed structure
	L_{crack}	Enclosed space floor thickness	**Res or nonres default**	Default = 10 cm for residential, 15 cm for nonresidential use based on EPA standards
	L_F	Distance below grade to bottom of enclosed space floor	**Res or nonres default**	Default values for slab on grade (10 cm) and basement (200 cm)
	ER	Indoor air exchange rate	**.25/hour or select from table of values for nonres**	Based on EPA's vapor intrusion guidance (U.S. EPA 2002) or table of values for nonresidential use which are based on ASHRAE Standard 62.1
	L_B	Enclosed space floor length	**Res or nonres default**	Default = 10 m for residential, 20 m for nonresidential
	W_B	Enclosed space floor width	**Res or nonres default**	Default = 10 m for residential, 20 m for nonresidential
	H_B	Enclosed space height	**Res or nonres default**	Based on research showing average residential height = 2.66 meters, average commercial height = 3.33 meters
	W	Floor/wall seam crack width	0.1 cm	Carried forward from Tiers 1 and 2
	η	Crack ratio	0.00038	Carried forward from Tiers 1 and 2
		Crack soil type	**Actual or site soil type**	Value may be replaced by actual site data or default to site soil type selected
		moisture content of crack soil	**Actual or selected soil type value above the capillary fringe**	Value may be replaced by actual site data or default to moisture content based on site soil type selected
	f_{oc}	Soil organic carbon weight fraction	**.002 or actual**	Value may be replace by actual site data or default to the values established in Tier 2 (.002)
	DP	Soil/building differential pressure	4 Pa	Carried forward from Tiers 1 and 2
Site/Physical Variables	CHC/PHC	Type of COC	**CHC/PHC**	Carried forward from Tier 2
	Ts	System temperature (soil and groundwater temp)	**Actual or average**	Carried forward from Tier 2
	r_b^A	Soil dry, bulk density	**Sand, loamy/sand, sandy/loam, loam; OR alternate**	Carried forward from Tier 2
	$n^{A\ (or\ V)}$	Soil total porosity		
	q_w^A	Soil-water-filled porosity		
	q_r	Residual soil water content		
	M	Van Genuchten shape parameter		
	K_S	Soil-saturated hydraulic conductivity		
	D	Mean particle diameter		

B. Possible Outcomes/Decisions from Tier 3

To determine possible outcomes from Tier 3, parties should answer the following questions for:

Option A: J&E-developed criteria based on site (geological), land use, and building variable modifications

Is the site above Tier 3, Option A criteria?	**No**	The vapor intrusion pathway is addressed. However, the property may require a deed restriction to limit the building type or location, as well as the property use assumptions utilized in Tier 3. The facility can be considered for closure under Parts 201 and 213 without any type of mitigation being implemented.
	Yes	The property is still considered a facility under Parts 201 and 213, and parties must proceed to remedy.

Option B: Alternate site- (geological) and/or building-specific criteria

a) Is the site above Tier 3, Option B criteria that assumes unrestricted residential land use?	**No**	No further investigation is required and the property is not considered a facility under Part 201 if the values developed result in no land use or resource use restrictions (e.g., unrestricted residential)
	Yes	The property is still considered a facility under Parts 201 and 213, and parties must proceed to remedy.
b) Is the site above Tier 3, Option B criteria that modifies geological, land use and/or building variables?	**No**	The vapor intrusion pathway is addressed. However, the property may require a deed restriction to limit the building type or location, as well as the property use assumptions utilized in Tier 3. The facility can be considered for closure under Parts 201 and 213 without implementing any type of mitigation.
	Yes	The property is still considered a facility under Parts 201 and 213, and parties must proceed to remedy.

RESPONSE ACTIONS

A. Process

If the analysis using Tiers 1, 2, or 3 has determined that the vapor intrusion pathway poses a risk, property owners must remediate the site and/or implement building controls that limit exposure to identified COCs.

The analysis completed in Tier 3 and the updated CSM will inform the selection of the remediation strategy or building control approach. Remediation could include removing contaminant sources and/or preventing vapors from migrating into an occupied structure. Building controls could include restricting property use and/or implementing mitigation options similar to those presented by the Interstate Technology and Regulatory Council (ITRC 2007).

Parties should propose a remedy that is appropriate for the vapor intrusion risk and site-specific conditions, and should work with the MDEQ as necessary.

B. Possible Outcomes/Decisions from Step 5

Once remedies have been implemented, there are several possible outcomes, depending on the nature of the site and whether it was determined to be a facility. Potential outcomes include:

Closure of the facility	Depending on the remedial objectives and measures taken, and the resulting monitoring values, the property should be considered for closure. Remedial measures and subsequent monitoring will determine whether any property/deed restrictions will be necessary.
Due care obligations met	If the implemented remedy actions prevent migration of vapors into a structure, properties are considered to be meeting due care obligations.

Endnotes

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Appendix A:

Recommended Additional Work to Address Remaining Issues

In its discussions regarding updating the criteria for vapor intrusion under Part 201, TAG #3 identified three issues which require additional research, discussion, and decision by MDEQ regarding updates to the Part 201 rules:

- Developing groundwater criteria for sites where there may be intrusion of groundwater itself into the (existing or future) structure through direct contact with the structure, periodic flooding, or consistent presence in basement sumps
- Streamlining the process for reviewing and approving facility closures based on detailed building/site or alternate approach criteria (Tier 3)
- Implementing the methodology for calculating finite mass soil criteria

The TAG had significant discussions regarding the above topics, but did not have enough time within the current CSA process to sufficiently evaluate and make recommendations regarding the approach for addressing these topics. Below is a summary of the TAG's discussion on these topics.

Development of Groundwater Criteria to Shallow Sites

The TAG discussed at length and agreed that generic screening levels and site-specific (geologic) criteria must be based on worst-case scenarios for building construction. Tier 1 and Tier 2 values are based on unrestricted residential use, and for the purposes of developing groundwater values, assume that the structure includes basement construction. As such, groundwater less than three meters (< 3 meters) is assumed to potentially be directly in contact with a building and could periodically or persistently intrude into the basement space.

To address this, the TAG has recommended that Tier 1 and Tier 2 screening levels and criteria be based on depth to groundwater of three meters or more (≥ 3 meters). In the time available for the vapor intrusion TAG deliberations, the TAG could not resolve how to address potential volatilization of COCs from groundwater that intrudes into basement construction. The group agreed that it is essentially a separate pathway, and that MDEQ may need to have another advisory group evaluate this pathway and recommend an approach for evaluating the potential risks from volatilization from the water to the indoor air.

Streamlining the Process for Reviewing and Approving Facility Closures Based on Detailed Building/Site or Alternate Method Criteria (Tier 3)

In the TAG's discussions, it became clear that some parties may want to use a detailed and/or alternative method for developing and applying site- (geological) specific criteria when that data is available in order to determine facility status. The recommended approach in the main body of this document reflects this. However, in its discussions, the TAG recognized that Tier 3, especially Option B, may not be effective if MDEQ cannot provide a streamlined, clearly articulated process for reviewing and approving facility closures with restrictions or without (if the alternative method is based on unrestricted residential use).

The vapor intrusion TAG simply did not have time to resolve and make recommendations about that approach, but believes that if this or another group was tasked with this effort, recommendations could be developed within a modest amount of time.

Implementing the Methodology for Calculating Finite Mass Soil Criteria

The TAG also spent considerable time discussing options for incorporating finite mass calculations into the vapor intrusion investigation process. The group agreed that utilizing finite mass is best done in Tier 3 as part of a more detailed site-specific or alternative method approach. The TAG did not have enough time to fully evaluate and make recommendations on an appropriate finite mass calculation, but there was initial agreement in principle that one of the ways that finite mass criteria could be calculated is to use the following equation:

Soil concentration = $(ASL*ER*H_b*ED)/(\rho_b*d_s)$

Where:

ASL = Indoor air screening levels ($\mu g/m^3$) as provided by other TAGs

ER = Air exchange rate (per hr) is .25 residential in Tier 2; additional modification possible in Tier 3 for nonresidential scenarios

H_b = Mixing Height (m) of 2.44 based on slab-on-grade construction in Tier 2. The slab-on-grade scenario will be the most conservative because the mixing height is the lowest. Other values may be used in Tier 3.

ED = Exposure Durations (in hours) as provided by other TAGs

ρ_b = Soil dry bulk density (kg/m^3), based initially on sand, but can be modified similarly to groundwater [e.g., Option A - visually (4 types); Option B - sieve analysis (12 types)

d_s = Thickness of source (m) = **[A more logical default (in the absence of sufficient site characterization data) is to base this on the depth to groundwater,.]**2.44 m as a generic value for unrestricted residential use or based on depth to groundwater **(**which would give the maximum possible contaminated soil thickness between the foundation and the water table). Further characterization could be done to reduce it in a Tier 3 evaluation or possibly even increase it.[5]

The TAG recommends that the MDEQ (with input from the TAG, CSA, or other experts) review, modify, and approve a standard methodology (based on the calculation above) for determining finite mass.

[5] For source thickness, the "thinner" or "smaller" the mass is, the higher the allowable concentrations are. Conversely, the "thicker" or "larger" the source is, the lower the allowable concentration. In essence, a 50 percent decrease in the thickness of the mass results in a 100 percent increase in the concentration.

Addendum to the Technical Advisory Group 3 Final Report*: Updating Part 201 Vapor Intrusion Criteria*

Addendum Dated: November 7, 2014

After the issuance of TAG 3's final report (vapor intrusion), there was discussion among the Criteria Stakeholder Advisory Group regarding whether indoor air sampling for the evaluation of vapor intrusion risk would be allowed under revised Part 201 rules. The final report recommends that in Tier 3, parties be allowed to use "an alternative method or model for assessing vapor intrusion risk that utilizes only site-specific (geologic) variables or a combination of site- and building-specific variables. The approach must be scientifically sound and supported by adequate site information."

It is the opinion of TAG 3 that indoor air sampling data could be considered as part of an alternative method (as identified in the September 10, 2014, final report) and a line of evidence to determine whether the vapor intrusion pathway is relevant and is posing risks to human health. When indoor air sampling is used as part of the vapor intrusion investigation, the sampling strategy must be scientifically sound and account for actual site conditions, including background sources of contaminants and any potential spatial or seasonal variability.

Appendix D:

TAG 4 Final Report: Key Legal Issues for Updating Michigan's Generic Cleanup Criteria

Final Report:

Part 201:Key Legal Issues for Updating Michigan's Generic Cleanup Criteria

October 2014

Prepared for
The Criteria Stakeholder Advisory Group (CSA)

Submitted by
TAG 4: Legal

In collaboration with
Public Sector Consultants
Lansing, Michigan
www.pscinc.com

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TECHNICAL ADVISORY GROUP MEMBERS

Exhibit 1 details the TAG membership:

EXHIBIT 1. TAG Members

James Clift	Michigan Environmental Council
Troy Cumings	Warner, Norcross & Judd LLP
Anna Maiuri	Dickinson Wright PLLC
Polly Synk	Attorney General's Office for MDEQ

KEY LEGAL QUESTIONS

The TAG was asked to review and address the following questions and issues from the CSA:

1. The Administrative Procedures Act (APA) requires any agency regulation, statement, standard, or policy to follow the rule-promulgation process if they have the force and effect of law and bind persons other than the agency. Part 201 authorizes the MDEQ to establish cleanup criteria and require a person to take certain actions if the concentration of a hazardous substance on that person's property exceeds a cleanup criterion established by the MDEQ. When establishing new and updated criteria, is the inclusion of an algorithm in the rule sufficient or do the results of the algorithm need to be included in the rule (for example, Toxicological and Chemical-Physical Data [Table 4])? Is the process utilized by the MDEQ since 2002 to select chemical-specific values, including toxicity values and physical chemistry parameters, appropriate? If not, what should be changed?

The TAG shortened Question 1 as follows:

> "The Administrative Procedures Act requires any agency regulation, statement, standard, or policy to follow the rule-promulgation process if they have the force and effect of law and bind persons other than the agency. Part 201 authorizes the MDEQ to establish cleanup criteria and requires a person to take certain actions if the concentration of a hazardous substance on that person's property exceeds a cleanup criterion established by the MDEQ. When establishing new and updated criteria is the inclusion of an algorithm in the rule sufficient or do the results of the algorithm need to be included in the rule (such as in Table 4)?"

2. The APA authorizes an agency to incorporate, by reference in a rule, any part of a code, standard, or regulation that has been adopted by a U.S. agency or a nationally recognized organization or association. The reference must fully identify the adopted matter, including the date, and cannot cover any later amendments or editions of the adopted matter. Rather, the agency must amend the rule or promulgate a new rule to incorporate the adopted matter. May a rule establishing cleanup criteria incorporate changes to referenced codes standards, or regulations automatically without following the process to promulgate a revised rule?

3. What legal options are available to create a process whereby stakeholders may oversee the MDEQ's process to establish new or revised cleanup criteria?

Executive Summary

The Technical Advisory Group 4 (TAG) met three times in September and October 2014 to review, discuss, and develop responses to three questions that were outlined by the Criteria Stakeholder Advisory Group (CSA) addressing key legal questions related to updating Michigan's Part 201 generic criteria. This final report to the CSA presents the TAG's findings, analysis, and discussion.

TAG members drew a distinction between questions of a legal and policy nature and decided that they could provide an opinion(s) regarding legal matters and help evaluate policy alternatives for consideration by the CSA. Essentially, TAG 4 focused on how the Administrative Procedures Act (APA) must be followed for updating Michigan's generic criteria, considering the following questions:

1. Is the inclusion of an algorithm and a process for updating inputs promulgated in rule sufficient?
2. Do the inputs to the algorithm and the results (i.e., Table 4) also need to be established through rule promulgation, including future changes to inputs?

Generally, the TAG agreed that the APA would likely need to be followed, but to what degree was debated. Two views emerged within the TAG, with some members suggesting that TAG 1's recommended approach of promulgating only the algorithms in rule would meet the requirements. Others suggested that it may not. TAG members reviewed the APA definition of a rule and discussed whether promulgation of some parts of the criteria development process, but not all, would meet the APA requirements. It was suggested that if the algorithm and an update process was clear, transparent, and open to public review and comment, that individual inputs and future changes to the inputs would not need to go through the rulemaking process to result in enforceable and reliable criteria able to withstand legal challenge. An alternative, given the varying professional opinions associated with the determination of, or changes to, the inputs to the criteria development process, such as toxicity data, would necessitate review through the rulemaking process pursuant to Part 201 and the APA.

It was also noted that other divisions (e.g., Air Quality Division) within the MDEQ do not go through the APA rulemaking process when making updates to various criteria, which establishes a precedent that updates to the criteria do not need to be promulgated through the APA rulemaking process. To date, no challenges have emerged. However, a preliminary review of Part 31 (air) and Part 55 (water) was conducted by a TAG member that draws a distinction between Part 201, Part 31 and Part 55 (See Appendix C).

Another member indicated that regardless of what process is used to determine the inputs, the MDEQ has the decision-making authority on the matter, which may include varying professional opinions, and that the use of the APA rulemaking process would be equally acceptable as an approach outside of the APA.

TAG members discussed underlying reasons why the APA rulemaking or an alternative process may or may not be desirable. All TAG members agreed that the process to update criteria needs to include opportunities for meaningful stakeholder input. TAG members also agreed that some current APA requirements such as the cost-benefit analysis may not add value to the rulemaking process, nor is the MDEQ best positioned to prepare such studies. It was noted that the economic impact of a proposed rule would arise during the stakeholder engagement or public comment period, sufficient for it not to be required within the APA. Another member suggested that the alternative approach would include more opportunities for public comment than the APA rulemaking process and that, while carried out independently of the APA, could meet its requirements. The TAG discussed a potential policy recommendation to revise the APA statute to allow for the criteria to be updated through an alternative means to the APA rulemaking process, though consensus was not achieved.

TAG members did reach consensus that a rule establishing cleanup criteria may not incorporate changes to referenced codes, standards, or regulations automatically without following the process to promulgate a revised rule. TAG members noted that the incorporation by reference of a standard results in that standard being "frozen in time" at the time of the rule publication.

The TAG did reach consensus that a four-year update process proposed by TAG 1 was too long, suggesting that a one to two year process would be feasible, but concluded that required time frames or schedules for promulgation are not legally required and may not serve a beneficial purpose. TAG members suggested that it may be more appropriate to reevaluate the criteria as new science emerges rather than on a periodic basis (e.g. every four years).

Questions, Answers, and Discussion

The following section presents each question, a summary of the TAG's answer and discussion, and analysis.

Question 1 (shortened)

The Administrative Procedures Act requires any agency regulation, statement, standard, or policy to follow the rule-promulgation process if they have the force and effect of law and bind persons other than the agency. Part 201 authorizes the MDEQ to establish cleanup criteria and requires a person to take certain actions if the concentration of a hazardous substance on that person's property exceeds a cleanup criterion established by the MDEQ. When establishing new and updated criteria is the inclusion of an algorithm in the rule sufficient or do the results of the algorithm need to be included in the rule (i.e., "Table 4").

Summary Answer: TAG members did not achieve consensus on whether the algorithms alone, specific criteria (i.e., Table 4), and periodic updates to criteria need to be established in rule. Generally, the TAG agreed that the APA would likely need to be followed, but to what degree was debated. On the question of the algorithms, criteria, and updates, two opinions from TAG 4 are presented for consideration by the CSA:

Opinion 1: Place the algorithms, inputs and resulting tables into the rules (including future updates to inputs) pursuant to Part 201 and the APA.

Although Section 20120a does not explicitly state that the MDEQ must establish cleanup criteria through rules, other sections of Part 201 show the legislature's intent that the MDEQ should do so. Further, following the rule-promulgation process to establish criteria is likely required by the APA. Every court to analyze the definition of a "rule" under the APA has held that the term is to be read broadly, while any exceptions are to be read narrowly. The current state of the law interpreting the one exception that is potentially relevant, although the cases are somewhat inconsistent, likely would lead to the conclusion that the exception does not apply to establishing generic cleanup criteria under Part 201.

Background

Section 20120a authorizes the MDEQ to establish cleanup criteria and approve of remedial actions in four categories: residential, nonresidential, limited residential, and limited nonresidential. Unfortunately, the section does not state whether the MDEQ must follow the APA rule-promulgation process to establish the categorical criteria. Subsection (18) requires the MDEQ to "evaluate and revise" the cleanup criteria by December 31, 2013. But this subsection does not necessarily allow the MDEQ to do so outside the APA rule process. Indeed, the legislature amended this subsection to extend the date from December 31, 2012 to December 31, 2013 because the MDEQ was not able to promulgate new rules by the end of 2012.

Further, the public act containing this amendment repealed the cleanup criteria rules effective on December 31, 2012 for the sole purpose of forcing the MDEQ to actually review and revise the criteria through new rules. In fact, the MDEQ did promulgate new rules in December of 2013 to comply with this subsection. Moreover, the requirement in subsection (18) for the MDEQ to "prepare and submit to the legislature a report detailing any revisions made to cleanup criteria under this section" is not inconsistent with the APA rule-promulgation process. That process requires a specific report to be submitted to the Joint Committee on Administrative Rules rather than the legislature as a whole. Subsection (18) requires more than the APA rule-promulgation process, which is not unusual considering the broad impact of cleanup criteria to the state and the historic difficulties in reaching consensus among the MDEQ and regulated community.

In addition, other sections of Part 201 demonstrate the legislature's intent that the MDEQ follow the APA rule-promulgation process when developing the categorical cleanup criteria. In Section 20118(2)(c), the legislature clarifies how a liable person must meet the categorical cleanup criteria when pursuing remedial actions:

(2) Remedial action undertaken under subsection (1) at a minimum shall accomplish all of the following:

(c) Except as otherwise provided in subsections (5) and (6), be consistent with any cleanup criteria incorporated in rules promulgated under this part.

Subsections (5) and (6) then cite to the now-revised cleanup-criteria rules promulgated by the MDEQ. This is an explicit endorsement by the legislature of following the APA rule-promulgation.

Similarly, the legislature has endorsed the now-revised cleanup criteria rules when defining the term "background concentration:"

(e) "Background concentration" means the concentration or level of a hazardous substance that exists in the environment at or regionally proximate to a facility that is not attributable to any release at or regionally proximate to the facility. A person may demonstrate a background concentration for a hazardous substance by any of the following methods:

(i) The hazardous substance complies with the statewide default background levels under R 299.5746 of the Michigan administrative code.[1]

Further, the legislature has also explicitly stated its intent that the algorithms used to develop the categorical cleanup criteria must also follow the APA rule-promulgation process:

(2) Site-specific criteria approved under subsection (1) may, as appropriate:

(a) Use the algorithms for calculating generic criteria established by rule or propose and use different algorithms.[2]

Finally, the legislature's clarification throughout Part 201 that both the categorical criteria and the algorithms used to develop those criteria are to be established by rule is consistent with the legislature's general statement in Part 201 that the MDEQ's implementation of the statute is to be done through rules:

Sec. 20104. (1) The department shall coordinate all activities required under this part and may promulgate rules necessary to implement this part.[3]

Additional statutory references are included in Appendix A.

Opinion 2: Place the algorithms in the rule; publish the inputs along with a process for revising those inputs similar to a process outlined below. Therefore, there would always be a table of the criteria based on the current inputs plugged into the algorithms as established by rule.

If the rule includes the algorithm and a method of publishing and revising the inputs to the algorithms, and the resulting value table (that included a robust public participation component), the rule would survive any challenge under the APA.

[1] MCL 324.20101(1)(e).
[2] MCL 324.20120b(2)(a).
[3] MCL 324.20104(1).

Background

The only reference in Part 201 to rulemaking is included in Section 20120b as it references the algorithms having to be promulgated through rules. Therefore, the argument is that the algorithms being included in rule are a minimum, but that department would have the discretion to revise the inputs using a process other than the rule promulgation process. That interpretation would be bolstered by the discretion given to the department to revise the inputs under section 20120b on a site-specific basis (even if the modification is not directly related to site-specific factors). In addition, multiple other programs at the department allow revisions to permit emission levels based on new science and the revision to the inputs used in a manner similar to the cleanup standards.

The alternative argument endorsed in Opinion 1 is that the language of the APA would require all information to be included within the rule itself. The cases interpreting the APA on this point can be used to bolster arguments on both sides, and thus are not dispositive.

Another legal concept which may be helpful is whether failure to include the input and tables in the rule would render them vague and unenforceable. The Supreme Court on that issue has set forth the following general rule:

> "A statute may be unconstitutionally vague on any of three grounds: (1) it is overbroad, impinging on First Amendment freedoms, (2) it fails to provide fair notice of the conduct proscribed, or (3) it is so indefinite that it confers unlimited and unstructured discretion on the trier of fact to determine whether an offense has occurred. To evaluate a vagueness challenge, this Court must examine the entire text of the statute and give the words of the statute their ordinary meanings. 'To afford proper notice of the conduct proscribed, a statute must give a person of ordinary intelligence a reasonable opportunity to know what is prohibited'."[4]

In general, the rules regarding cleanup criteria and similar programs are among the most complex in the administrative code. An argument that all parts of the criteria development process must be promulgated could be made if the rule failed to require that the department "publish" its inputs to the algorithms, and follow a public process for revising them over time. However, if the algorithms are promulgated, the inputs published, and a public process is outlined in the rules and followed by the department when making any changes, the rule coupled with the statutory provisions should survive any challenge based on vagueness or a party arguing they didn't know what the standard was.

The process to update the rules could be based on a similar one recommended in the air program and would follow these steps:

(1) The department would announce its intention to re-evaluate a number of candidate chemicals (5-10 a year). It would allow 30 days for any party to nominate additional chemicals which they thought should be reviewed along with supporting documentation of why it should be considered.

(2) After review of the any petitions submitted, the department would provide notice of the list of each chemical under review, the proposed change in treatment, along with explanation of the science being relied on to support the change in treatment. They would take public comment on the proposed changes for a period of 60-90 days.

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[4] People v Hrlic, 277 Mich App 260, 262-263; 744 NW2d 221 (2007)

(3) Within 90-120 days following the receipt of comments and full consideration thereof, the department would finalize and publish the list and the associated change in treatment together with a response to substantive comments received.

(4) The changes would be implemented 30 days later.

If rules (without the tables) were challenged and struck down by the court, the department could immediately remedy the problem through the issuance of emergency rules while going through the process of curing any defect identified by the courts.

Question 2

The Administrative Procedures Act authorizes an agency to incorporate by reference in a rule any part of a code, standard, or regulation that has been adopted by an agency of the U.S. or by a nationally recognized organization or association. The reference must fully identify the adopted matter, including the date. And the reference cannot cover any later amendments or editions of the adopted matter. Rather, the agency must amend the rule or promulgate a new rule to incorporate the adopted matter. May a rule establishing cleanup criteria incorporate changes to referenced codes standards, or regulations automatically without following the process to promulgate a revised rule?

TAG members reached consensus that a rule establishing cleanup criteria may not incorporate changes to referenced codes, standards, or regulations automatically without following the process to promulgate a revised rule. TAG members noted that the incorporation by reference of a standard results in that standard being "frozen in time" at the time of the rule publication.

Question 3

What legal options are available to create a process whereby stakeholders may oversee the MDEQ's process to establish new or revised cleanup criteria?

Summary Answer: TAG members noted that, within the context of their discussion, the answer to Question 1 would inform the answer to Question 3. It was noted that both the APA rulemaking process and the process recommended by TAG 1 include opportunities for stakeholder input. The group discussed standing stakeholder committees established in other states that review criteria updates. TAG members discussed whether such an approach would be desirable for Michigan, though no specific recommendation was offered.

Appendices

- **Appendix A:** Statutory References for Opinion 1
- **Appendix B:** Statutory References for Opinion 2
- **Appendix C:** Preliminary Review of Part 31 (air) and Part 55 (water)

Appendix A:
Statutory References for Opinion 1

1. Part 201 when read as a whole probably requires the MDEQ to follow the APA rulemaking process when establishing the generic cleanup criteria, including the algorithms and the criteria themselves.

- Section 20120a authorizes the MDEQ to establish cleanup criteria and approve of remedial actions in four categories: residential, nonresidential, limited residential, and limited nonresidential. Unfortunately, the section does not explicitly state whether the MDEQ must follow the APA rule-promulgation process to establish the categorical criteria.
- Other sections of Part 201 demonstrate the legislature's intent that the MDEQ follow the APA rule-promulgation process when developing the categorical cleanup criteria
    - Section 20118(2)(c):

      (2) Remedial action undertaken under subsection (1) at a minimum shall accomplish all of the following:

. . .

      (c) Except as otherwise provided in subsections (5) and (6), be consistent with any cleanup criteria incorporated in rules promulgated under this part.

- Subsections (5) and (6) then cite to the now-revised cleanup-criteria rules promulgated by the MDEQ.

    - Section 20101(1)(e):

      (e) "Background concentration" . . . A person may demonstrate a background concentration for a hazardous substance by any of the following methods:
      (i) The hazardous substance complies with the statewide default background levels under R 299.5746 of the Michigan administrative code.[5]

    - Section 20120b(2)(a):

      (2) Site-specific criteria approved under subsection (1) may, as appropriate:
      (a) Use the algorithms for calculating generic criteria established by rule or propose and use different algorithms.[6]

- Section 20104(1):

  Sec. 20104. (1) The department shall coordinate all activities required under this part and may promulgate rules necessary to implement this part.[7]

2. In addition to legislature's direction in Part 201, the MDEQ's establishing of generic cleanup criteria fits within the APA's definition of "rule."

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[5] MCL 324.20101(1)(e).
[6] MCL 324.20120b(2)(a).
[7] MCL 324.20104(1).

- The APA defines a rule to include "an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency."[8]

- Courts have consistently held that "with a preference for policy determinations pursuant to rules the definition of 'rule' is to be broadly construed, while the exceptions are to be construed narrowly."[9]

- Establishing generic cleanup criteria under Part 201 fits within the definition of "rule" under the APA. The cleanup criteria are a "regulation" or "standard" of "general applicability" under the APA definition. Under Part 201, generic cleanup criteria are used to determine whether every property in the state is a "facility" and whether response activities are required to address contamination. The generic cleanup criteria also "implement[] or appl[y] law enforced or administered by the agency", namely the authorization in Section 20120(a) to establish cleanup criteria.[10]

3. **Establishing generic cleanup criteria under Part 201 does not fit within an exception to the APA's definition of "rule."**

- The only exception to the definition of "rule" that could possibly apply to establishing general cleanup criteria under Part 201 is "a decision by an agency to exercise or not to exercise a permissive statutory power, although private rights or interests are affected."[11]

- The development of the case law interpreting this exception has been inconsistent—with early Court of Appeals cases interpreting the exception broadly and more recent and binding Supreme Court cases interpreting the exception narrowly.

- For example, in the most recent Supreme Court case, the Court held that the exception did not apply to the department's development of form contracts: "[W]hile the department has discretion regarding whether to contract for the provision of statutorily mandated services, once it chooses to do so, it cannot abdicate its responsibilities under the ... APA and set standards and policies that regulate the provision of such services without complying with the APA's procedural requirements."[12]

- Under the Supreme Court's reasoning, the MDEQ's decision whether or not to establish categorical criteria under Section 20120a would not be subject to the APA rulemaking process. But if the MDEQ decided to establish criteria, it must do so through the APA rulemaking process.

4. **The requirement to follow the APA rulemaking process when establishing generic cleanup criteria should apply to the algorithms, the inputs to the algorithms, and the criteria.**

- Some have argued that promulgating only the algorithms would comply with Part 201 and the APA. This argument would essentially allow the MDEQ to establish criteria outside the

[8] MCL 24.207.
[9] AFSCME v Michigan Dep't of Mental Health, 452 Mich 1, 10 (1995).
[10] MCL 324.20120a(3).
[11] MCL 24.207(j).
[12] AFSCME v Michigan Dep't of Mental Health, 452 Mich 1, 10 (1995), citing Spear v Michigan Rehabilitation Serv's, 202 Mich App 1 (1993).

rulemaking process because the inputs to the algorithms are subjective.

- The legislature, however, has acknowledged that both the algorithms and the criteria are to be promulgated in rules. And the inputs to the algorithms and the criteria clearly fit within the definition of “rule” in the APA and are likely not excepted under the above analysis.

Appendix B:
Statutory References for Opinion 2

The statutory sections addressing this question are mainly section 20120a and 20120b as listed below (in part, emphasis added):

Sec. 20120a.

(1**) The department may establish cleanup criteria and approve of remedial actions in the categories listed in this subsection.** The cleanup category proposed shall be the option of the person proposing the remedial action, subject to department approval if required, considering the appropriateness of the categorical criteria to the facility. The categories are as follows:

(a) Residential.

(b) Nonresidential. The nonresidential cleanup criteria shall be the former industrial categorical cleanup criteria developed by the department pursuant to this section until new nonresidential cleanup criteria are developed and published by the department pursuant to subsection (17).

(c) Limited residential.

(d) Limited nonresidential.

(2**) As an alternative to the categorical criteria under subsection (1), the department may approve a response activity plan or a no further action report containing site-specific criteria that satisfy the requirements of section 20120b and other applicable requirements of this part.** The department shall utilize only reasonable and relevant exposure pathways in determining the adequacy of a site-specific criterion. Additionally, the department may approve a remedial action plan for a designated area-wide zone encompassing more than 1 facility, and may consolidate remedial actions for more than 1 facility.

(3) The department shall develop cleanup criteria pursuant to subsection (1) based on generic human health risk assessment assumptions determined by the department to appropriately characterize patterns of human exposure associated with certain land uses. The department shall utilize only reasonable and relevant exposure pathways in determining these assumptions. The department may prescribe more than 1 generic set of exposure assumptions within each category described in subsection (1). If the department prescribes more than 1 generic set of exposure assumptions within a category, each set of exposure assumptions creates a subcategory within a category described in subsection (1). The department shall specify facility characteristics that determine the applicability of criteria derived for these categories or subcategories.

…

(9) The department may establish cleanup criteria for a hazardous substance using a biologically based model developed or identified as appropriate by the United States environmental protection agency if the department determines all of the following:

(a) That application of the model results in a criterion that more accurately reflects the risk posed.

(b) That data of sufficient quantity and quality are available for a specified hazardous substance to allow the scientifically valid application of the model.

(c) The United States environmental protection agency has determined that application of the model is appropriate for the hazardous substance in question.

…

(17) Remedial actions that rely on categorical cleanup criteria developed pursuant to subsection (1) shall also consider other factors necessary to protect the public health, safety, and welfare, and the environment as specified by the department, if the department determines based on data and existing information that such considerations are relevant to a specific facility. These factors include, but are not limited to, the protection of surface water quality and consideration of ecological risks if pertinent to the facility based on the requirements of this part.

….

(18) Not later than December 31, 2013, the department **shall evaluate and revise the cleanup criteria derived under this section.** The evaluation and any revisions shall incorporate knowledge gained through research and studies in the areas of fate and transport and risk assessment and shall take into account best practices from other states, reasonable and realistic conditions, and sound science. **Following this revision, the department shall periodically evaluate whether new information is available regarding the cleanup criteria and shall make revisions as appropriate. The department shall prepare and submit to the legislature a report detailing any revisions made to cleanup criteria under this section.**

Sec. 20120b

(1) The department shall approve numeric or nonnumeric site-specific criteria in a response activity under section 20120a if such criteria, in comparison to generic criteria, better reflect best available information concerning the toxicity or exposure risk posed by the hazardous substance or other factors.

(2) Site-specific criteria approved under subsection (1) may, as appropriate:

(a) **Use the algorithms for calculating generic criteria established by rule or propose and use different algorithms.**

(b) Alter any value, parameter, or assumption used to calculate generic criteria.

(c) Take into consideration the depth below the ground surface of contamination, which may reduce the potential for exposure and serve as an exposure barrier.

(d) Be based on information related to the specific facility or information of general applicability, including peer-reviewed scientific literature.

(e) Use probabilistic methods of calculation.

(f) Use nonlinear-threshold-based calculations where scientifically justified.

The other statute which comes into play is the Administrative Procedures Act (APA).

The APA defines a "rule" to mean:

[A]n agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency.[13]

[13] MCL 24.207.

Appendix C:
Preliminary Review of Parts 31 (water) and Part 55 (air)

During a TAG meeting, research provided by a TAG member proposed that the way the legislature drafted specific provisions in Part 201enhances the position that the legislative intent was for the MDEQ to follow the rule promulgation process when developing cleanup criteria. However, the research was not dispositive of the issue, so the TAG decided that a review of the rule related provisions of Part 31 (water) and Part 55 (air) might help provide more insight on the legislative intent for Part 201. Consequently, another TAG member did a search of all the provisions in Parts 31, 55 and 201 of the word "rule" and analyzed how the word was used in each part. The results are presented below:

All 3 Parts have the following similar language allowing MDEQ to promulgate rules. The language is found toward the beginning of each Part and states:

<u>Part 31:</u>

Sec. 3103 (2): The department shall enforce this part and may promulgate rules as it considers necessary to carry out its duties under this part. However, notwithstanding any rule-promulgation authority that is provided in this part, except for rules authorized under section 3112(6), the department shall not promulgate any additional rules under this part after December 31, 2006.

Sec. 3103 (3): The department may promulgate rules and take other actions as may be necessary to comply with the federal water pollution control act, 33 USC 1251 to 1387, and to expend funds available under such law for extension or improvement of the state or interstate program for prevention and control of water pollution. This part shall not be construed as authorizing the department to expend or to incur any obligation to expend any state funds for such purpose in excess of any amount that is appropriated by the legislature.

<u>Part 55:</u>

Sec. 5503. The department may do 1 or more of the following:

(a) Promulgate rules to establish standards for ambient air quality and for emissions.

<u>Part 201:</u>

Sec. 20104 (1) The department shall coordinate all activities required under this part and may promulgate rules necessary to implement this part.

Of the three parts, Part 201 has the least amount of language concerning the establishment of rules. In both Parts 31 and 55, the legislature seemed to use more forceful, prescriptive language when it felt it did not want to give discretion to the agency for rulemaking. For example, Sections 3106, 3107, 5505(4) all start out with the preface "[t]he department **may** promulgate rules to/for ….." [Emphasis added.] In Sections 3104(6), 3109(a), 3109 (e), 3131, 5504(5), 5505(2), 5506(4) and 5512, the language changes to "[m]inor project categories **shall** be established by rule" or "[t]he department **shall** promulgate rules for …." [Emphasis added.]

Nevertheless, Sec. 20120b (2) (a) explicitly implies that the algorithms are to be part of the rulemaking process by stating:

(2) Site-specific criteria approved under subsection (1) may, as appropriate:

(a) Use **the algorithms for calculating generic criteria established by rule** or propose and use different algorithms. [Emphasis added.]

As discussed during a TAG meeting, there appears to be a different type of statutory construction for Parts 31 and 55 versus Part 201. The reason may be that Parts 31 and 55 are prospective in that they provide for permit limits or emissions limits to operate or conduct an activity in the future. Part 201 is addressing current or historical conditions and trying to establish a cleanup standard to address a release that has often occurred historically. This may also be a primary reason why the regulated community appears more interested in having input on the cleanup rules for Part 201 than with the other statutes. Many of the cleanups or due care obligations under Part 201 are undertaken by non-liable parties who had not caused the contamination and therefore are more interested in containing costs. Those regulated under Parts 31 and 55 are folks with operating facilities who have much more control over their activities going forward and need a permit to continue their operation so they may be less likely to contest new limits. Therefore, more opportunities for input from the regulated community for any criteria changes under Part 201 may not necessarily spill over to the way the other divisions have historically operated.