

1 **EXECUTIVE SUMMARY**

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3 This report was prepared by the Science Advisory Board (SAB) Risk and Technology  
4 (RTR) Review Panel (the “Panel”) in response to a request by EPA’s Office of Air  
5 Quality Planning and Standards (OAQPS) to review their draft methodologies for  
6 conducting Risk and Technology Review assessments (hereafter referred to as the  
7 Agency RTR document). The proposed methodologies are demonstrated through the use  
8 of two case studies, (1) petroleum refineries and (2) Portland cement manufacturing  
9 facilities. The Panel reviewed the case studies to provide input on the RTR methodology  
10 and did not address their regulatory implications.

11  
12 The Panel deliberated on the charge questions during a July 28-29, 2009 face-to-face  
13 meeting and discussed its draft report in a subsequent conference call on December 3,  
14 2009. The final draft of the panel’s report was reviewed and approved during a meeting  
15 of the chartered SAB on XXXXXXXX. The charge questions focused on seven topics  
16 within the RTR document, including, the derivation of emissions estimates, inputs for the  
17 dispersion modeling, selection of dose-response values, estimating chronic inhalation  
18 exposures, developing estimates of acute inhalation risk, developing an ecological risk  
19 assessment and an overall risk characterization.

20  
21 This Executive Summary highlights the Panel’s major findings and recommendations  
22 resulting from their deliberations. The responses that follow represent the views of the  
23 Panel. The Panel commends the Agency on the technical quality of the RTR document  
24 and the thought and effort it has put into developing the residual risk methodology. The  
25 Panel found the case studies extremely valuable in illuminating both strengths and  
26 limitations of the methodology. The issues involved in residual risk estimation are  
27 extremely complex and the available information is limited. The comments and  
28 recommendations offered below are intended to assist OAQPS staff as they seek to  
29 improve their RTR assessments going forward, and are not meant to detract from the  
30 general excellence of the report or the efforts to date.

31  
32 *1. Revisions to emissions data*

33  
34 As described in Section 2.2.1 of the Agency’s RTR document (*i.e.*, the Petroleum  
35 Refineries case study), the 2002 National Emissions Inventory (NEI) serves as the  
36 starting point for RTR risk assessments. EPA performs an engineering review of data  
37 from each source category to identify and correct readily apparent limitations and issues  
38 with the emissions data. The dataset is then published through an Advanced Notice of  
39 Proposed Rulemaking (ANPRM), making it available for public comment. EPA  
40 evaluates comments and corrections for quality and engineering consistency, revises the  
41 dataset, and develops a draft risk assessment. The dataset and the risk assessment are  
42 provided with a Notice of Proposed Rulemaking (NPRM) for a second 60-day comment

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1 period, after which further comments and corrections are evaluated and incorporated, as  
2 appropriate. The final rulemaking is then developed.

3  
4 Evaluations of petroleum refinery emissions estimates

5  
6 The Panel notes that emissions data are one of the most critical inputs to a residual risk  
7 assessment. The Panel agrees that the overall approach described in Section 2.2.1 of the  
8 Agency document is rigorous and transparent, resulting in a consistent and well  
9 documented starting point for emission scenarios. However, the panel is concerned that  
10 the NEI, which reports *estimates* of *actual* emissions, may not be the most appropriate  
11 starting point for developing emissions data for the RTR risk assessments, due to possible  
12 underestimation bias and the potential that emissions could be increased within current  
13 regulatory limits. Where applicable, facility-specific *allowable* emissions should be  
14 considered as a first step, to assess the effectiveness of the current MACT standards.

15  
16 Overall, the Panel found the evaluations and comparative analyses described in  
17 Appendixes A, L and P to be informative and scientifically credible. Comparisons  
18 between alternative inventory estimation methods of the maximum individual cancer  
19 risks (MIR), cancer incidence and population exposure, Hazardous Air Pollutant (HAP)  
20 emissions, and toxicity weighted HAP emissions are useful for illustrating the key  
21 uncertainties in the current approach. However, the overarching result that emerges from  
22 the evaluations is the indication that self-reported facility specific emissions data in the  
23 NEI are either incomplete or biased low and that the comment and revision process fails  
24 to correct this bias.

25  
26 Appendix A compares risk assessment results for petroleum refineries using the  
27 emissions data from the engineering review and using emission data that were revised  
28 following the public comment period. In both cases, the analysis relies on reported  
29 emissions and does not identify or reflect further changes that may be needed to represent  
30 what MACT 1 petroleum refineries actually emit or are allowed to emit. Appendix A  
31 indicates that comments were more likely to be provided for facilities for which  
32 individual cancer risk estimates in the ANPRM were relatively high and that these  
33 comments generally reduced the risk estimates. It remains unclear whether community  
34 representatives have access to resources or information needed to provide informative  
35 comments reflecting their concerns.

36  
37 Appendix L compares ambient benzene concentrations with modeled concentrations for  
38 two petroleum refineries as a way to assess the emissions data. The analysis suggests the  
39 emissions data may be biased low, although inappropriate treatment of calm periods in  
40 this modeling analysis could be contributing to the apparent bias. The Panel recommends  
41 expanding the assessment to include up to 15 randomly selected refineries (~ 10 % of the  
42 total) to better represent the distribution in error across facilities. The current assessment  
43 could also be improved by better coupling of the measurements at the source and receptor  
44 and discussing the confidence in the inventory for both facilities.

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2 Appendix P compares risk estimates developed using NEI-based emissions inventory  
3 data with estimates developed using a process-based emissions model, the Refineries  
4 Emissions Model (REM). The comparison demonstrates differences in total emissions  
5 from refinery MACT 1 sources of a factor of almost 3 (underestimation) for benzene and  
6 a factor of 50 (overestimation) for methanol. Estimated cancer incidence for the source  
7 category is 3-4 times higher using REM emission data relative to RTR emission  
8 estimates. The Panel finds the analysis in this appendix particularly useful, as it most  
9 directly compares results based on reported NEI emissions versus estimates based on  
10 MACT compliance or “allowable” emissions.

11  
12 In summary, the Panel recommends EPA modify its approach, so that facility-specific  
13 allowable emissions are modeled as a first step, to assess the effectiveness of the current  
14 MACT standards. A second step would then be modeling actual facility emissions to  
15 assess the current risk in the surrounding community. The RTR case study focuses on this  
16 second issue, but does not adequately address the concern that facilities can increase HAP  
17 emissions to MACT-allowable levels.

18  
19 Estimating dioxin and furan (D/F) emissions

20  
21 The Panel recommends that residual risk assessments be conducted using the current  
22 source-specific National Emission Standard for Hazardous Air Pollutants (NESHAP)  
23 allowable emission rate in combination with each facility’s maximum permitted  
24 production rate. This should be done whenever NESHAP emission limits have been set  
25 for specific hazardous air pollutants. In particular, using estimated emissions that exceed  
26 the NESHAP limit is not appropriate for the residual risk assessment. Because allowable  
27 limits were not modeled for dioxin and furan (D/F) emissions from Portland cement  
28 facilities, the Panel does not believe the approach used in the case study represents the  
29 best available methodology in support of a residual risk analysis. There is no need to  
30 estimate D/F emissions for Portland cement facilities, when allowable limits exist.

31  
32 Additionally, the NESHAP compliance testing information for D/F emissions from each  
33 facility should be collected and critically evaluated to determine if it is technologically  
34 feasible to reduce the current Portland cement NESHAP D/F emission limits. This  
35 compliance information should be readily available upon request from the states or EPA  
36 regional offices. This should be done whenever NESHAP emission limits have been set  
37 for specific hazardous air pollutants. In contrast, use of the 95% Upper Confidence Limit  
38 (UCL) of available actual data as a default emission rate estimate may be appropriate for  
39 1) source categories that do not have a NESHAP emission limit for D/F, and 2) all other  
40 HAPs that do not have a current NESHAP emission limit.

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## 1 Estimating emissions of radionuclides

2  
3 The Panel commends the Agency for its effort to estimate emissions and cancer risks due  
4 to radionuclide emissions from Portland cement facilities. Emissions of isotope-specific  
5 radionuclides warrant careful characterization and evaluation for Portland cement  
6 facilities and other facilities that have the potential to emit relevant radionuclides.  
7 However, the proposed analysis should not be formally included in the RTR assessment  
8 until further progress is made to quantify the isotope-specific radionuclide emissions and  
9 the associated risks. The assumptions need to be improved, as described in the body of  
10 the report, before radionuclide risk estimates are incorporated into RTR assessments.  
11 The Agency's analysis demonstrates that isotope-specific radionuclide emissions  
12 estimates are needed instead of using 2002 NEI data that do not include such speciation.

13  
14 The radionuclide content of feedstocks used to produce Portland cement should be  
15 characterized at important locations across the US where these feedstocks are mined.  
16 With information on radionuclide content of feedstocks, screening material balance  
17 calculations such as those done by Leenhouts et al. (1996) for the Maastricht facility  
18 should be performed to estimate isotope-specific radionuclide emissions from Portland  
19 cement facilities. Results from radionuclides stack tests required for compliance  
20 assurance may also provide useful data.

## 23 *2. Dispersion Modeling*

24  
25 Section 2.2.2 describes the Agency's inputs to the AERMOD dispersion model for RTR  
26 assessments. The Agency performed these analyses in an effort to better understand the  
27 uncertainties and/or potential bias that may be introduced by some of these inputs.

28  
29 The Panel believes that the dispersion modeling for primary HAPs used in risk  
30 assessments is well developed and appropriate. Any modeling entails uncertainties, and  
31 the series of case studies presented in Section 4 of the RTR document provide a broad  
32 picture of model performance and sensitivity for this risk assessment. The Agency has  
33 presented calculations justifying the use of several simplifications for performing longer-  
34 term impact and risk assessments. Some simplifications were shown to introduce  
35 relatively minor changes to risk estimates most of the time. However, there were some  
36 areas where simplifications introduced changes in risk estimates that could be  
37 appreciable, and in other areas further investigation is required in order to adequately  
38 justify the conclusions. In particular, it appears that there is a potentially serious  
39 underestimation bias in the dispersion modeling due to the ambiguous treatment of  
40 "calm" periods that have no definable wind directions.

41  
42 The Panel noted that the choice of meteorological data for performing risk assessments  
43 appears to have a significant impact on calculated risks, as demonstrated in the sensitivity  
44 studies presented in section 4.5. The Panel also suggests that use of more than one year

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1 of meteorological observations is desirable in order to capture worst-case scenarios. The  
2 methods for choosing an individual year for risk assessment suggested here could be  
3 applied to other source categories, but depending on source stack characteristics, some of  
4 the quantitative conclusions of the Agency's sensitivity studies may not transfer.

5  
6 The results of the Agency's analysis of omitting HAP *decay* and deposition in risk  
7 assessments could be applied to other source categories. However, it is possible that  
8 secondary HAP *formation* could be significant for some source categories. Further  
9 sensitivity studies of secondary HAP formation would be required to rule out the  
10 necessity of including complex photochemical modeling for future HAP risk  
11 assessments.

12  
13 In order to correctly assess whether consideration of impacts at census block centroids  
14 reasonably assesses risks at actual residences within census blocks, the HEM-AERMOD  
15 system should be run twice with different sets of receptors: (1) a receptor grid of census  
16 block centroids, and (2) a receptor grid with residences tagged as receptors. Maximum  
17 health risk impacts would be directly compared using these two receptor grids for a  
18 number of facilities. It is possible that differences between block centroids and individual  
19 residences could be greater than the differences shown in this sensitivity study for source  
20 categories that are characterized by elevated buoyant emissions from smokestacks.

### 21 22 23 *3. Dose-Response Assessment*

24  
25 Section 2.2.6 of the Agency's RTR document describes the process of selecting and  
26 prioritizing dose-response values for RTR human health risk assessments. The Agency  
27 selected chronic dose-response values in the same way it does for NATA, a process that  
28 the SAB has already reviewed in the context of NATA, but not one of regulatory  
29 decision-making. The Agency has also developed an analysis (presented in Appendix O)  
30 of the possible importance of HAPs that lack chronic dose-response values. This analysis  
31 suggests that only a few HAPs lacking such values could be important in the chronic risk  
32 assessment, with the degree of importance heavily dependent on the conservatism of the  
33 input assumptions.

34  
35 The Agency developed its selection process for acute dose-response values more recently  
36 than the one for chronic values, and it has not yet undergone SAB review. The acute risk  
37 assessment process must deal with more gaps and inconsistencies in health benchmarks,  
38 compared to the chronic risk assessment.

#### 39 40 Selecting and prioritizing chronic dose-response values

41  
42 The Panel found the approach used in the RTR assessments was reasonable, but too  
43 simplistic in that it accepts dose-response numbers at face value, without closely  
44 examining the quality or validity of the value(s) chosen. In many cases, the differences

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1 in alternative chronic dose-response values will not significantly alter the RTR risk  
2 assessment, but any significant differences should be carefully considered. To assist in  
3 this effort, the Panel recommends that a table of chronic toxicity values be created,  
4 including all the chemicals under consideration and all of the eligible dose-response  
5 values, along with the source of the value, the year the value was last updated, and a  
6 qualitative description of the effect. If the chronic dose-response values are significantly  
7 different, especially if the value is a driver for the risk assessment, a review should be  
8 conducted to understand why the values differ. Professional judgment should then be  
9 used to select values for use in the assessments. If a chemical for which dose-response  
10 values have not been updated recently appears to be a driver of the assessment, a  
11 literature search should be performed to identify studies that may alter or update the value  
12 and the chemical should be considered for recommendation to the Integrated Risk  
13 Assessment System (IRIS) high priority revision list.

14  
15 The preferred database for chronic dose-response data is and should be the IRIS database.  
16 However, some chemicals of interest do not have IRIS values, and values for other  
17 chemicals have not been reviewed recently. The Panel strongly recommends that the  
18 Agency address these gaps and provide the resources necessary to maintain the updating  
19 process. The use of additional sources of data should be considered; however, if  
20 additional sources of data are used they should be ones that have undergone adequate and  
21 rigorous scientific peer review.

22  
23 The Panel recommends that the Agency expand the methods discussion in Appendix O to  
24 better describe the toxicity weighted emissions (TWEs) estimates for chemicals having  
25 no unit risk estimates (UREs) or reference concentrations (RfCs). In addition, the  
26 discussion of how surrogates were chosen should be clarified. Limitations about the  
27 emissions data need to be identified and addressed. The Panel recommends that the  
28 Agency prepare or compile toxicity profiles for each of the HAPs that Appendix O  
29 identifies as having the potential to drive the RTR assessment.

30  
31 The issue of children's hazard should be presented as an uncertainty with regard to non-  
32 cancer dose-response assessment and carcinogen dose-response assessment - especially  
33 as only two mutagenic carcinogens receive the age-adjusted potency factor approach in  
34 the RTR, in spite of the fact that numerous other mutagens (e.g., 1,3-butadiene) are  
35 analyzed. It is not clear whether the inter-individual uncertainty factor for non-  
36 carcinogens and the standard cancer unit risk derivation adequately protect children.

37  
38 The Panel was not charged with critiquing the IRIS methodology itself, however, we note  
39 below that inhalation risk methods for children are still developing and that California's  
40 Office of Environmental Health Hazard Assessment (OEHHA) has very recently updated  
41 its methodology in ways that could affect the development of RfC and URE values. EPA  
42 should examine these developments to make sure that the RTR process adequately covers  
43 children's residual risks.

44

1 Selection of acute benchmark values

2  
3 The case studies characterize acute risk adequately, but this may be due to the unique  
4 circumstances of these two case studies; thus, there is a need to pay attention to the  
5 principles and practices used. The incorporation of the available California Reference  
6 Exposure Levels (RELs) for the assessment of acute effects is a conservative and  
7 acceptable approach to characterize acute risks.

8  
9 The Panel does not recommend the use of the ATSDR MRLs in the risk assessments as  
10 their use would require a correction for the temporal mismatch and that correction would  
11 require formal peer-review.

12  
13 The Panel has some concern with the use of the Acute Exposure Guidelines Limits  
14 (AEGs) and Emergency Response Planning Guidelines (ERPGs). When AEGL-  
15 1/ERPG-1 emergency guideline values must be used, the Panel recommends adjusting  
16 them by a factor of 3 if the value is based on a LOAEL rather than a NOAEL. AEGL-2  
17 and ERPG-2 values should never be used in residual risk assessments because they  
18 represent levels that if exceeded could cause serious or irreversible health effects.  
19 Spacecraft Maximum Allowable Concentrations for Selected Airborne Contaminants  
20 could also be considered, again with appropriate adjustments to account for the need to  
21 protect sensitive subpopulations from experiencing effects. [American Conference of](#)  
22 [Governmental Industrial Hygienists Threshold Limit Values \(ACGIH TLVs\)](#) values  
23 could also be considered for use in the risk assessments, with appropriate adjustment  
24 (e.g., a factor of 10 or more) to ensure the protection of sensitive sub-populations. TLV  
25 values should only be used after thorough and critical evaluation.

26  
27 As recommended for chronic dose-response values, all the acute values for a given  
28 chemical should be arrayed in a table that displays their similarities and differences.  
29 Expert judgment should then be applied to select the most appropriate value with a clear  
30 rationale for the selection. Care must be exercised to ensure that the value chosen has  
31 undergone appropriate peer-review.

32  
33  
34 *4. Chronic Health Assessment*

35  
36 Section 2.2.3 of the RTR document describes the process by which the Agency estimated  
37 chronic human inhalation exposures based on modeled average ambient concentrations at  
38 census block centroids. For these case studies, this process did not include consideration  
39 of either daily behavior pattern or long-term migration behavior. Section 2.2.3 presents a  
40 rationale for omitting daily behavior, and Appendix N presents a case study that adjusts  
41 inhalation-based lifetime cancer risk estimates for individuals to account for long-term  
42 migration.

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1 For persistent and bioaccumulative HAPs (PB-HAPs), the RTR document describes a  
2 two-step approach. As described in Appendix C, the TRIM modeling system is first used  
3 to develop what the Agency calls “*de minimis* emission rates” such that emissions below  
4 these levels should not produce unacceptable risks in reasonable worst-case conditions.  
5 Facilities emitting PB-HAPs at higher rates might require refined multi-pathway  
6 modeling, as illustrated in section 3.4 and Appendix I in a case study of a Portland  
7 cement facility.

8  
9 Estimating Inhalation exposures

10  
11 In general, EPA’s overall approach appears to be reasonable as a *screening* approach for  
12 localized impacts that can be refined if needed in individual cases. However, an  
13 overarching concern with the Agency’s chronic inhalation exposure estimates is that  
14 children’s exposures do not appear to have been adequately addressed. With regard to  
15 the chronic inhalation exposure estimates, the Panel finds the rationale for omitting daily  
16 behavior to be convincing. Given the age of available activity pattern data and the  
17 inherent community-scale activity pattern uncertainties between locations, the decision to  
18 omit daily behavior is justified. The Panel further recommends that long-term migration  
19 not be incorporated into the risk assessment. It does not add value to the risk assessment  
20 and introduces additional uncertainty.

21  
22 TRIM model as a screening tool

23  
24 In responding to this charge question, the Panel focused on how TRIM.FaTE results were  
25 applied in the risk assessment process. The Panel did not evaluate the details of the  
26 equations in TRIM.FaTE and did not itself evaluate the validity of the model. The Panel  
27 recommends that the Agency continue to identify and acquire additional field data to  
28 estimate modeling parameters and to evaluate the TRIM.FaTE model components and  
29 other aspects of the modeling system on an ongoing basis.

30  
31 With the caution that continued efforts are needed to evaluate the TRIM.FaTE model, the  
32 Panel finds that the Agency’s screening approach is based on an appropriate framework  
33 and should provide a useful screen for sources that do not need a detailed site-specific  
34 multipathway analysis. The screening-level multipathway assessment is thorough and  
35 conservatively includes local subsistence agricultural and fishing scenarios, adding  
36 exposures across intake pathways to yield total PB-HAP exposure.

37 While the Panel supports the Agency’s screening approach, we recommend EPA avoid  
38 using the term “*de minimis*” to describe the threshold emissions estimates it has derived.  
39 In particular, when the *background* concentration of a PB-HAP already exceeds a safe  
40 level (e.g., where a fish advisory is already in effect) the public may not understand a  
41 local source’s contribution being characterized as *de minimis*. Furthermore, the model  
42 results should be clearly presented to show 1) the relative fraction of the local source’s  
43 emissions that are deposited locally versus being transported to add to regional burdens,

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1 and 2) the relative contributions to total multipathway exposure from local and regional  
2 background sources.

3  
4 Given the current status of information on radionuclide emissions, the Panel agrees it is  
5 acceptable to omit them from the multimedia assessment. However, EPA should work  
6 towards including them, as non-inhalation pathways are often important for radionuclides  
7 that can accumulate in biota and subsequently be ingested.

8  
9  
10 *5. Acute Health Assessment*

11  
12 Section 2.2.5 of the RTR document describes the Agency’s process for developing  
13 screening and refined estimates of acute inhalation risk. For acute screening purposes,  
14 the Agency has assumed that, in the worst case, a person could be exposed for one hour  
15 to ten times the highest hourly concentration calculated by the dispersion model. This in  
16 effect assumes a 1-hour emission rate of ten times (10X) the annual average (assuming  
17 continuous emissions), simultaneous occurrence of “worst-case” meteorological  
18 conditions, and also the presence of a person at this worst-case downwind location.

19  
20 The Panel agreed there is a critical need for better data addressing short-term exposures  
21 to HAPs and that in the absence of chemical- and site-specific data, the use of the 10X  
22 screening assumption for petroleum refineries seems reasonable. However, the methods  
23 used to derive and justify the 10X screening assumption need to be more clearly  
24 presented. For petroleum refineries, the Panel also suggests that following the screening  
25 process, the chemicals of highest concern (drivers) be evaluated against the list of  
26 chemicals reported in the Houston area (Appendix B), to ensure they are adequately  
27 represented. Although the Panel generally agreed that the 10X assumption could be used  
28 for other geographic areas, it was felt that the actual releases would be dependent upon  
29 the manufacturing processes involved which may or may not be captured in the Houston  
30 example. As one example, adjustments may need to be made for other source categories  
31 where facilities operate during only part of the day or part of the year.

32  
33 The Panel also recommends that the Agency examine the likelihood that a 10X release  
34 would occur under the most hazardous meteorological conditions, and how likely it  
35 would be for 10X releases of multiple chemicals to occur simultaneously. If it is  
36 concluded that simultaneous releases under adverse meteorological conditions would be  
37 very unlikely, then summing the acute hazard quotients by target organ would not be  
38 necessary.

39  
40  
41 *6. Ecological Risk Assessment*

42  
43 Section 3.5 and Appendix J of the RTR document describe a refined, site-specific  
44 application of TRIM to conduct an ecological risk assessment for PB-HAPs emitted by

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1 the same Portland cement facility evaluated in the human health risk assessment.  
2 Appendix J also describes a nationwide facility ranking exercise that identifies Portland  
3 cement facilities with the highest potential for causing indirect ecological effects via  
4 acidification of the environment by hydrogen chloride emissions. Appendix K describes  
5 an analysis of possible direct effects on plant foliage of air concentrations of hydrogen  
6 chloride emitted from Portland cement facilities that are below human health thresholds.  
7

8 The Panel found the ecological risk assessment (ERA) presented in Appendix J to be an  
9 impressive effort tackling an extremely complex issue. While it is a good first step, the  
10 ERA needs to be improved, as the Agency's ERA guidelines were not followed well.  
11 The heavy reliance of the ERA case study on TRIM.FaTE is a concern, as the Agency's  
12 model has not been well validated in the peer-reviewed literature for ERAs, and an  
13 adequate sensitivity analysis with ground-truthing is lacking. Overall, many of the  
14 Panel's concerns and issues with the ecological risk assessment could be addressed by  
15 conducting a ground-truthing ERA at a site such as Ravenna Pond, or by a comparison of  
16 TRIM.FaTE predictions with more conventional ERA methods.  
17

18 The Panel recommends EPA further investigate the numerous peer-reviewed studies that  
19 are relevant to this process, many of which have focused on mercury and highly  
20 chlorinated compounds such as dioxins. In Appendix J, section 3.2.3, EPA discusses and  
21 rejects the option of using Toxicity Reference Values (TRVs) expressed in terms of tissue  
22 concentrations instead of chemical intake. However, reporting TRVs in terms of tissue  
23 concentrations (rather than intake as commonly done for human risk assessments) would  
24 allow for more and better comparisons with the peer-reviewed literature and predictions  
25 of risk, as there are fewer peer-reviewed literature reports of intake values.  
26

27 The Panel found that the process to select the Portland cement facilities of greatest  
28 potential concern for HCl deposition using pH, hardness, alkalinity and soil type data was  
29 very good. However, it is important to recognize that for site-specific ERAs, other site  
30 characteristics may need to be considered  
31

### 32 33 *7. Risk Characterization* 34

35 The risk characterizations for the two case studies (Sections 2.3 and 3.6 of the RTR  
36 document) represent the Agency's current practices in providing information to decision-  
37 makers responsible for RTR rulemaking. The analyses presented in the appendices are  
38 by and large illustrative of what can currently be done in the regulatory context, given  
39 knowledge, time, and resource constraints.  
40

41 The Panel believes that the authors of RTR document took great care in summarizing and  
42 providing justification and explanation for most of the results, including attention to  
43 uncertainties. However, a number of improvements are possible. In the RTR case  
44 studies, the presentation of methods, risk assessment results, and risk characterization are

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1 intermingled, such that the purposes of the risk characterization are not met. This can be  
2 improved by focusing more on the purpose of the characterization to communicate with  
3 decision makers as the primary audience, recognizing that transparency is important and  
4 that the audience will inevitably be broad. While other sections of the RTR assessments  
5 should document the technical details, the risk characterization sections should stand  
6 alone. To this end, the Panel recommends that EPA develop a separate methods  
7 document that contains a full description (including uncertainties) of all of the common  
8 components of the source-specific risk assessments. Source-specific risk  
9 characterizations could refer back to this master document, while providing additional  
10 information particular to the source category at issue.

11  
12 Decision makers and communities need to understand the broad community risk and  
13 contributors to it. However, because the Clean Air Act requires separate assessments by  
14 source category, EPA's RTR approach only partially accounts for potential human health  
15 or ecological risk of facilities that fall into more than one category. For example, the  
16 petroleum refinery MACT 1 case study omits refineries' combustion processes. The risk  
17 characterization should clearly explain this limitation. Furthermore, the risk  
18 characterization should put the results in the broader context of aggregate and cumulative  
19 risks, including background concentrations and contributions from other sources in the  
20 area.

21  
22 While recognizing that RTR assessments must proceed, even though most will have a  
23 relatively long list of uncertainties, the Panel recommends that the Agency perform a  
24 sensitivity analysis to identify the major uncertainties in both the human health and  
25 ecological risk assessments. The Agency should then proceed to: (1) explain them  
26 clearly in the risk characterization section and (2) take steps to reduce them.

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## 1.0 Background and Introduction

EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the Science Advisory Board (SAB) review their draft methodologies for conducting Risk and Technology Review assessments (RTR assessments) as required by the Clean Air Act. These assessments evaluate the effects of industrial emissions of hazardous air pollutants (HAPs) on public health and the environment. The proposed methodologies are demonstrated through the use of two case studies, (1) petroleum refineries and (2) Portland cement manufacturing facilities.

The Clean Air Act establishes a two-stage regulatory process for addressing emissions of HAPs from stationary sources. In the first stage, the Act requires EPA to develop technology-based standards based on Maximum Achievable Control Technology (MACT) for categories of industrial sources. EPA must review each MACT standard at least every eight years and revise them as necessary. In the second stage of the process, EPA is required to assess the health and environmental risks that remain after MACT has been applied. EPA must develop standards to address these remaining risks if necessary to protect the public health with an ample margin of safety or to prevent adverse environmental effects. This second stage of the process is known as the residual risk review, and must be completed within eight years of promulgation of the initial MACT standards for each source category.

In order to streamline and standardize the residual risk review for the large number of source categories at issue, EPA has developed a process by which it (1) conducts a risk assessment using currently available source and emissions data; (2) requests public comment on the source and emissions data, along with preliminary risk assessment results, through an Advance Notice of Proposed Rule Making (ANPRM); (3) addresses comments received on the ANPRM; and (4) revises the risk assessment as needed. The results of the revised risk assessment are intended to support proposals and promulgation of technology- and risk-based regulatory decisions through notice-and-comment rulemaking.

Previous SAB panels and other internal Agency and external peer review panels have reviewed aspects of the RTR methodology, as documented in the following reports:

- 1) The *Residual Risk Report to Congress*, a document describing the Agency's overall analytical and policy approach to setting residual risk standards, was issued to Congress in 1999 following an SAB peer review. Many of the design features of the RTR assessment methods were described in this report, although individual elements have generally been improved over the techniques described in that document. (available at: [http://www.epa.gov/ttn/oarpg/t3/reports/risk\\_rep.pdf](http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf))
- 2) Individual residual risk assessments – several internal peer reviews and one external peer review were conducted on risk assessments for individual source categories,

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1 including Coke Ovens ([http://www.epa.gov/ttn/atw/coke/coke\\_ rra.pdf](http://www.epa.gov/ttn/atw/coke/coke_ rra.pdf)),  
2 Perchloroethylene Dry Cleaning (<http://www.epa.gov/ttn/atw/dryperc/11-14-05riskassessment.pdf>), and Halogenated Solvent Cleaners (downloadable from:  
3 <http://www.epa.gov/ttn/atw/degrea/halopg.html>). Each of these assessments used  
4 emission estimates from the National Emissions Inventory (NEI), human exposure  
5 modeling at the census block level, dose-response methodologies, and risk  
6 characterization that are similar to those for the planned RTR assessment.  
7  
8

- 9 3) The National Air Toxics Assessment, or NATA, for 1996 was peer-reviewed by an  
10 SAB panel in 2001-2002 (the SAB peer review report is available at:  
11 [http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/\\$File/ecadv02001.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf)). NATA 1996 was a comprehensive and cumulative risk  
12 assessment designed to include all mobile sources, small industrial sources, and large  
13 industrial sources, as well as background contributions of air toxics. Because of  
14 significant uncertainties, the SAB did not believe that it was appropriate for  
15 regulatory purposes. The assessment at that time did not carry a census block-level  
16 resolution, but rather was performed at the census tract level. For this reason, on  
17 EPA's NATA website (<http://www.epa.gov/ttn/atw/natamain/>), the estimated risks are  
18 characterized as "starting points" for developing refined assessments.  
19  
20
- 21 4) AERMOD, a recently-developed source-to-receptor air quality dispersion model, was  
22 the subject of significant interagency cooperation and peer review. It is now EPA's  
23 preferred local-scale air dispersion model for industrial sources of air pollution.  
24 ([http://www.epa.gov/scram001/dispersion\\_prefrec.htm#aermod](http://www.epa.gov/scram001/dispersion_prefrec.htm#aermod))  
25
- 26 5) The individual dose-response assessment values used in the RTR assessment have  
27 themselves been the subject of peer reviews through the agencies that developed them  
28 (including EPA, through its Integrated Risk Information System, or IRIS; the  
29 California Environmental Protection Agency, or CalEPA, and the Agency for Toxic  
30 Substances and Disease Registry, or ATSDR). EPA proposes to select dose-response  
31 values for long-term exposures from these sources in the same priority order it used  
32 for NATA (*i.e.*, IRIS, then ATSDR, then CalEPA). For acute exposure toxicity, we  
33 array several indices without prioritization. This area is a source of significant,  
34 usually unquantifiable uncertainty. (IRIS - <http://cfpub.epa.gov/ncea/iris/index.cfm>,  
35 ATSDR - <http://www.atsdr.cdc.gov/mrls/>, CalEPA -  
36 [http://www.oehha.org/air/toxic\\_contaminants/index.html](http://www.oehha.org/air/toxic_contaminants/index.html))  
37
- 38 6) An earlier peer review of multi-pathway risk assessment methodologies was  
39 conducted by the EPA's SAB in 2000. The final SAB advisory is available at:  
40 [http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/\\$File/ecadv05.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/1F1893E27059DB55852571B9004730F7/$File/ecadv05.pdf).  
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1 Of particular relevance to the current review, a prior SAB panel provided a formal  
2 consultation on the *proposed* RTR Assessment methodologies in June 2007.<sup>1</sup> OAQPS  
3 revised its process to incorporate many of the SAB panel's suggestions, added significant  
4 new analysis and methods, and developed illustrative risk assessments based on the  
5 revised methodology. The current review examines the revised and expanded  
6 methodology, as illustrated through case studies for the petroleum refining and Portland  
7 cement source categories.

8  
9 The Risk and Technology Review (RTR) Methods Panel met through a public  
10 teleconference call on June 30, 2009 for a briefing on EPA's Risk and Technology  
11 Review methodology and to review the charge questions presented by the Agency. The  
12 Panel then met in a public meeting on July 28 – 29, 2009 in Research Triangle Park, NC,  
13 to review the RTR methods report. The Panel held a subsequent teleconference call on  
14 December 3, 2009 to discuss its draft advisory report. The Chartered SAB conducted  
15 quality reviews of this document on ...

## 16 17 18 19 **2.0 EPA's Charge Questions**

20  
21 EPA's charge questions for the peer review were organized into seven topic areas  
22 covering the major aspects of the proposed risk assessment methodologies. As indicated  
23 by the boxes around the text below, charge questions for several of the topic areas were  
24 grouped to focus on more specific aspects of the methodologies and case studies to which  
25 they were applied.

### 26 27 *1. Revisions to emissions data:*

28  
29 As described in Section 2.2.1 of the Report (*i.e.*, the Petroleum Refineries case study), the  
30 2002 National Emissions Inventory (NEI) serves as the starting point for RTR risk  
31 assessments. EPA performs an engineering review of data from each source category to  
32 identify and correct readily-apparent limitations and issues with the emissions data. The  
33 dataset is then published through an Advanced Notice of Proposed Rulemaking  
34 (ANPRM), making it available for public comment. EPA evaluates comments and  
35 corrections for quality and engineering consistency, revises the dataset, and develops a  
36 draft risk assessment. The dataset and the risk assessment are provided with a Notice of  
37 Proposed Rulemaking (NPRM) for a second 60-day comment period, after which further  
38 comments and corrections are evaluated and incorporated. The final rulemaking is then  
39 developed. We have attempted to assess the quality of this process in three ways.

40  

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<sup>1</sup> EPA-SAB-07-009 (2007), Available at the following URL:  
[http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf)

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- 1 • Appendix A contains a comparison of risk estimates based on EPA’s initial  
2 inventory as amended by engineering review and risk estimates based on the  
3 inventory as revised by public comment.  
4
- 5 • Appendix L contains a comparison of modeled and monitored benzene  
6 concentrations around two petroleum refineries, with the intent showing if  
7 benzene emissions from refineries may have been underestimated at these  
8 facilities.  
9
- 10 • Appendix P contains compares petroleum refinery emissions estimates and  
11 facility risk estimates using the current RTR process to emission and risk  
12 estimates from the same facilities derived using a model plant approach based on  
13 generic emission factors. The goal of this analysis was two-fold: 1) to develop a  
14 bounding estimate regarding the potential underestimation of emissions in our  
15 baseline emissions dataset; and 2) to provide an indication of how much risk  
16 estimates might change based on this potential underestimation.  
17

18 1A. Do these comparisons provide useful information about the quality of the emissions  
19 data, and ultimately the risk estimates? Can you suggest improvements to these analyses,  
20 or others that might be more useful? Should we use these results to revise our risk  
21 assessment for petroleum refineries? Given that we have relatively high confidence  
22 about benzene emissions from refineries, can you suggest ways that we can develop  
23 similar analyses for other HAPs and source categories?

24  
25 As described in Section 3.2.1 and Appendix F, we developed mean and upper confidence  
26 limit estimates for dioxins emitted from Portland cement facilities.  
27

28 1B. Does the approach used to estimate dioxin and furan emissions from Portland cement  
29 facilities represent the best available methodology in support of a risk analysis? Can you  
30 suggest improvements?

31  
32 As described in Section 3.2.2 and Appendix G, we estimated potential emissions of  
33 radionuclides, and associated inhalation cancer risks, from two Portland cement facilities  
34 using very limited data and three different derivations. The results vary by many orders  
35 of magnitude, but suggest that these risks could be substantial.  
36

37 1C. Is this approach rigorous enough to consider placing it in the RTR assessment,  
38 which has regulatory implications? If not, given the lack of reliable emissions data for  
39 radionuclides, how can we improve the approach? If the quality of emissions data  
40 remains an irreducible stumbling block, can you suggest ways to obtain better emissions  
41 data?  
42  
43  
44

1 2. *Dispersion modeling:*

2  
3 Section 2.2.2 describes our inputs to the AERMOD dispersion model for RTR  
4 assessments. We have performed the following analyses in an attempt to better  
5 understand the uncertainties and/or potential bias that may be introduced by some of  
6 these inputs:

- 7
- 8 • Section 4.4 compares exposure estimates based on one and five years of  
9 meteorological data.
- 10
- 11 • Section 4.5 presents an analysis of how the location of the meteorological station  
12 used for modeling affects the outcome.
- 13
- 14 • Section 4.6 presents an analysis of the effect on risk estimates of omitting  
15 atmospheric chemistry from the modeling of a high-impact refinery.
- 16
- 17 • Section 4.7 presents an analysis of the effect on risk estimates of omitting  
18 deposition from the modeling of Portland cement facilities.
- 19
- 20 • Section 4.8 and Appendix M present a sensitivity analysis of the uncertainties  
21 arising in the refineries assessment by estimating exposures at census block  
22 centroids rather than at the nearest residence.
- 23

24 2. Do these analyses adequately support the practices of (1) using a single year of  
25 meteorological data, (2) using facility-supplied meteorological data, when available, (3)  
26 omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling,  
27 and (5) using block centroids as surrogate exposure locations for these case studies? If  
28 so, can any or all of the analyses be applied to other source categories? If not, can you  
29 suggest ways we might improve them?

30  
31 3. *Dose-response assessment:*

32  
33 Section 2.2.6 of the Report describes our process of selecting and prioritizing dose-  
34 response values for RTR human health risk assessments. We select chronic dose-  
35 response values in the same way that we do for NATA, a process that the SAB has  
36 already reviewed in the context of NATA but not one of regulatory decision-making. We  
37 have also developed an analysis (presented in Appendix O) of the possible importance of  
38 HAPs that lack chronic dose-response values. This analysis suggests that only a few  
39 HAPs lacking such values could be important, with the degree of importance heavily  
40 dependent on the conservatism of the input assumptions.

41  
42 3A Is our process of selecting and prioritizing chronic dose-response values appropriate  
43 for RTR risk assessments? Should we consider additional sources, or a different  
44 prioritization process? Can the analysis of unassessed HAPs be improved by developing

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1 prior assumptions regarding the toxicity of these HAPs, and if so, how should this be  
2 done? Are there other ways we can improve it? Is this approach inherently limited to the  
3 current bounding exercise and tool for identifying research needs, or can it be further  
4 developed and incorporated into RTR assessments? Can you provide advice on how we  
5 can incorporate HAPs lacking dose-response values into our risk characterizations?

6  
7 We developed our selection process for acute dose-response values more recently than  
8 the one for chronic values, and it has not yet undergone SAB review. The universe of  
9 acute health benchmarks contains many gaps, as shown in Table 2-5. In addition, some  
10 of the benchmarks correspond to “no-effect” levels (e.g., CalEPA acute reference  
11 exposure levels, which are analogous to chronic RfCs), while others correspond to “mild-  
12 effect” or “severe-effect” levels (e.g., acute exposure guideline levels) that are intended  
13 to guide authorities in making emergency evacuation decisions. For these reasons we  
14 have not applied a prioritization scheme.

15  
16 We have not generally included acute minimum risk levels (MRLs, developed by the  
17 Agency for Toxic Substances and Disease Registry, or ATSDR) as dose-response values  
18 in our assessments of acute risks because of a temporal mismatch between the exposure  
19 estimates (based on one hour) and the MRLs (based on 24 hours to two weeks).

20  
21 3B. Given these gaps and inconsistencies among available acute benchmarks, do the case  
22 studies characterize acute risks adequately? Should we include ATSDR MRLs in our  
23 assessments, and if so, how can we solve the temporal mismatch? Is the use of  
24 emergency guidelines in our assessments adequately described and interpreted? Are  
25 there other acute health metrics EPA should consider using for these assessments? Do  
26 you have suggestions for improvements in any of these areas?

27  
28 *4. Chronic health assessment:*

29  
30 Section 2.2.3 describes the process by which we estimate chronic human inhalation  
31 exposures based on modeled average ambient concentrations at census block centroids.  
32 For these case studies, this process did not include consideration of either daily behavior  
33 pattern or long-term migration behavior. Section 2.2.3 presents a rationale for omitting  
34 daily behavior, and Appendix N presents a case study that adjusts inhalation-based  
35 lifetime cancer risk estimates for individuals to account for long-term migration.

36  
37 4A. Does our process of estimating inhalation exposures adequately support regulatory  
38 rulemaking? Is our rationale for omitting daily behavior convincing, or does the  
39 omission compromise the value of our assessments? Should this, or some other,  
40 adjustment for long-term migration be incorporated into our risk assessments?

41  
42 Appendix C describes a novel application of TRIM in the development of protective *de*  
43 *minimis* emission rates for 14 persistent and bioaccumulative HAPs (PB-HAPs). We  
44 believe that emissions below *de minimis* thresholds should not produce unacceptable

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1 risks in reasonable worst-case conditions. Facilities emitting below these values would  
2 not need to conduct a multipathway exposure and risk assessment.

3  
4 Section 3.4 and Appendix I describe a refined application of the TRIM model in  
5 assessing multi-pathway pollutant transport and its subsequent impacts on human health  
6 from Portland cement facility air emissions identified as having a high potential to  
7 present significant impacts on human health.

8  
9 We have limited our development of radionuclide risk estimates (described in Section  
10 3.2.2 and Appendix G) to those associated with inhalation exposure. Radionuclides were  
11 not included in the multipathway risk assessment.

12  
13 4B. Is our use of the TRIM model to develop *de minimis* emission rates appropriate as a  
14 screening tool? Are the methodologies used in the refined multipathway assessment  
15 consistent with the best available science regarding multi-pathway pollutant transport and  
16 human exposures? Are the application of the model and the assumptions used clearly  
17 articulated? Are the resultant estimates of media concentrations and exposures clearly  
18 presented, explained, and interpreted? Given the large uncertainties surrounding the  
19 radionuclide inhalation assessment, are we justified in omitting radionuclides from the  
20 multipathway assessment?

21  
22 *5. Acute health assessment:*

23  
24 Section 2.2.5 describes our process for developing screening and refined estimates of  
25 acute inhalation risk. For acute screening purposes we have assumed that, in the worst  
26 case, a person could be exposed for one hour to ten times the highest hourly  
27 concentration calculated by the dispersion model. This in effect assumes a 1-hour  
28 emission rate of ten times the annual average (assuming continuous emissions),  
29 simultaneous occurrence of “worst-case” meteorological conditions, and also the  
30 presence of a person at this worst-case downwind location.

31  
32 Appendix B presents an effort to evaluate the protectiveness of this screening assumption  
33 using detailed short-term emission data for a limited geographic area. Appendix E  
34 describes our refinement of acute risk estimates for refineries that failed the acute 10X  
35 screen, by using more accurate emission points and property boundaries.

36  
37 Our refined acute assessments do not combine acute hazard quotients associated with  
38 different HAPs because of the inconsistent nature of acute health benchmarks and the  
39 inherent conservatism of our exposure assumptions.

40  
41 5. Does the 10X acute screening assumption for petroleum refineries appear to be  
42 appropriately protective? If not, is it under- or over-protective? Given that this analysis  
43 applies only to sources in the Houston area, can we apply the 10X assumption to HAPs in  
44 other source categories or should we consider some other approach for some other HAPs,

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1 e.g., metals? Is there some other way we might address high emission events such as  
2 startup or shutdown of processes? Are the refinements to the acute screening assessment  
3 objectively employed and scientifically defensible? Should we sum acute hazard  
4 quotients by target organ in the same way we do for chronic hazard quotients, *i.e.*, a  
5 target organ specific hazard index (TOSHI) approach, or are our reasons for not doing so  
6 adequate?

7  
8 *6. Ecological assessment:*  
9

10 Section 3.5 and Appendix J describe a refined, site-specific application of TRIM to  
11 conduct an ecological risk assessment for PB-HAPs emitted by the same Portland cement  
12 facility evaluated in the human health risk assessment. Appendix J also describes a  
13 nationwide facility ranking exercise that identifies Portland cement facilities with the  
14 highest potential for causing indirect ecological effects via acidification of the  
15 environment by hydrogen chloride emissions. Appendix K describes an analysis of  
16 possible direct effects on plant foliage of air concentrations of hydrogen chloride emitted  
17 from Portland cement facilities that are below human health thresholds.  
18

19 6. Is the ecological assessment case study scientifically defensible? Does it conform to  
20 EPA risk assessment guidance (*e.g.*, *Guidelines for Ecological Risk Assessment, Risk*  
21 *Characterization Handbook, etc.*)? If not, how can we improve it? Are the elements of  
22 the ranking scheme adequate to identify the facilities most likely to be of concern? Are  
23 there better data sources or approaches for drawing conclusions for specific locations?  
24 With regard to investigating the potential for direct ecological effects at air  
25 concentrations below human health thresholds from other sources or source categories,  
26 what suggestions can be made for prioritizing additional HAPs for literature searches  
27 similar to that done for hydrogen chloride in Appendix K?

28  
29 *7. Risk characterization:*  
30

31 The risk characterizations for these two case studies (Sections 2.3 and 3.6) represent our  
32 current practices in providing information to decision-makers responsible for RTR  
33 rulemaking. The analyses presented in the appendices are by and large illustrative of  
34 what can currently be done in the regulatory context, given time and resource constraints.  
35

36 7. Do these characterizations objectively and completely incorporate the goals and  
37 principles of EPA's *Risk Characterization Handbook* to the extent scientifically feasible?  
38 In particular do they provide a complete and transparent discussion of uncertainties and  
39 limitations? If not, how can the risk characterizations be improved? Can you suggest  
40 where we might focus any additional efforts and resources in order to have the biggest  
41 impact on refining risk characterizations for these RTR assessments, ultimately leading to  
42 better regulatory decision-making?  
43

### 3.0 Response to Charge Questions

#### Charge Question 1

As described in Section 2.2.1 of the Report (*i.e.*, the Petroleum Refineries case study), the 2002 National Emissions Inventory (NEI) serves as the starting point for RTR risk assessments. EPA performs an engineering review of data from each source category to identify and correct readily-apparent limitations and issues with the emissions data. The dataset is then published through an Advanced Notice of Proposed Rulemaking (ANPRM), making it available for public comment. EPA evaluates comments and corrections for quality and engineering consistency, revises the dataset, and develops a draft risk assessment. The dataset and the risk assessment are provided with a Notice of Proposed Rulemaking (NPRM) for a second 60-day comment period, after which further comments and corrections are evaluated and incorporated. The final rulemaking is then developed. We have attempted to assess the quality of this process in three ways.

- Appendix A contains a comparison of risk estimates based on EPA's initial inventory as amended by engineering review and risk estimates based on the inventory as revised by public comment.
- Appendix L contains a comparison of modeled and monitored benzene concentrations around two petroleum refineries, with the intent showing if benzene emissions from refineries may have been underestimated at these facilities.
- Appendix P contains compares petroleum refinery emissions estimates and facility risk estimates using the current RTR process to emission and risk estimates from the same facilities derived using a model plant approach based on generic emission factors. The goal of this analysis was two-fold: 1) to develop a bounding estimate regarding the potential underestimation of emissions in our baseline emissions dataset; and 2) to provide an indication of how much risk estimates might change based on this potential underestimation.

1A. Do these comparisons provide useful information about the quality of the emissions data, and ultimately the risk estimates? Can you suggest improvements to these analyses, or others that might be more useful? Should we use these results to revise our risk assessment for petroleum refineries? Given that we have relatively high confidence about benzene emissions from refineries, can you suggest ways that we can develop similar analyses for other HAPs and source categories?

#### Panel Response

Emissions data are one of the most critical inputs to a residual risk assessment. The process for deriving emission factors for the risk and technology review (RTR) risk

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1 assessments begins with the 2002 National Emissions Inventory (NEI) data compiled for  
2 individual facilities in a given source category. The data are reviewed and revised by  
3 EPA (engineering review) followed by a two-stage public comment process (ANPRM  
4 and NPRM) leading to further revisions in response to comments. EPA has invested a  
5 great deal of effort into adapting and applying the existing NEI data to construct  
6 emissions scenarios for the RTR assessments. The Panel agrees that the overall approach  
7 described in Section 2.2.1 of the Report is rigorous and transparent, resulting in a  
8 consistent and well documented starting point for emission scenarios based on an existing  
9 and well documented data set. However, the panel is concerned that the NEI data, which  
10 reports *estimates* of *actual* emissions, may not be the most appropriate starting point for  
11 developing emissions data for the RTR risk assessments, due to possible underestimation  
12 bias and the potential that emissions could be increased within current regulatory limits.  
13 Where applicable, the Panel recommends that facility-specific *allowable* emissions be  
14 considered as a first step, to assess the effectiveness of the current MACT standards.  
15

16 EPA performed three modeling analyses for the petroleum refineries case study to assess  
17 the quality of the process for developing RTR emissions data. The first analysis  
18 (Appendix A) compares the outcome of the risk assessment using emissions data from  
19 before and after the comment period to explore how the public comment process  
20 influenced the outcome. The second (Appendix L) compares modeling results for  
21 benzene concentrations to monitoring results at two facilities to determine if emission  
22 factors may be underestimated. The third (Appendix P) compared the current approach to  
23 a category specific emissions modeling approach using generic emission factors to  
24 explore the potential for underestimation of emissions in the base-line scenario and how  
25 this might influence risk estimates.  
26

27 Overall, the Panel found the analyses described in Appendixes A, L and P to be  
28 informative and scientifically credible. Comparisons in the analyses such as the  
29 maximum individual cancer risks (MIR), cancer incidence and population exposure, HAP  
30 emissions, and toxicity weighted HAP emissions are useful for illustrating the key  
31 uncertainties in the current approach. However, the overarching result that emerges from  
32 the evaluations is the indication that self-reported facility specific emissions data in the  
33 NEI are either incomplete or biased low and that the comment and revision process fails  
34 to correct this bias.  
35

36 It is the Panel's understanding that the Agency is aware of the deficiencies in the  
37 petroleum refineries emission estimates. The City of Houston recently submitted a  
38 request for correction of information under the Data Quality Act and EPA's Data quality  
39 guidelines<sup>2</sup>. The request cites reports of underestimation of emissions by up to two  
40 orders of magnitude for refineries and chemical manufacturing plants. The EPA  
41 responded in a letter<sup>3</sup> dated April 7, 2009, expressing concurrence with the City's  
42 concerns and acknowledging the inaccuracy and uncertainty of emission estimates in the

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<sup>2</sup> <http://www.greenhoustontx.gov/reports/epaletter20080709.pdf>

<sup>3</sup> <http://www.greenhoustontx.gov/reports/dataquality20090407.pdf>

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1 inventory, particularly where there is heavy reliance on emission factors in the NEI. The  
2 Agency outlined a number of specific tasks that are currently on-going to address and  
3 fully understand this uncertainty. The planned outcome of this work, as described by the  
4 EPA, is to use the results of the emission factor verification project to help: a) evaluate  
5 risk to exposed populations; b) conduct comparisons to existing emission estimates (e.g.  
6 TRI) for specific facilities; and c) better characterize the cost effectiveness of controls.  
7 The Panel is concerned that any residual risk decision made for the petroleum refinery  
8 source category without the use of this updated and verified emissions information would  
9 be premature.

10  
11 The Panel's review of the appendices is discussed below followed by recommendations  
12 for improving the emission estimates for the RTR process.

13  
14 Appendix A: The stated purpose of Appendix A is to compare the risk assessment results  
15 using the emissions data from the engineering review with results using revised emission  
16 data that were revised following the public comment period. In addition to changes in the  
17 emissions data, a number of other changes were made to the risk assessment between the  
18 two cases. For example, Appendix A indicates that although the same risk assessment  
19 model (HEM3/AERMOD) was used in both assessments, several updates were made in  
20 the version used with the post-comment emissions data. Specifically, the meteorological  
21 data included additional meteorological stations and a newer version of the AERMET  
22 model was used along with meteorological data from different (more recent) years. In  
23 addition, updated dose-response data were used for the post-comment assessment. The  
24 appendix is silent on the potential impact of these changes relative to changes in the  
25 emissions data. Although it is likely that emissions are the dominant factor influencing  
26 the changes in the results, the validity of this assumption is not demonstrated.

27  
28 The comparison in Appendix A is focused on reported actual emissions. Thus the  
29 assessment does not identify or reflect further changes that may be needed to represent  
30 what MACT 1 petroleum refineries actually emit (as opposed to what they report  
31 emitting) or what they might emit if emissions were increased to allowable levels under  
32 existing MACT standards. The analysis would be more informative if it included  
33 adjustments to the HAP emissions from all facilities needed to reflect representative  
34 emissions across the source category.

35  
36 Another important observation from Appendix A is the relationship between the  
37 likelihood of receiving input during the public comment period and the magnitude of the  
38 individual risk values reported in the ANPRM. Figure 6 of Appendix A highlights the  
39 fact that comments were more likely to be provided for facilities for which individual  
40 cancer risk was relatively high and that these comments generally reduced the risk  
41 estimates. There is clear incentive for facilities associated with higher risk to offer  
42 corrections to the NEI data but it is unclear whether similar incentives are present to help  
43 identify underreporting facilities. The analysis would have benefited from a summary of  
44 the source of information received during the comment period to evaluate whether the

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1 comments originating from groups representing the facilities are generally balanced with  
2 comments from groups representing the community, or if facility-specific emissions data  
3 were submitted by state and local air pollution agencies. In many cases, community  
4 representatives might not have the expertise or access to emissions information to provide  
5 substantive input to the review process. Most state and local air pollution agencies rely on  
6 the emission factors contained in EPA's AP-42 Fifth Edition Compilation of Air  
7 Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources<sup>4</sup> to estimate  
8 facility emissions unless they have facility specific emissions testing data.  
9

10 Appendix L: The Panel recognizes that evaluating model performance using empirical  
11 observations is very important for increasing confidence in model-based assessments. In  
12 this Appendix, ambient benzene concentrations measured at two sampling locations were  
13 compared to modeled concentrations at or near the same sample locations for two  
14 facilities as a way of assessing the emissions data used in the risk assessment at these  
15 facilities. The assessment assumes that the dominant source of variation in modeled  
16 concentrations at the sample locations is the emissions data used in the model runs. The  
17 Appendix shows that modeled concentrations are significantly lower than monitored  
18 concentrations with the difference for one facility (Marathon facility) being much greater  
19 than the other. The report points out that a statistically significant difference does not  
20 necessarily imply practical importance. However, the analysis clearly shows both an  
21 apparent low bias in the emissions data and a low precision in the predictions from the  
22 two facilities. The analysis thus suggests the emissions data may be biased low, although  
23 inappropriate treatment of calm periods in this modeling analysis could be contributing to  
24 the apparent bias.  
25

26 While the model results suggest that emissions are biased low, it is notable that the results  
27 for the two facilities are very different. Annual averaged modeled concentrations are  
28 within 11% of the corresponding monitored values for the BP facility, but only within  
29 72% for the Marathon facility. Correspondingly, the absolute errors between the  
30 measured and modeled annual average concentrations are  $0.5 \mu\text{g}/\text{m}^3$  and  $3.4 \mu\text{g}/\text{m}^3$  for  
31 the two petroleum refineries. Given that the  $1 \times 10^{-6}$  cancer risk benchmark for benzene is  
32 an annual average concentration of  $0.128 \mu\text{g}/\text{m}^3$ , the absolute error is considerable. The  
33 difference in error between the two refineries highlights the problem with using a small  
34 sample size ( $n=2$  out of 154 refineries) to assess model performance. The small and co-  
35 located sample of two facilities makes it difficult to conclude that a high level of  
36 confidence exists in the evaluation of benzene emissions based on these results.  
37 Furthermore, the analysis depends on extensive assumptions about averaging of  
38 emissions, characterizing surface roughness, and characterizing the meteorology. The  
39 comments offered by the internal EPA reviewer about not using data from the same time  
40 periods, difficulties in characterizing wind speed and direction closer to the receptors, and  
41 not including emissions from additional sources (e.g., ship/barge traffic) are appropriate  
42 and may limit the value of this assessment.

---

<sup>4</sup> AP-42 Fifth Edition Compilation of Air Pollutant Emission Factors, Volume 1: Stationary Point and Area Sources. Available On-Line: <http://www.epa.gov/ttnchie1/ap42/>

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1  
2 Monitored ambient concentrations represent the sum of contributions from all sources. In  
3 order to estimate the portion of the ambient concentration that could be attributed to the  
4 source category or the specific facility, EPA used the following general methodology: 1)  
5 monitors in close proximity to the source were used, 2) data were evaluated by wind  
6 direction so that it could reasonably be assumed that concentrations at the monitor were  
7 related to the source (when the monitor was downwind from the source) and, 3)  
8 concentrations not attributed to the source (e.g., on-road mobile, background estimated  
9 from NATA) were subtracted from the total concentration seen at the monitor. The  
10 background estimate appears to be a type of correction factor and an attempt to account  
11 for the contributions from other sources. It is unclear where the background estimate  
12 came from and/or if dispersion modeling was used to derive it. It may be that the  
13 background value is actually a crude combination of unaccounted for fugitive emissions  
14 and error from under reporting in the emission inventory. Because the background may  
15 reflect errors in reported emissions, it may not be appropriate to subtract this source off  
16 hand from the ambient concentrations. While it is important to account for background  
17 given the long half-life of benzene, the analysis should provide a better description of the  
18 background estimate, including where it comes from and its spatial distribution.

19  
20 The choice of using meteorology from the more distant site (Galveston) when local  
21 information was available seems incorrect. Ordinarily the closest meteorological monitor  
22 should be utilized. The model-to-data comparison in this appendix needs to be  
23 appropriately adjusted under the assumption that a potentially significant error could have  
24 been introduced into these comparisons by using incorrect meteorology. The fact that  
25 there is general agreement of the plume positioning with wind direction suggests that the  
26 winds in Galveston statistically resemble the winds further inland at the refinery location,  
27 but hour-by-hour discrepancies may be significant. Although clustering of sites that  
28 behave in a similar manner is seen farther up the ship channel, the Galveston airport site  
29 is likely to act more independently given its location. This site is open and closer to the  
30 Gulf. Uncertainty in the wind direction and speed could be brought into the model and  
31 spatially assessed. EPA defends its use of data from the Galveston airport site by pointing  
32 out questions in the representativeness of the Texas City Ball Park site, which is closer to  
33 the refineries. Re-evaluation which includes a margin of error is the only way to ascertain  
34 the influence of the issues with the wind data. An additional examination of the model to  
35 monitor comparison for these two facilities using the closer meteorological data set  
36 would be useful.

37  
38 The assessment could also be improved by better coupling of the measurements at the  
39 source and receptor and discussing the confidence in the inventory for both facilities.  
40 This would strengthen the analyses. From the background documentation contained in the  
41 Air Docket (EPA-HQ-OAR-2003-0146) it appears that the BP-Texas City facility has  
42 provided a credible assessment of their inventory based on the limited model to monitor  
43 comparisons and the findings of the 22 facility study that indicated BP-Texas City  
44 seemed to properly account for benzene emissions from their storage tank facilities in

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1 comparison to other facilities.<sup>5</sup> The confidence in the inventories for the two facilities  
2 could also be discussed in the light of other findings from the 22 facility study, such as  
3 the finding that many facilities underestimate their benzene emissions from the  
4 wastewater stream by as much as factor of 40 to 1400.

5  
6 The Panel recommends expanding the assessment to include up to 15 randomly selected  
7 refineries (~ 10 % of the total) to better represent the distribution in error across facilities.  
8 It is unlikely that the discrepancy between reported and actual emissions can be assumed  
9 to be constant between facilities. To achieve a better idea of the modeled to measured  
10 error, a stratified random sample of refineries assigning strata based on, for example:  
11 size of the facility (our experience suggests that large facilities, even those that are well  
12 run, tend to have more fugitive emissions error and more error in general simply from  
13 having more sources); age of the facility (older facilities may not operate as well);  
14 compliance record (facilities with more violations may have larger under reporting error  
15 than other facilities). It appears there may be a more robust dataset (more benzene  
16 ambient air monitors located near petroleum refineries) that could be assembled and  
17 evaluated in a more comprehensive manner.

18  
19 If the analysis is limited by available monitoring data, the Panel recommends that rather  
20 than using a strict comparison of the model and monitoring results, the two data sets  
21 might be used in conjunction to provide a more comprehensive understanding of the  
22 probability or range of outcomes using for example a Bayesian approach. At a minimum,  
23 it would be useful to include a more formal uncertainty analysis and consider propagation  
24 of errors to better quantify the uncertainties and characterize the agreement with the  
25 benzene concentration data (See Bevington's book "Data Reduction and Error Analysis").

26  
27 Finally, Appendix L attempts to put the potential error into context of the overall errors  
28 expected in the risk assessment, but may be misleading in this regard. The statement on  
29 page L-1 regarding the analysis of the measured to modeled concentrations says,  
30 "[The analysis] attempts to answer the question, "are benzene emission estimates  
31 truly lower by a factor of 10 to 100 (at least for these 2 facilities), or are they  
32 close enough to be useful in residual risk decision-making?" We attempt to  
33 answer this last part keeping in mind the 2 orders of magnitude range of MIR  
34 values embodied in the residual risk decision framework."

35 This statement is not very clear, but could be interpreted to mean that the Agency might  
36 not view the level of uncertainty resulting from emissions estimates as a large concern,  
37 given that the risk range for risk management decisions under the Clean Air Act spans  
38 two orders of magnitude. But such a view could be misleading. Even if less than a factor  
39 of 10, an *underestimation bias* in the emissions estimates should still raise concerns, as it  
40 could prevent a source category from falling into the residual risk range that would  
41 otherwise require remedial action. In contrast, as discussed below, questions such as  
42 whether the centroid of a census block is modeled or population migration is included

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<sup>5</sup> Lucas, Bob. (2007). Technical Memorandum to EPA Docket No. EPA-HQ-2003-0146 from Bob Lucas, EPA/SPPD dated August 20, 2007.

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1 may be on a level of detail and sophistication rendered obsolete given the inherent  
2 uncertainty of the emissions input data.

3  
4 Appendix P: This appendix compares risk estimates developed using RTR emissions  
5 inventory data with estimates developed using emissions estimates from a process-based  
6 emissions model, the Refineries Emissions Model (REM). The results are informative.  
7 The comparison demonstrates differences in total emissions from refinery MACT 1  
8 sources (Appendix P, Table 1) of a factor of almost 3 for benzene and a factor of 50 for  
9 methanol. However, xylenes and POM 72002 are in agreement to within about 50%.  
10 There is a wide range in the ratio of REM MIR value to RTR MIR value for individual  
11 facilities (p. P-23), ranging from 0.1 to 5,000,000 (with all but one value ranging from  
12 0.1 to 5,000). Also, estimated cancer incidence for the source category is 3-4 times higher  
13 using REM emission data relative to RTR emission estimates (Appendix P, Table 3).  
14 Instructive comparisons are also provided for specific emission sources such as fugitive  
15 equipment leaks, cooling towers, HAP storage vessels, and areas for wastewater  
16 collection and treatment.

17  
18 The assessment illustrates the problem the EPA encountered with the development of the  
19 emissions inventory for this source category. The analysis in this appendix actually  
20 almost addressed the Panel's concerns about the use of actual emissions as reported in the  
21 2002 NEI. It states that the modeled REM emissions are based on MACT compliance or  
22 allowable emissions. The difference shown in Table 3 between the RTR-estimated  
23 "actual" HAP emissions (6,820 tons/year) and the REM allowable HAP emissions  
24 (17,800 tons/year) that are known to be emitted by MACT 1 petroleum refineries is stark.  
25 It is difficult to compare the risk results between these two emissions estimates and agree  
26 with the conclusion that the REM database results in a "modest increase in risk  
27 estimates" for the following reasons:

- 28 (1) the RTR used site specific emission point data (18 to 42% of the time) to  
29 estimate community impacts while the REM used default emission source release  
30 parameters for all HAP emissions placed them in the centroid of petroleum  
31 refining facilities and then estimated the risk at the centroid of the census block.  
32 This approach can underestimate the resultant MIR risk. The impact of  
33 consolidating emissions points into a centroid emissions point for large facilities  
34 with multiple emissions points has been found to underestimate impacts in the  
35 area close to the facility property boundary by a factor of 3 to 7<sup>6</sup>;
- 36 (2) the emissions estimates change the MIR cancer risk drivers (REM drivers are  
37 benzene, naphthalene and POM as compared to the RTR drivers naphthalene and  
38 POM);
- 39 (3) the REM-based analysis excludes two more toxic groups of POM that would  
40 result in an increase of the MIR and cancer incidence;

---

<sup>6</sup> USEPA, 1998. Analysis Performed for the Risk Screening Environmental Indicators. Office of Pollution Prevention and Toxics. Available On-Line: <http://www.epa.gov/oppt/rsei/pubs/index.html>

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1 (4) the REM analysis results in increases in the cancer incidence and MIR ranking  
2 of the facilities even though the two more toxic groups of POM are excluded; and  
3 (5) neither the RTR nor the REM emissions inventories attempt to account for  
4 emission releases due to upsets and malfunctions.  
5

6 The Panel does not agree with the closing statement of Appendix P, “Petroleum  
7 Refineries are highly regulated facilities for which emissions are thought to be relatively  
8 *well understood* (emphasis added) compared to many other source categories. The  
9 relative similarity in MIRs may be unique in this case. It is difficult to generalize the  
10 results of this analysis to other source categories”. This Panel is concerned this statement  
11 may convey a false degree of confidence in the emissions inventory that is not warranted  
12 for the source category as a whole, based on the information provided in the case studies.  
13  
14

15 Recommendations related to Charge 1A: The comparisons provided in Appendices A, L,  
16 and P provide a transparent and useful look at the quality of the available emissions data  
17 for use in the RTR assessments. However, the results do not instill a high degree of  
18 confidence about the hazardous air pollutant (HAP) emissions inventory. The HAP  
19 emissions inventory is the foundation of the residual risk assessment. A poor emissions  
20 inventory will result in a poor residual risk assessment. The underestimation of emissions  
21 will result in false negatives or underestimation of community risk while the  
22 overestimation of emissions and reporting of HAPs that are not expected to be emitted  
23 from the source category will result in false positives or overestimation of community  
24 risk.  
25

26 It is readily apparent that the quality of the facility-specific HAP emissions inventories  
27 ranges from good to poor. Table 2-6 (p. 2-22) clearly illustrates this problem. There are  
28 156 facilities in this data set and they do not consistently report emissions that are  
29 expected for MACT 1 petroleum refinery processes. For example only 146 out of 156  
30 facilities report benzene emissions, 129 facilities report xylene emissions, 136 facilities  
31 report toluene emissions, 130 facilities report hexane emissions and 104 report  
32 naphthalene emissions. There is no consistent reporting of polycyclic organic matter  
33 (POM) across facilities, although POM is one of the identified RTR cancer risk drivers.  
34 There are emissions of polyaromatic hydrocarbons (PAHs) total, POM, 16-PAH and  
35 individual PAHs by the facilities. It is unclear how any meaningful risk analysis could be  
36 undertaken for these emissions. There are five facilities that report a total of three tons of  
37 carbon tetrachloride emissions. The production and use of this HAP has been banned  
38 under the 1990 Clean Air Act. While there are expected to be regional differences for  
39 some HAPs emitted from this source category (i.e. methanol and MTBE), some HAPs  
40 (e.g., benzene, xylene, toluene, and hexane) should be reported by all facilities in the  
41 source category.<sup>7</sup>  
42

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<sup>7</sup> Lucas, Bob. (2007). Technical Memorandum to EPA Docket No. EPA-HQ-2003-0146 from Bob Lucas, EPA/SPPD dated August 6, 2007.

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1 The RTR case study models actual emissions using the 2002 National Emissions  
2 Inventory (NEI) and there apparently was an adjustment of these emissions using site-  
3 specific data from 22 refineries as provided by the American Petroleum Institute.  
4 However, it is not clear what adjustments were made. In particular, it is not clear  
5 whether all of the facilities' emissions inventories were adjusted by using the information  
6 contained in the August 6, 2007 technical memorandum on the Average Refinery Stream  
7 Composition. This technical memorandum clearly identifies the product specific HAP  
8 emissions that should be expected from the sources subject to the MACT 1 Petroleum  
9 Refineries NESHAP.

10  
11 The Panel recommends that EPA classify the emissions inventory (actual emissions) for  
12 the 156 facilities subject to this MACT standard by simple degrees of confidence (high,  
13 medium or low). The categorization of the 156 facilities should consider size, throughput  
14 capacity and product refined. This evaluation should also include statements about the  
15 confidence in the AP-42 emission factors for the source category. The AP-42 manual  
16 already has a ranking system for all of the individual chemical emission factors. So a  
17 characterization of the confidence in these values for the specific process emissions under  
18 evaluation should be included in the residual risk assessment.

19  
20 The primary goal of the residual risk assessment should be to assess the impacts of HAPs  
21 in the surrounding community within the bounds of what is permissible or allowable by  
22 the National Emission Standard for Hazardous Air Pollutants. As a first step, the facility-  
23 specific MACT 1 allowable emissions should be modeled. The modeling of NESHAP or  
24 MACT allowable emissions is necessary since the individual facilities are allowed by  
25 federal regulation to emit HAPs in these quantities into the surrounding community. The  
26 EPA cannot accurately assess effectiveness of the NESHAP to reduce risk and be  
27 protective of public health and the environment by modeling actual emissions from these  
28 facilities, especially if the actual emissions are way below what is allowed to be emitted  
29 by the NESHAP. Beyond modeling residual risk from allowable emissions, a second step  
30 would be the modeling of actual facility emissions to assess the current risk in the  
31 surrounding community. The RTR case study focuses on this second issue, but it does not  
32 adequately address the issue that these facilities can increase HAP emissions to  
33 permissible NESHAP levels.

34  
35 The Panel recommends that EPA model REM allowable emissions using the same  
36 emissions point information and toxicity factors as used in the RTR to properly assess the  
37 residual risk associated with sources regulated by the National Emission Standards for  
38 Hazardous Air Pollutants from Petroleum Refineries (Code of Federal Regulations Part  
39 63 Subpart CC) (MACT1 Petroleum Refineries). This type of analysis will better assist  
40 EPA to meet with greater confidence the two-fold goal of the RTR as stated in the June  
41 17, 2009 charge memorandum.

42  
43 The Panel has some additional suggestions for improving the HAP emissions inventory  
44 for these and other source categories subject to residual risk assessments. First, EPA

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1 could adopt a consolidated emissions reporting rule for hazardous air pollutants that  
2 requires all major facilities subject to Part 63 NESHAPs to uniformly report their actual  
3 and allowable emissions along with emission point parameters on an annual or semi-  
4 annual basis. The two case studies presented in this review and previous residual risk  
5 assessments appear to have suffered because of the lack of a federal requirement to report  
6 HAP emissions in a consistent and uniform manner. An alternative way to address this  
7 issue is to rely on facility specific compliance inspection information (state and federal)  
8 and Section 114 data requests. The information collected during compliance and  
9 enforcement proceedings is some of the most thorough information collected on facility  
10 specific emissions. Unfortunately, these data are usually sealed until an enforcement  
11 action is completed and in most cases will reflect sources that are out of compliance with  
12 state and federal air pollution standards. The mining of these data is also labor intensive.  
13 A third alternative would be to work closely with state and local air pollution control  
14 agencies to gather any facility specific emissions testing data that can be useful in the  
15 preparation of residual risk assessments.

**Charge Question 1B**

19 As described in Section 3.2.1 and Appendix F, we developed mean and upper confidence  
20 limit estimates for dioxins emitted from Portland cement facilities.

22 1B Does the approach used to estimate dioxin and furan emissions from Portland cement  
23 facilities represent the best available methodology in support of a risk analysis? Can you  
24 suggest improvements?

**Panel Response**

28 The primary purpose of the risk and technology review (RTR) for Portland cement  
29 facilities is two-fold: (1) to evaluate the residual risk to public health and the environment  
30 that remains after the application of the initial technology or emission limits contained in  
31 the Portland cement NESHAP; and (2) to critically analyze the performance of the air  
32 pollution control requirements of the current NESHAP and evaluate whether the original  
33 allowable dioxin/furan (D/F) emission limits could be reduced further, if this is shown to  
34 be technologically feasible by actual testing data. For the first step of this process, the  
35 Panel recommends that residual risk assessments be conducted using the current source-  
36 specific NESHAP allowable emission rate in combination with each facility's maximum  
37 permitted production rate. This should be done whenever NESHAP emission limits have  
38 been set for specific hazardous air pollutants. In particular, using estimated emissions that  
39 exceed the NESHAP limit is not appropriate for the residual risk assessment. Because  
40 allowable limits were not modeled for D/F emissions from Portland cement facilities, we  
41 do not believe the approach used in the case study represents the best available  
42 methodology in support of a residual risk analysis. There is no need to estimate D/F  
43 emissions for Portland cement facilities, when allowable limits exist.

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1 The final Portland Cement NESHAP, 40CFR Part 63 LLL contains two D/F emission  
2 limits: (i) 0.20 nanograms per dry standard cubic meter ( $8.7 \times 10^{-11}$  grains per dry  
3 standard cubic foot) (TEQ); or (ii) 0.40 nanograms per dry standard cubic meter ( $1.7 \times$   
4  $10^{-10}$  grains per dry standard cubic foot) (TEQ) when the average of the performance test  
5 run average temperatures at the inlet to the particulate matter control device is 204 °C  
6 (400 °F) or less. For new and existing Portland cement kilns, the residual risk assessment  
7 should model these currently allowable emission rates of D/F in combination with stack  
8 flow rates corresponding to maximum permitted production rates for each facility. The  
9 information needed for this assessment should be available from the required compliance  
10 testing information for every Portland cement facility identified in the case study. If  
11 these allowable D/F emission limits result in an unacceptable risk to public health and the  
12 environment after the completion of the multi-pathway risk assessment as conducted in  
13 the case study, a decision to lower these existing D/F limits should be made.

14  
15 It appears that if EPA used allowable D/F emissions in its analysis, none of the Portland  
16 cement facilities considered would screen out of needing a refined multipathway  
17 assessment based on the emission thresholds presented in Appendix C-4.5.1. However,  
18 since the risk from D/F exposure is primarily driven by the fish and beef/dairy  
19 consumption exposure pathways, EPA could consider screening out facilities that have  
20 negligible potential to impact fishable waters and beef and dairy farms.

21 In the second step of the RTR process, the NESHAP compliance testing information for  
22 D/F emissions from each facility should be collected and critically evaluated to determine  
23 if it is technologically feasible to reduce the current Portland cement NESHAP D/F  
24 emission limits. This compliance information should be readily available upon request  
25 from the states or EPA regional offices. The information presented in the case study  
26 demonstrates that the D/F emissions from the various kiln types can significantly vary.  
27 The review of actual compliance data by kiln type could lead to the establishment of  
28 lower D/F emission limits by kiln type sub-categorization as determined through a  
29 technology review of the existing compliance data. The review should also address the  
30 issue that many Portland cement kilns burn alternative fuels that are not classified as  
31 hazardous waste (tire-derived fuel, used oil) and the influence of these materials on  
32 dioxin emissions needs to be considered and noted in any future analyses. The  
33 availability of the D/F compliance testing data for this source category should result in a  
34 more robust analysis of the technological feasibility of lowering these D/F limits by kiln  
35 type, which is independent of the residual risk assessment requirement.

36  
37 A specific comment about how the risk assessment information for D/F is presented in  
38 Portland cement case study is warranted. The Agency should be cognizant of how the  
39 results of the residual risk assessments will be perceived by the public in the impacted  
40 communities. Public concerns about the impacts of D/F emissions are extremely high.  
41 The methodology used in the case study could raise unnecessary public concern about  
42 fish consumption in the community, the consumption of beef and dairy produced in the  
43 surrounding area, and adverse effects on wildlife that would not be warranted if the

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1 Ravena plant is in compliance with the current NESHAP D/F emission limit. Based on  
2 additional information that EPA provided to the SAB panel, the use of the 95% UCL  
3 emission factor developed for wet kilns and listed in Table F-3 would result in a violation  
4 of the current NESHAP D/F emission limit. The application of this emission factor in the  
5 residual risk assessment would result in a false positive risk result or an overestimate of  
6 the MIR risk. In general, residual risk assessments should rely on the use of NESHAP  
7 allowable emission rates when available for specific hazardous air pollutants in  
8 combination with maximum production rates. In contrast, use of the 95% UCL of  
9 available actual data as a default emission rate estimate may be appropriate for i) source  
10 categories that do not have a NESHAP emission limit for D/F, and ii) all other HAPs that  
11 do not have a current NESHAP emission limit.

12  
13 Finally, EPA needs to carefully verify the emission point parameters it uses in its analysis  
14 for the Portland cement industry. The stack exit temperature they used in the case study  
15 for the Ravena facility appears to be off by 115 °F. The report lists it as 350°F whereas  
16 the 2003 stack testing report for the facility indicates it is 465 °F.

**Charge Question 1C**

17  
18  
19  
20 As described in Section 3.2.2 and Appendix G, we estimated potential emissions of  
21 radionuclides, and associated inhalation cancer risks, from two Portland cement facilities  
22 using very limited data and three different derivations. The results vary by many orders  
23 of magnitude, but suggest that these risks could be substantial.

24  
25 1C Is this approach rigorous enough to consider placing it in the RTR assessment, which  
26 has regulatory implications? If not, given the lack of reliable emissions data for  
27 radionuclides, how can we improve the approach? If the quality of emissions data  
28 remains an irreducible stumbling block, can you suggest ways to obtain better emissions  
29 data?

**Panel Response**

30  
31  
32  
33 The Panel commends EPA for its effort to estimate emissions and cancer risks due to  
34 radionuclide emissions from Portland cement facilities. Emissions of isotope-specific  
35 radionuclides warrant careful characterization and evaluation for Portland cement  
36 facilities and other facilities that have the potential to emit relevant radionuclides.

37  
38 EPA's proposed approaches to estimating inhalation cancer risks due to radionuclide  
39 emissions from Portland cement facilities indicate that such risks could be substantial.  
40 EPA found more than 80 of the 91 facilities assessed had estimated Maximum  
41 Incremental Risks (MIR) from radionuclide releases in excess of  $2 \times 10^{-6}$  (Exhibit G-12).  
42 However, the proposed analysis should not be formally included in the RTR assessment  
43 until further progress is made to quantify the isotope-specific radionuclide emissions and  
44 the associated risks. The revised approach should also consider the potential for multi-

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1 pathway exposure of isotope specific radionuclides (e.g., dietary exposure pathways,  
2 Exhibit G-13).

3  
4 The draft RTR report relies heavily on non-isotope specific radionuclide emissions  
5 reported in the 2002 National Emissions Inventory (NEI) for two Portland cement  
6 facilities in California and on results from emission modeling for radionuclides at the  
7 Maastricht Portland cement facility in the Netherlands (Leehouts et al., 1996,  
8 <http://rivm.openrepository.com/rivm/bitstream/10029/10172/1/610053003.pdf>). EPA  
9 provided alternative evaluations with emissions estimated by scaling <sup>210</sup>Po and <sup>222</sup>Rn to  
10 clinker production; scaling to particulate matter (PM) emissions; and by assuming all  
11 radionuclide emissions reported to the NEI were either <sup>210</sup>Po or <sup>222</sup>Rn. EPA clearly stated  
12 the assumptions used in estimating the radionuclide emissions under each approach.  
13 However, the assumptions need to be improved as described below before radionuclide  
14 risk estimates are incorporated into RTR assessments.

15  
16 EPA's analysis demonstrates that isotope-specific radionuclide emissions estimates are  
17 needed instead of using 2002 NEI data that do not include such speciation. In particular,  
18 emissions and risk estimates EPA obtained by assuming NEI radionuclide mass  
19 emissions were all <sup>210</sup>Po were implausible, illustrating the importance of completing  
20 careful engineering review of input data before beginning risk modeling.

21  
22 Radionuclides such as uranium and thorium also exist in many geological materials at  
23 ppm(m) concentrations. The radionuclide content of feedstocks used to produce Portland  
24 cement should be characterized at important locations across the US where these  
25 feedstocks are mined. Other toxic trace elements, such as mercury, could also be  
26 considered at the same time. Such information should be available in the literature, as it is  
27 for other geologic materials such as fossil fuels. EPA's Indoor Environments Division  
28 (IED, located within ORIA and under OAR), the US Geological Survey (e.g.,  
29 Radioactive Elements in Coal and Fly Ash: Abundance, Forms, and Environmental  
30 Significance, USGS Fact Sheet FS-163-97, Oct 1997), the National Institute of Standards  
31 and Testing (NIST), the US Nuclear Regulatory Commission, and nuclear engineering  
32 and geology departments at academic institutions are possible sources of such  
33 information. Any source category that has the potential to cause increased local  
34 exposure to airborne radon and polonium needs to have this issue addressed as part of the  
35 RTR process.

36  
37 With information on radionuclide content of feedstocks, screening material balance  
38 calculations such as those done by Leenhouts et al. (1996) for the Maastricht facility  
39 should be performed to estimate isotope-specific radionuclide emissions from Portland  
40 cement facilities. This analysis should use data for US feedstocks and estimate the  
41 atmospheric emissions that would occur after implementing MACT. Thus, a much  
42 improved screening for potential radionuclide emissions should be performed by using  
43 mean and upper confidence limit literature data for isotopes in the feed materials and  
44 information about the operating conditions of the facility (e.g., temperature and chemical

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1 reactions in the process). Such information may also provide insight as to how to reduce  
2 radionuclide emissions during the production of Portland cement.

3  
4 If results from revised screening calculations are not acceptable or data are not available  
5 to support such analyses, then source information describing isotope-specific  
6 radioactivity should be obtained from select Portland cement facilities, including results  
7 from stack tests. Such information should include descriptions of the isotope-specific  
8 radionuclides that are processed and then emitted from the Portland cement facilities.

9  
10 Emission characterization of the radionuclides could also be improved by evaluating  
11 closure between measured radioactivity at receptors near a Portland cement facility to  
12 radioactivity predicted using estimated source strengths and dispersion modeling; this  
13 evaluation would be similar to what was done for the petroleum refinery case study in  
14 this review. The feasibility of undertaking such an evaluation assumes ambient  
15 radioactivity levels are detectable near the sources, considering background values and  
16 detection limits of analytical techniques.

## 17 Charge Question 2

18  
19  
20 Section 2.2.2 describes our inputs to the AERMOD dispersion model for RTR  
21 assessments. We have performed the following analyses in an attempt to better  
22 understand the uncertainties and/or potential bias that may be introduced by some of  
23 these inputs:

- 24  
25 • Section 4.4 compares exposure estimates based on one and five years of  
26 meteorological data.
- 27  
28 • Section 4.5 presents an analysis of how the location of the meteorological station  
29 used for modeling affects the outcome.
- 30  
31 • Section 4.6 presents an analysis of the effect on risk estimates of omitting  
32 atmospheric chemistry from the modeling of a high-impact refinery.
- 33  
34 • Section 4.7 presents an analysis of the effect on risk estimates of omitting  
35 deposition from the modeling of Portland cement facilities.
- 36  
37 • Section 4.8 and Appendix M present a sensitivity analysis of the uncertainties  
38 arising in the refineries assessment by estimating exposures at census block  
39 centroids rather than at the nearest residence.
- 40

41 2 Do these analyses adequately support the practices of (1) using a single year of  
42 meteorological data, (2) using facility-supplied meteorological data, when available, (3)  
43 omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling,  
44 and (5) using block centroids as surrogate exposure locations for these case studies? If

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1 so, can any or all of the analyses be applied to other source categories? If not, can you  
2 suggest ways we might improve them?

3  
4 **Panel Response**

5  
6 The dispersion modeling for primary HAPs used in risk assessments is well developed  
7 and appropriate. Any modeling entails uncertainties, and the series of case studies  
8 presented in Section 4 provide a broad picture of model performance and sensitivity for  
9 this risk assessment. EPA has presented calculations justifying the use of several  
10 simplifications for performing longer-term impact and risk assessments. Some  
11 simplifications were shown to introduce relatively minor changes to risk estimates most  
12 of the time. However, there were some areas where simplifications introduced changes in  
13 risk estimates that could be appreciable, and in other areas further investigation is  
14 required in order to adequately justify the conclusions.

15  
16 Use of a single year of meteorology: The sensitivity analysis of the use of one versus five  
17 years of meteorological observations is well done, and shows that most of the time,  
18 uncertainties of less than 10% are introduced in calculated concentrations, although  
19 maximum annual or hourly concentrations can differ by up to 10-40% at some locations  
20 and times. While the conclusion of this section suggests that uncertainties in risk  
21 estimates due to the inclusion of more meteorological observations are minor if reported  
22 risk estimates are limited to one significant figure, we suggest that use of more than one  
23 year of meteorological observations is desirable in order to capture worst-case scenarios.  
24 At most sites, numerous years of meteorology observations are available and should be  
25 examined to ensure impacts are not underestimated.

26  
27 If more meteorological observations are used in any longer-term impact analysis,  
28 markedly higher concentrations and impacts may be encountered on hourly scales, while  
29 annual averages are expected to fluctuate by smaller amounts (relative to maximum  
30 hourly impacts) under the influence of more smoothly-varying averaged year-to-year  
31 meteorological variations. It is standard EPA procedure in New Source Review  
32 permitting to utilize five years of meteorological data, and the SAB recommends  
33 following this protocol when feasible. Unless there are serious computational or labor  
34 resource limitations, we suggest that maximum annual-average impacts be defined from  
35 the worst year of several years' analysis. Acute impacts should be calculated using the  
36 worst 1-h impacts calculated using whatever number of years worth of meteorological  
37 data are available for analysis.

38  
39 It appears that there is a potentially serious underestimation bias in the dispersion  
40 modeling due to the ambiguous treatment of "calm" periods that have no definable wind  
41 directions. This factor could be contributing to AERMOD calculating lower  
42 concentrations than observed, as seen in the petroleum refineries case study (Appendix  
43 L). The highest concentrations generally occur during calm periods, and the emissions  
44 modeling analysis appears to ignore calm periods, treating them as equivalent to missing

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1 meteorological measurements. By ignoring these periods, potentially significant errors  
2 that underestimate maximum concentrations will result. Such a simplification needs to  
3 be investigated before concluding that emissions information might be biased low. EPA  
4 should clarify how calm periods are treated in AERMOD, and consider whether the  
5 approach needs to be revised to avoid underestimating risks and health impacts.

6  
7 The methods for choosing an individual year for risk assessment suggested here could be  
8 applied to other source categories, but depending on source stack characteristics, some of  
9 the quantitative conclusions of EPA's sensitivity studies may not transfer. Apparently for  
10 the refinery source category used in this 1 versus 5 year sensitivity study, HAP emissions  
11 were mostly ground-level sources without significant stack heights or plume rise. For  
12 other source categories that are emitted in buoyant plumes or from elevated stacks, the  
13 confounding effects of plume rise will appreciably influence calculated impacts, and it is  
14 possible that differences between 1 and 5 years of meteorology could be greater than the  
15 differences shown in this sensitivity study, which was dominated by ground-level  
16 sources.

17  
18 Use of facility-supplied meteorology<sup>8</sup>: The choice of meteorological data for performing  
19 risk assessments appears to have a significant impact on calculated risks, as demonstrated  
20 in the sensitivity studies presented in section 4.5. In this section, EPA compared risk  
21 estimates for four petroleum refineries that were derived using meteorological data from  
22 three to five different meteorological stations, each within about 200 km of the source.  
23 The "overall summary" of this section that "differences usually fall within rounding error  
24 for the one-significant-figure characterization of risk" is somewhat inconsistent with the  
25 results shown in Table 4-2, which show that differences greater than a factor of two are  
26 common, and there is no consistent trend in these differences with distance from emission  
27 source. In all likelihood, these appreciable differences result from the fact that even the  
28 closest National Weather Service meteorological monitor only crudely captures the  
29 hourly meteorology that is representative of conditions near emission sources and impact  
30 receptors. Over broad areas, especially in the western U.S., there can be gross errors  
31 introduced in air quality impacts calculated using the closest NWS meteorological  
32 monitor. Sometimes several mountain ridges or valleys may lie between a particular site  
33 and a meteorological monitor. Given the small horizontal scales of 1-hr winds (boundary-  
34 layer scale – less than 1-2 km), one would expect discrepancies similar to those shown in  
35 this sensitivity study for monitors separated by only 1-10 km from some source locations.  
36 As noted in comments on Appendix L, it would be desirable to use facility-provided  
37 meteorology for risk assessments if available. Unfortunately, site-specific meteorology is  
38 probably not available for most facilities, and this remains a significant source of

---

<sup>8</sup> It appears that this charge question is poorly worded, since the use of "facility provided" meteorology is not addressed in the sensitivity study. In the preamble to the charge question it is noted that the study covers the "location of meteorological station", and section 4.5 mentions that two refineries furnished meteorology data, but results from these "facility-supplied" meteorology are not presented. Therefore, the Panel interpreted the charge question to more generally consider EPA's selection of meteorological stations.

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1 uncertainty in any risk assessment calculation. The potential errors introduced by using  
2 meteorology that is not representative of a given source or receptor location is partially  
3 ameliorated by using as long a record of meteorological data as is computationally  
4 feasible, to increase the probability that high impact conditions are encountered.

5  
6 The underlying problem of using meteorology that is representative of each source  
7 location is an endemic problem for any risk assessment irrespective of the source  
8 category considered. The best method for quantifying whether the closest NWS station  
9 meteorology is “representative” of any emission source point would be to quantitatively  
10 compare source-specific onsite meteorology measurements with nearby NWS monitors,  
11 and perform sensitivity analysis comparing the use of onsite meteorology versus using  
12 the nearest NWS observations as input. This direct comparison was not done in this  
13 analysis, as onsite data were not included in the comparisons, so the conclusions of this  
14 section suggesting that using “nearest NWS” site meteorology introduces relatively minor  
15 uncertainties in risk assessments is not well established by the sensitivity studies  
16 presented here.

17  
18 Omitting atmospheric chemistry: Many emitted HAPs undergo relatively slow  
19 photochemical oxidation following release. The sensitivity study presented in section 4.6  
20 addresses only the decrease in concentrations of emitted (primary) HAPs due to oxidation  
21 during photochemical aging. It is well known that the time scales for photochemical  
22 transformations of most HAPs are considerably longer than the transport times between  
23 sources and highly impacted receptors, and therefore the concentrations of emitted HAPs  
24 will decrease by relatively small amounts due to photochemical processes. Under these  
25 conditions, ignoring atmospheric chemistry would be reasonable for these risk  
26 assessments, and the sensitivity study presented in section 4.6 adequately demonstrates  
27 this.

28  
29 However, several organic HAPs (e. g. formaldehyde) are formed during the oxidation of  
30 other emitted volatile organic compounds, and it is not obvious that ignoring  
31 photochemical formation of secondary (formed) HAPs is reasonable. Therefore, an  
32 additional study of secondary HAP *formation* needs to be performed in order to rule out  
33 the need for incorporating complex photochemistry in these risk assessments. Such a  
34 sensitivity study could involve running a short-term (2-4 hour simulation) photochemical  
35 “box model” including a gas-phase chemical mechanism under typical daytime  
36 conditions for a broad range of VOC/NO<sub>x</sub> emission profiles representative of various  
37 source categories, then estimating the secondary formation of HAPs such as  
38 formaldehyde. The calculated concentrations of secondary HAPs from a simple box  
39 model alone could provide concentrations that could then be used as inputs to screening  
40 models of potential risk assessments to ascertain whether secondary HAP formation  
41 could be an important contributor to air quality risk endpoints.

42  
43 The results of EPA’s analysis of the omission of HAP *decay* in risk assessments could be  
44 applied to other source categories. However, it is possible that secondary HAP *formation*

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1 could be significant for some HAP source categories. As noted above, further sensitivity  
2 studies of secondary HAP formation would be required to rule out the necessity of  
3 including complex photochemical modeling for future HAP risk assessments.  
4

5 Omitting deposition: It is well known that the time scales for deposition are considerably  
6 longer than the transport times between sources and highly impacted receptor locations,  
7 so during this time the concentrations of emitted HAPs will decrease by relatively small  
8 amounts due to deposition. Under these conditions, ignoring deposition would be  
9 reasonable for these risk assessments. Section 4.7 confirms this conclusion through a  
10 rigorous and reasonable comparison of risk assessments performed with and without  
11 deposition, showing changes of a few percent or less for a handful of facilities. Based on  
12 this study, it is expected that the simplification of omitting deposition could be  
13 generalized to other source categories when performing HAP risk assessments.  
14

15 Use of census block centroids rather than the nearest residence: This analysis suggests  
16 that cancer risks calculated at census block centroids are usually the same, or sometimes  
17 considerably greater than (up to 2000%!) risks calculated at individual residences within  
18 a census block. This analysis appears to contain some fundamental simplifications that  
19 render the results somewhat ambiguous. It appears that risk impacts have been  
20 interpolated to residence locations from centroid and polar grid receptors, rather than  
21 explicitly calculated using AERMOD (Appendix M). Furthermore, the residence impacts  
22 have been unrealistically set to centroid impacts if the census blocks are “small”, or if  
23 residences are “near” the centroid, or if the polar grid was “not adequate” to interpolate to  
24 a particular residence. These vague interpolation methods will produce residence impacts  
25 that are identical to the centroid impacts quite often in an unrealistic fashion. It is also  
26 possible that the conclusions of this sensitivity study may be an artifact of the particular  
27 configurations of census block maps and residence locations used for the subset of  
28 facilities (21 of 154) chosen. It is possible that large underestimations of risk could occur  
29 for other facilities, other source categories, or census block/residence configurations.  
30

31 In order to correctly assess whether impacts at census block centroids reasonably assesses  
32 risks at actual residences within census blocks, the HEM-AERMOD system should be  
33 run twice with different sets of receptors: (1) a receptor grid of census block centroids,  
34 and (2) a receptor grid with residences tagged as receptors. Maximum health risk impacts  
35 would be directly compared using these two receptor grids for a number of facilities. The  
36 AERMOD model itself should be run for actual residences in order to accurately assess  
37 risks at those residences.  
38

39 Another area of concern related to this sensitivity study entails the use of a limited subset  
40 (21 of 154) of facilities considered. In order to compare centroid versus residence impacts  
41 and draw general conclusions, it is not necessary to explicitly simulate all 154 facilities  
42 associated with this source category; a carefully chosen, stratified subset of facilities  
43 could be used to draw more general conclusions. In this study, the subset was restricted to  
44 the 21 facilities with the greatest MIR. These 21 facilities may not be representative of

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1 the range of possible census-block/ residence locations, meteorology, and source  
2 configurations that would influence the differences between impacts at residences and  
3 centroids. Clearly a better criterion must be used to define a “representative” subset of  
4 test cases. For example: urban, suburban and rural facility locations should probably be  
5 sampled, even if some of these facilities have low impacts.

6  
7 It is possible that the conclusions of any sensitivity study of receptor locations will not be  
8 generally applicable to other source categories. HAP emissions for this sensitivity study  
9 are dominated by ground-level sources without significant stack heights or plume rise.  
10 Under these conditions the greatest impacts will be in census blocks closest to the  
11 facilities. For other source categories that are emitted in buoyant elevated stacks, the  
12 confounding effects of plume rise can move the regions of greatest impact further from  
13 the source locations. It is possible that differences between block centroids and individual  
14 residences could be greater than the differences shown in this sensitivity study for source  
15 categories that are characterized by elevated buoyant emissions from smokestacks.

**Charge Question 3A**

16  
17  
18  
19 Section 2.2.6 of the Report describes our process of selecting and prioritizing dose-  
20 response values for RTR human health risk assessments. We select chronic dose-  
21 response values in the same way that we do for NATA, a process that the SAB has  
22 already reviewed in the context of NATA but not one of regulatory decision-making. We  
23 have also developed an analysis (presented in Appendix O) of the possible importance of  
24 HAPs that lack chronic dose-response values. This analysis suggests that only a few  
25 HAPs lacking such values could be important, with the degree of importance heavily  
26 dependent on the conservatism of the input assumptions.

27  
28 3A Is our process of selecting and prioritizing chronic dose-response values appropriate  
29 for RTR risk assessments? Should we consider additional sources, or a different  
30 prioritization process? Can the analysis of unassessed HAPs be improved by developing  
31 prior assumptions regarding the toxicity of these HAPs, and if so, how should this be  
32 done? Are there other ways we can improve it? Is this approach inherently limited to the  
33 current bounding exercise and tool for identifying research needs, or can it be further  
34 developed and incorporated into RTR assessments? Can you provide advice on how we  
35 can incorporate HAPs lacking dose-response values into our risk characterizations?

**Panel Response**

36  
37  
38  
39 Process of selecting and prioritizing chronic dose-response values: The approach used in  
40 the RTR assessments is reasonable, but too simplistic in that it accepts dose-response  
41 numbers at face value, without much understanding of the quality or validity of the  
42 value(s) chosen. Of concern is that some values have been developed quite some time  
43 ago using older data, which may be obsolete, while others have been developed more  
44 recently and incorporate new findings. Even dose-response values that use the same up-

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1 to-date database are not equivalent, as different agencies do not derive hazard values in  
2 the same way. For example, for the benchmark methods, EPA and CalEPA apparently  
3 both take the lower 95<sup>th</sup> confidence limit of the dose of interest, but then look at the dose  
4 level that causes a 10% (EPA) or a 1 or 5% (CalEPA) incidence of the critical effect. In  
5 many cases, the differences in chronic dose-response values will not significantly alter  
6 the RTR risk assessment, but they do suggest a need to carefully consider any significant  
7 differences in chronic dose-response values so that the credibility of the risk assessment  
8 is not impaired by selection of an outdated data point.  
9

10 To address this concern, the Panel recommends that a table of chronic toxicity values be  
11 created. The table should include all the chemicals under consideration, all of the eligible  
12 dose-response values (e.g., if both EPA and CalEPA have values for the same chemical,  
13 both should be included), the source of the value, the year the value was last updated,  
14 and a qualitative description of the effect (e.g., eye irritant, neurotoxicant, reproductive  
15 toxicant, cancer classification) as all effects do not have equal health impacts. The  
16 entries in the table should be reviewed for consistencies among the values available for  
17 each chemical. If the chronic dose-response values are significantly different between  
18 agencies, especially if the value is a driver for the risk assessment, a review should be  
19 conducted to understand why the values differ. By necessity, professional judgment will  
20 need to be used during the chronic dose-response value selection process to decide which  
21 value is most appropriate to use based upon thoroughness of the data review, consistency  
22 of the dose-response modeling with the underlying science base, and the agency's  
23 objectives for public health protection. All of this analysis can be part of an appendix,  
24 with the text only having the information selected for use in the assessment.  
25

26 Furthermore, if a chemical appears to be a driver of the assessment, the assessor should  
27 further review the value and examine how recently it had been developed. If it was  
28 developed more than 7 years ago, a literature search should be performed to identify  
29 studies that may alter or update the value. If such studies are identified, the chemical  
30 should be considered for recommendation to the Integrated Risk Assessment System  
31 (IRIS) high priority revision list for review of the dose-response value.  
32

33 The preferred database for chronic dose-response data should be the IRIS database. The  
34 Panel strongly recommends that EPA update the values in IRIS and provide the resources  
35 necessary to maintain the updating process. Concern about the quality of the IRIS  
36 database and approaches to keeping it up-to-date have previously been addressed by the  
37 SAB and others.<sup>9</sup> The Panel endorses these recommendations for change in the IRIS  
38 database and process for updating the database.  
39

---

<sup>9</sup> As stated on page 56 of the Residual Risk Report to Congress under the heading, Data Availability, Limitations, and Closing Data Gaps, the preferred source of dose-response data for conducting federal risk assessments is the IRIS database. However as discussed in a recent GAO report (available at <http://www.gao.gov/new.items/d09773t.pdf>), the IRIS database is at serious risk of becoming obsolete due to an absence of timely updates of existing IRIS values and a significant backlog of ongoing assessments.

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1 The use of additional sources of data should be considered; however, if additional sources  
2 of data are used they should be ones that have undergone adequate and rigorous scientific  
3 peer review. The inclusion of additional sources of dose-response values into the  
4 hierarchy needs to be adequately documented in a transparent manner in any residual risk  
5 assessment case study.

6  
7 The American Conference of Governmental Hygienists Threshold Limit Values (TLVs®)  
8 could be considered for use as an additional source of data for screening purposes, when  
9 other values are not available. The TLVs have been determined for healthy workers;  
10 therefore, for use in the residual risk process, the values would require time adjustment  
11 from a 40-hr workweek to a 24 hr/day, 7 day/ week exposure (168 hrs/week). Further  
12 adjustment for consideration of protection for susceptible populations would be needed,  
13 and if a TLV is not considered a No Observed Adverse Effect Level (NOAEL), another  
14 adjustment factor might be needed.

15  
16 Analysis of unassessed HAPs: The SAB has previously commented on the importance of  
17 having reliable dose-response values for all of the HAPs listed in the 1990 Clean Air  
18 Act.<sup>10</sup> The residual risk exercise emphasizes, once again, the importance of having  
19 accurate, current information in the Agency's IRIS database.

20  
21 Appendix O provides the rationale for selecting dose-response values based on chemicals  
22 that have already been thoroughly evaluated. It is an interesting attempt to fill the void  
23 and create some type of toxicity ranking scheme to prioritize HAPs for toxicity testing  
24 and dose-response assessment and for the use of surrogate reference concentrations (RfC)  
25 and unit risk estimate (URE) values in the residual risk assessment process. There  
26 appears to be extremely limited and highly variable information about the emissions of  
27 some of these HAPs, which handicaps the prioritization process. The HAPs that are  
28 being reviewed by this process have large data gaps for which professional judgment is  
29 needed to derive surrogate RfCs and UREs. This approach creates more uncertainty in  
30 the selection of a surrogate RfC or URE for use in the residual risk case studies.

31  
32 We assume based on our reading of the case study text that surrogates were chosen as  
33 follows: All values in Table 1 of the indicated reference were evaluated for percentiles,  
34 resulting in the table at the top of page O-2. Thus, a chemical having no URE or RfC is  
35 assumed to fall into the same percentiles as chemicals that had such values. Then the  
36 emissions of a chemical having no URE or RfC were multiplied by the percentiles,  
37 creating values that show up on Figure O-1. The Panel recommends that the Agency  
38 expand the methods discussion to include a better description of the toxicity weighted  
39 emissions (TWEs) for chemicals having UREs and RfCs, using some of the language  
40 from the Air Toxics Risk Assessment Reference Library (see

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<sup>10</sup> Review of the US EPA's report to Congress on Residual Risk. EPA-SAB-EC-98-013; Advisory on the USEPA's draft Case Study Analysis of the Residual Risk of Secondary Lead Smelters. EPA-SAB-EC-ADV-00-005; Advisory from the National-scale Air Toxics Assessment. NATA – Evaluating the National-Scale Air Toxics Assessment 1996 Data – SAB Advisory. EPA-SAB-EC-ADV-02-001.

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1 [http://www.epa.gov/ttn/fera/data/risk/vol\\_3/Appendix\\_B\\_April\\_2006.pdf](http://www.epa.gov/ttn/fera/data/risk/vol_3/Appendix_B_April_2006.pdf) or  
2 [http://www.epa.gov/ttn/fera/data/risk/vol\\_1/chapter\\_06.pdf](http://www.epa.gov/ttn/fera/data/risk/vol_1/chapter_06.pdf)).

3  
4 In addition, the discussion of how surrogates were chosen should be made clearer.  
5 Limitations about the emissions data need to be identified and addressed. For example,  
6 only one facility out of 104 Portland cement facilities reports 48 tons per year of carbonyl  
7 sulfide. This questionable emissions data drives the TWE process in Appendix O and  
8 carbonyl sulfide is listed as a priority HAP for further dose response evaluations. If our  
9 assumptions above about the calculations of surrogates are correct, and a verification of  
10 the emissions inventory is conducted the approach is adequate, if limited to screening  
11 purposes.

12  
13 Any unassessed HAPs that screen-in because of this evaluation process should then be  
14 followed-up by reviewing existing toxicity information to examine the likelihood that  
15 they could be a driver for the assessment process.

16  
17 The current bounding exercise and tool for identifying research needs is limited to this  
18 purpose and probably cannot be further developed and incorporated in the RTR  
19 assessments given the limitations of the emissions inventory for these HAPs. HAP-  
20 specific emissions testing would have to be conducted at these facilities in order to use  
21 and have confidence in weighting factors that are based on the amount of actual HAPs  
22 released.

23  
24 Incorporation of HAPs lacking dose-response values: The Panel recommends that the  
25 Agency prepare or compile toxicity profiles for each of the HAPs that Appendix O  
26 identifies as having the potential to drive the RTR assessment. They should receive a  
27 very high priority for evaluation according to the IRIS process that was recently  
28 redefined by Administrator Lisa Jackson. (See  
29 <http://www.gao.gov/new.items/d09773t.pdf> for a review of recommendations and  
30 changes to be made to the IRIS process). Residual risk decisions for these chemicals will  
31 have to be identified as awaiting peer review or Agency-wide consensus.

32  
33 Additional issues regarding chronic dose-response values: The Panel was not charged  
34 with critiquing the IRIS methodology itself and therefore was not constituted with the  
35 expertise for an in-depth review of the methodology. However, we note below that  
36 inhalation risk methods for children are still developing and that California Office of  
37 Environmental Health Hazard Assessment (OEHHA) has very recently updated its  
38 methodology in ways that could affect the development of RfC and URE values. US  
39 EPA should examine these developments to make sure that the RTR process adequately  
40 covers children's residual risks.

41  
42 In particular is the question of whether the interindividual variability factor for non-  
43 carcinogens and the standard cancer unit risk derivation adequately covers children. If it

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1 does not, it is a potentially significant uncertainty given the greater intake rate of children  
2 via inhalation and sensitivity to carcinogens and other toxicants.<sup>11</sup>  
3

4 California EPA/OEHHA has determined that inhalation dosimetry for children is  
5 sufficiently different from adults to warrant a full 10-fold intra-individual  
6 pharmacokinetic uncertainty factor (i.e., an extra 3-fold PK uncertainty for children  
7 relative to the IRIS method) as a default approach. In setting non-cancer reference  
8 exposure levels (RELs), Cal EPA/OEHHA also considers that children may be outliers in  
9 terms of chemical susceptibility and on a case-specific basis adds a children's  
10 pharmacodynamic factor of 3-fold, making the inhalation risk for children as much as 10  
11 times greater than adults).<sup>12</sup>  
12

13 This issue of children's hazard should be presented as an uncertainty with regard to non-  
14 cancer dose-response assessment and carcinogen dose-response assessment, especially  
15 considering that only two mutagenic carcinogens receive the age-adjusted potency factor  
16 approach in the RTR, even though numerous other mutagens (e.g., 1,3-butadiene) are  
17 analyzed. California's OEHHA uses the children's cancer potency adjustment factors on a  
18 much broader array of carcinogens than the narrow interpretation used in the draft RTR  
19 document.<sup>13</sup> This would be a natural area for sensitivity analysis (e.g., applying the age-  
20 adjusted potency factor to numerous carcinogens (at least all those that are mutagens) to  
21 determine the degree of uncertainty children's vulnerability can create in the cancer risk  
22 assessment.  
23

### 24 **Charge Question 3B**

25

26 We developed our selection process for acute dose-response values more recently than  
27 the one for chronic values, and it has not yet undergone SAB review. The universe of  
28 acute health benchmarks contains many gaps, as shown in Table 2-5. In addition, some  
29 of the benchmarks correspond to "no-effect" levels (e.g., CalEPA acute reference  
30 exposure levels, which are analogous to chronic RfCs), while others correspond to "mild-  
31 effect" or "severe-effect" levels (e.g., acute exposure guideline levels) that are intended  
32 to guide authorities in making emergency evacuation decisions. For these reasons we  
33 have not applied a prioritization scheme.  
34

35 We have not generally included acute minimum risk levels (MRLs, developed by the  
36 Agency for Toxic Substances and Disease Registry, or ATSDR) as dose-response values

---

<sup>11</sup> USEPA, 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens EPA/630/R-03/003; Barton HA, Cogliano J, Flowers L, Valcovic L, Setzer RW, Woodruff TJ. 2005. Assessing Susceptibility from Early-Life Exposure to Carcinogens. Environ Health Perspectives 113:1125-1133; Hattis D, Goble R, Russ A, Chu M, Ericson J. 2004. Age-related differences in susceptibility to carcinogenesis: a quantitative analysis of empirical animal bioassay data. Environ Health Perspectives 112:1152-1158.

<sup>12</sup> ([http://www.oehha.ca.gov/air/hot\\_spots/2008/NoncancerTSD\\_final.pdf](http://www.oehha.ca.gov/air/hot_spots/2008/NoncancerTSD_final.pdf))

<sup>13</sup> [http://www.oehha.ca.gov/air/hot\\_spots/tsd052909.html](http://www.oehha.ca.gov/air/hot_spots/tsd052909.html)

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1 in our assessments of acute risks because of a temporal mismatch between the exposure  
2 estimates (based on one hour) and the MRLs (based on 24 hours to two weeks).  
3

4 3B Given these gaps and inconsistencies among available acute benchmarks, do the case  
5 studies characterize acute risks adequately? Should we include ATSDR MRLs in our  
6 assessments, and if so, how can we solve the temporal mismatch? Is the use of  
7 emergency guidelines in our assessments adequately described and interpreted? Are  
8 there other acute health metrics EPA should consider using for these assessments? Do  
9 you have suggestions for improvements in any of these areas?

10  
11  
12 **Panel Response**  
13

14 Adequacy of the case studies in characterizing acute risks: The case studies characterize  
15 acute risk adequately, but this may be due to the unique circumstances of these two case  
16 studies. Thus, there is a need to pay attention to the principles and practices used. The  
17 most effective way to deal with the dearth of acute values that are optimal for residual  
18 risk assessment is to ensure that IRIS develops them on a high priority basis. The  
19 incorporation of the available California Reference Exposure Levels (RELs) for the  
20 assessment of acute effects is a conservative and acceptable approach to characterize  
21 acute risks.  
22

23 The Panel has some concern with the use of the acute Exposure Guidelines Limits  
24 (AEGLs) and Emergency Response Planning Guidelines (ERPGs). These limits were  
25 developed for accidental release emergency planning and are not appropriate for residual  
26 risk assessments without modification because, as described in the AEGL and ERPG  
27 documentation, adverse effects may occur at these levels. For example, at the AEGL-1  
28 level, "...the general population, including susceptible individuals, could experience  
29 notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the  
30 effects are not disabling and are transient and reversible upon cessation of exposure."  
31 (citation-in each AEGL document). Some of the AEGLs and ERPGs listed in Table 2-5  
32 are higher than values used to protect healthy workers from acute effects in occupational  
33 settings. The Panel recommends considering reducing the AEGL-1/ERPG-1 emergency  
34 guideline values by a factor of 3, when the value is based on a LOAEL rather than a  
35 NOAEL. This would better approximate a "no-effect" level, as in RfC's. In particular,  
36 AEGL-2 and ERPG-2 values should never be used in residual risk assessments because  
37 they were derived on the basis of maximum concentrations that would result in serious or  
38 irreversible health effects if they were exceeded. Thus, they provide a false sense of  
39 public health protection.  
40

41  
42 The short-term exposure levels (STELs) and ceiling levels used by the American  
43 Conference of Industrial Hygienists (ACGIH), Occupational Safety and Health  
44 Administration (OSHA) and the National Institute of Occupational Safety and Health

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1 (NIOSH) were developed to protect healthy workers from short exposures that may  
2 routinely occur in the workplace. The use of acute dose response values that are greater  
3 than occupational values used to protect healthy workers does not provide a high degree  
4 of confidence that the dose response values used in the case studies have adequately  
5 characterized the acute risk of HAP exposures for sensitive subpopulations within a  
6 community. For example, the use of the AEGL-1 for 1,3-butadiene (1500 mg/m<sup>3</sup>) versus  
7 the OSHA short-term exposure limit (11 mg/m<sup>3</sup>) calls into question the adequacy of the  
8 use of emergency planning values in any residual risk assessment.  
9

10 The Panel does not recommend the use of the ATSDR MRLs in the risk assessments as  
11 their use would require a potentially complex correction for the temporal mismatch. In  
12 order to use the MRL values, the risk assessors would have to recalculate an acute value  
13 based on the critical endpoint(s) identified in the ATSDR documentation. Appropriate  
14 safety factors would have to be determined and applied to the critical endpoint to  
15 determine an acceptable acute exposure value. Without peer review of the calculated  
16 value, the credibility of the assessment would be questionable even in a screening  
17 assessment.  
18

19 It is recommended that adjusted occupational values (ACGIH TLV) be considered for use  
20 in the risk assessments. The TLV values represent an evaluation of the literature that  
21 could be adjusted and then considered for use using expert judgment. For example, the  
22 TLV-STEL and TLV-C can be divided by a factor of 10 or greater to ensure the  
23 protection of sensitive sub-populations. TLV values should only be used after thorough  
24 and critical evaluation.  
25

26  
27 Other sources of peer-reviewed health values are the Spacecraft Maximum Allowable  
28 Concentrations for Selected Airborne Contaminants (SMACS).<sup>14</sup> SMACS are defined as  
29 “the maximum concentrations of airborne substances that will not produce adverse health  
30 effects, cause significant discomfort, or degrade crew performance” and are classified  
31 into 1- and 24-hour emergency SMACS and 7-, 30-, and 180-d continuous SMACS.  
32 SMACS are developed in a similar way to other health values, except that they typically  
33 do not include an uncertainty factor for susceptible subpopulations because the target  
34 population is a healthy adult population. Furthermore, many of the SMACS represent  
35 effect levels, rather than “safe” levels, so they would need to be dealt with in a manner  
36 similar to emergency values. It is recommended that EPA add these documents to its list  
37 of sources for analysis. Because susceptibilities are not accounted for, these values  
38 would need to be divided by an uncertainty factor of 3 or 10 (similar to the adjustment  
39 recommended for AEGLs or other acute values), and then compared to other values.

---

<sup>14</sup> Spacecraft Maximum Allowable Concentrations for Selected Airborne Contaminants:  
Volume 5 (2008) Committee on Spacecraft Exposure Guidelines, Committee on Toxicology, National  
Research Council (available at [http://www.nap.edu/catalog.php?record\\_id=12529](http://www.nap.edu/catalog.php?record_id=12529)). All five volumes are  
available at [www.nap.edu](http://www.nap.edu).

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1 Also, if the SMAC was related to a LOAEL, another uncertainty factor (3 or 10) would  
2 be needed to adjust to a NOAEL.

3  
4 As per the recommendations for the chronic table, a table of acute values should be  
5 developed, with the following columns created for each table: CAS, AEGL-1, etc. (as in  
6 the top row now, as modified based on the recommendations above). For each value, the  
7 year the value was last updated should be included and a qualitative description of the  
8 effect should be provided (e.g., describe the critical effect used as the basis of the  
9 calculation). Next, the table should be examined for consistencies. For example, if the  
10 values from different agencies are different, the reasons should be explored. Perhaps one  
11 value is more recent than another; perhaps the critical effect is different. Such a table is  
12 complex and therefore a candidate for an appendix, with the summary result being in the  
13 main text.

14  
15 Minor recommendations for clarification:

- 16  
17 a. p. 2-13 bottom. The text should be revised to identify that the acute REL is for 1  
18 hour. They also have 8 hour values, but we presume the analysis used the 1-hour  
19 values to make them equivalent to others.  
20  
21 b. p. 2-14 top description of AEGLs. In the middle of the paragraph, it says that the  
22 values range from 10 minutes to 8 hours. This is true, but they have explicit  
23 values for 10 minutes, 30 minutes, 1 hour, 4 hours, and 8 hours. Thus, the text  
24 should be expanded to indicate this. We presume the analysis used the 1 hour  
25 value for consistency.

26  
27  
28  
29 The following minor edits are recommended. On page 2-16 Table 2-5:

- 30 (a) The table title should be revised to say 1-hour acute exposure.  
31 (b) The table should be footnoted to define the AEGL-1, etc. (The definition is in the text,  
32 but tables should stand alone.)

33  
34  
35 **Charge Question 4A**

36  
37 Section 2.2.3 describes the process by which we estimate chronic human inhalation  
38 exposures based on modeled average ambient concentrations at census block centroids.  
39 For these case studies, this process did not include consideration of either daily behavior  
40 pattern or long-term migration behavior. Section 2.2.3 presents a rationale for omitting  
41 daily behavior, and Appendix N presents a case study that adjusts inhalation-based  
42 lifetime cancer risk estimates for individuals to account for long-term migration.  
43

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1 4A Does our process of estimating inhalation exposures adequately support regulatory  
2 rulemaking? Is our rationale for omitting daily behavior convincing, or does the  
3 omission compromise the value of our assessments? Should this, or some other,  
4 adjustment for long-term migration be incorporated into our risk assessments?

5  
6 **Panel Response**

7  
8 An overarching concern with EPA's chronic inhalation exposure estimates is that  
9 children's exposures do not appear to have been adequately addressed. The differences in  
10 exposure between children and adults should be carefully considered and discussed in the  
11 exposure assessment. Otherwise, EPA's overall approach appears to be a reasonable  
12 *screening* approach for localized impacts (e.g. neglecting processes like deposition,  
13 plume depletion, atmospheric degradation) that can be refined further. In addition, EPA  
14 identifies some assumptions that could potentially lead to downward bias, such as not  
15 considering population growth or future expansion of production. Although these  
16 assumptions may be appropriate given the need to simplify the analysis, periodic  
17 reassessment may be needed, especially in circumstances where there are substantial  
18 changes in population growth and production levels.

19  
20 With regard to the chronic inhalation exposure estimates, the Panel finds the rationale for  
21 omitting daily behavior to be convincing. Given the age of available activity pattern data  
22 and the inherent community-scale activity pattern uncertainties between locations, the  
23 decision to omit daily behavior is justified. The assessment report should make it clear  
24 that consideration was given to daily behavior in terms of time spent indoors and past  
25 experience has shown it makes little difference in risk estimates.

26  
27 The Panel further recommends that long-term migration not be incorporated into the risk  
28 assessment. It does not add value to the risk assessment and introduces additional  
29 uncertainty. As discussed in Appendix N, the migration data that would be used to  
30 modify the risk estimates have not been scientifically peer-reviewed and are limited in  
31 their geographical representativeness. While this preliminary analysis does not merit  
32 being part of the central assessment, it is worth leaving in the appendix and referencing in  
33 the text.

34  
35 **Charge Question 4B**

36  
37 Appendix C describes a novel application of TRIM in the development of protective *de*  
38 *minimis* emission rates for 14 persistent and bioaccumulative HAPs (PB-HAPs). We  
39 believe that emissions below *de minimis* thresholds should not produce unacceptable  
40 risks in reasonable worst-case conditions. Facilities emitting below these values would  
41 not need to conduct a multipathway exposure and risk assessment.

42  
43 Section 3.4 and Appendix I describe a refined application of the TRIM model in  
44 assessing multi-pathway pollutant transport and its subsequent impacts on human health

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1 from Portland cement facility air emissions identified as having a high potential to  
2 present significant impacts on human health.

3  
4 We have limited our development of radionuclide risk estimates (described in Section  
5 3.2.2 and Appendix G) to those associated with inhalation exposure. Radionuclides were  
6 not included in the multipathway risk assessment.  
7

8 4B Is our use of the TRIM model to develop *de minimis* emission rates appropriate as a  
9 screening tool? Are the methodologies used in the refined multipathway assessment  
10 consistent with the best available science regarding multi-pathway pollutant transport and  
11 human exposures? Are the application of the model and the assumptions used clearly  
12 articulated? Are the resultant estimates of media concentrations and exposures clearly  
13 presented, explained, and interpreted? Given the large uncertainties surrounding the  
14 radionuclide inhalation assessment, are we justified in omitting radionuclides from the  
15 multipathway assessment?

16  
17 **Panel Response**

18  
19 Screening model framework and methodologies: In responding to this charge question,  
20 the panel focused on how TRIM.Fate results were applied in the risk assessment process.  
21 The panel did not evaluate the details of the equations in TRIM.Fate and did not itself  
22 evaluate the validity of the model. Appendix C describes a series of analyses that provide  
23 some confirmation that the screening model results are generally reasonable based on  
24 qualitative comparisons with environmental and food chain concentrations and  
25 partitioning, but these comparisons necessarily fall short of providing the level of  
26 confidence that could be gained by detailed comparison of model results and observations  
27 for a range of real-world applications. Appendix C indicates that EPA subsequently  
28 evaluated TRIM.FaTE's performance for modeling mercury and dioxins and furans, but  
29 does not discuss the results. As recommended by previous SAB panels,<sup>15</sup> we recommend  
30 that EPA continue to identify and acquire additional field data to estimate modeling  
31 parameters and to evaluate the TRIM.FaTE model components and other aspects of the  
32 modeling system on an ongoing basis. The NRC report *Models in Environmental*  
33 *Regulatory Decision Making*<sup>16</sup> provides useful guidance for these recommended efforts.  
34

35 With the caution that continued efforts are needed to evaluate the TRIM.FaTE model, the  
36 panel finds that EPA's screening approach is based on an appropriate framework and  
37 should provide a useful screen for sources that do not need a detailed site-specific  
38 multipathway analysis. The screening-level multipathway assessment is thorough and

---

<sup>15</sup> EPA-SAB-EC-ADV-99-003 (1998) Advisory on the Total Risk Integrated Methodology (TRIM), <http://www.epa.gov/science1/pdf/eca9903.pdf>; SAB-EC-ADV-00-004 (2000) Advisory on the Agency's "Total Risk Integrated Methodology (TRIM)," <http://www.epa.gov/science1/pdf/ecadv04.pdf>.

<sup>16</sup> *Models in Environmental Regulatory Decision Making*. Committee on Models in the Regulatory Decision Process, National Research Council, The National Academies Press, Washington, DC (267 pp, 2007).

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1 conservatively includes local subsistence agricultural and fishing scenarios, adding  
2 exposures across intake pathways to yield total PB-HAP exposure. Children and adults  
3 are modeled with doses calculated on an average daily dose (ADD) lifetime basis to  
4 assess chronic risk of these HAPs. This modeling is generally appropriate, although  
5 developmental and reproductive endpoints associated with mercury and dioxin can  
6 involve shorter windows of vulnerability than lifetime exposure and so the dose rate  
7 averaging might need to be shorter for such endpoints. Use of an ADD may undervalue  
8 peak exposures that occur in early life or during pregnancy. Therefore, some discussion  
9 should be provided regarding whether consideration of early life windows of  
10 vulnerability and less than lifetime exposures should be considered.

11 Appendix C presents sensitivity analysis results to identify the most influential input  
12 variables in the screening assessment. As EPA recognizes, facilities with emissions  
13 exceeding the screening level thresholds might end up doing so because of assumptions  
14 in one particular area (e.g., soil to vegetation uptake rate; beef biotransfer factors; fish  
15 ingestion). This analysis could be refined so that these particular factors are evaluated in  
16 a distributional sense to enable Monte Carlo analysis, leading to an overall multipathway  
17 probability distribution of risk rather than a bright line estimate. In this way, the  
18 probability that a facility's emissions could lead to unacceptable risk could be estimated  
19 and presented to risk managers to weigh against other factors.

20 Communication of assumptions and results: The panel considered it reasonable for the  
21 agency to set an emission threshold below which detailed site-specific multipathway  
22 analysis (including potentially extensive data collection) would not be necessary for each  
23 source. However, the choice of the term "*de minimis*" to describe this threshold was  
24 unfortunate, as it obscures the conclusions of the near-source multipathway analysis. In  
25 particular, when the *background* concentration of a PB-HAP already exceeds a safe level  
26 (e.g., where a fish advisory is already in effect) the public may not understand a local  
27 source's contribution being characterized as *de minimis*. Additionally, although such risk  
28 may not be deemed "unacceptable", it is not clear that a threshold set at a 1 in 1 million  
29 cancer risk or chronic HQ of 1 should be characterized as *de minimis* in the absence of  
30 elevated background contributions.

31 Risk assessments must be credible to the public. Exhibit 4-7 showed modeled  
32 concentrations in sediment and surface water for the screening scenario that were higher  
33 than most of the values from the literature. For example, in the screening scenario the  
34 modeled concentration in sediment is about an order of magnitude higher than reported  
35 for Minnesota lakes, and Minnesota has a statewide fish advisory for Hg. Thus EPA's  
36 finding that the corresponding Hg<sup>+2</sup> emissions rate of 1.6E-01 TPY (320 lbs) (Exhibit 2-  
37 3) is "below a level of concern" may not be credible to the public.

38 Instead of "de minimis emissions levels", it would be better to describe EPA's screening  
39 model results as providing an "action threshold for local hot-spot analysis." Using a  
40 model to estimate the relative contributions of local and background sources of a  
41 pollutant is useful for informing policy choices and communicating with the public.

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1 However, the model results need to be clearly presented to show 1) the relative fraction  
2 of the local source's emissions that are deposited locally versus being transported to add  
3 to regional burdens, and 2) the relative contributions to total multipathway exposure from  
4 local and regional background sources. If the local source contribution is small relative to  
5 background, refined site-specific modeling would provide little information beyond what  
6 could be obtained from a regional or national-scale analysis, so screening out individual  
7 sources from further analysis is appropriate. Nevertheless, the contribution the source  
8 category makes to overall emissions of PB-HAPs should still be considered.

9 From a scientific standpoint, EPA must also ensure that ignoring background pollutant  
10 levels of PB-HAPs does not lead to incorrect results due to nonlinear physical and  
11 chemical processes in the fate and transport model. Where nonlinear processes are at  
12 issue, individual source contributions can be tagged for tracking, but all contributions  
13 including "background" must be considered in the fate and transport model.

14 Previous SAB review panels have similarly recommended that EPA characterize  
15 background as well as incremental risks in its residual risk assessments. Quoting from the  
16 SAB Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk of  
17 Secondary Lead Smelters (p. 11) "[a] residual risk analysis that does not add exposures to  
18 baseline contamination to the estimates of on-going contamination may vastly  
19 underestimate the hazard quotient at the site and incorrectly conclude that the on-going  
20 releases pose risks at less than threshold levels."<sup>17</sup> The Secondary Lead Smelters review  
21 also noted (p. 25) "The [Residual Risk] Report to Congress (USEPA, 1999)<sup>18</sup> discusses  
22 the need to include background risk and the difficulty associated with this specific issue.  
23 ... The absence of an assessment of background risk seriously impacts statements about  
24 the conservative nature of the refined screening assessment." Our Panel concurs with  
25 these comments. The need to characterize background as well as incremental risks also  
26 arises in the case of some non-PB-HAPs such as benzene, but the issue stands out for the  
27 PB-HAPs because of their nature as persistent and bioaccumulative and because for most  
28 pollutants evaluated with EPA's screening scenario, a large fraction of the emitted mass  
29 was lost from the model domain through advection downwind (See Exhibit 4-1,  
30 Appendix C).

31 Omission of radionuclides from the multipathway assessment: Local impacts of  
32 radionuclides, including naturally occurring isotopes, need to be considered based on  
33 better data for radionuclide concentrations in geological feed materials to mineral  
34 processing industries. The comprehensive analysis presented in Leenhouts (1996) and the  
35 results of the Portland cement case study suggest that radionuclide emissions may be a  
36 risk for any industry category that grinds and heats large amounts of natural mineral  
37 feedstock. Radionuclides need to be considered in the residual risk assessment process,

---

<sup>17</sup> See EPA-SAB-EC-ADV-00-005 (2000) An SAB Advisory On The US EPA's Draft Case Study Analysis Of The Residual Risk Of Secondary Lead Smelters

<sup>18</sup> See EPA-453/RR-99-001 (1999) US EPA's Report to Congress on Residual Risk

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1 but as discussed in response to charge question 1C, preliminary work is needed before  
2 attempting to use TRIM. There is currently no reporting of actual radioactive isotope type  
3 and unit of radioactivity for Portland cement feedstocks.

4 At this early stage of the assessment of radionuclide emissions the panel agrees it is  
5 acceptable to omit the multimedia assessment. Ultimately, however, a multipathway  
6 assesment is needed because non-inhalation pathways are often important for  
7 radionuclides that can accumulate in biota and subsequently be ingested. Radon is not  
8 likely to bioaccumulate as it is an inert gas, but the fate of its decay products need to be  
9 considered. The literature on <sup>210</sup>Po in the food chain needs to be reviewed to determine  
10 if it bioaccumulates. The literature on multipathway exposure from <sup>210</sup>Po in phosphate  
11 fertilizer may provide information on this issue.

12 Particle bound HAPs: A potentially serious omission from the Appendix C analysis is  
13 the issue of HAPs associated with coarse fraction (PM<sub>2.5-10</sub>µm) and very coarse (>  
14 10µm) particles. Large particles deposit rapidly, thus causing relatively high impacts near  
15 a source. If the HAPs-containing particles are injected into the air near ground level  
16 (fugitive emissions and resuspended road dust) then the fraction deposited nearby is  
17 much higher compared to the same particles being emitted from a stack. The  
18 methodologies used in the case studies would not detect local multipathway risk caused  
19 by deposition of particle-bound HAPs near the source site.

### 21 Charge Question 5

22  
23 Section 2.2.5 describes our process for developing screening and refined estimates of  
24 acute inhalation risk. For acute screening purposes we have assumed that, in the worst  
25 case, a person could be exposed for one hour to ten times the highest hourly  
26 concentration calculated by the dispersion model. This in effect assumes a 1-hour  
27 emission rate of ten times the annual average (assuming continuous emissions),  
28 simultaneous occurrence of “worst-case” meteorological conditions, and also the  
29 presence of a person at this worst-case downwind location.

30  
31 Appendix B presents an effort to evaluate the protectiveness of this screening assumption  
32 using detailed short-term emission data for a limited geographic area. Appendix E  
33 describes our refinement of acute risk estimates for refineries that failed the acute 10X  
34 screen, by using more accurate emission points and property boundaries.

35  
36 Our refined acute assessments do not combine acute hazard quotients associated with  
37 different HAPs because of the inconsistent nature of acute health benchmarks and the  
38 inherent conservatism of our exposure assumptions.

39  
40 5 Does the 10X acute screening assumption for petroleum refineries appear to be  
41 appropriately protective? If not, is it under- or over-protective? Given that this analysis  
42 applies only to sources in the Houston area, can we apply the 10X assumption to HAPs in

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1 other source categories or should we consider some other approach for some other HAPs,  
2 *e.g.*, metals? Is there some other way we might address high emission events such as  
3 startup or shutdown of processes? Are the refinements to the acute screening assessment  
4 objectively employed and scientifically defensible? Should we sum acute hazard  
5 quotients by target organ in the same way we do for chronic hazard quotients, *i.e.*, a  
6 target organ specific hazard index (TOSHI) approach, or are our reasons for not doing so  
7 adequate?

### 8 9 **Panel Response**

10  
11 Use of 10X annual emissions for short-term exposure estimates: The Panel agreed there  
12 is a critical need for better data addressing short-term exposures to HAPs. However, in  
13 the absence of chemical- and site-specific data, the use of the 10X screening assumption  
14 for petroleum refineries seems reasonable, with the following caveats.

15  
16 The methods used to derive and justify the 10X screening assumption are not readily  
17 apparent from Appendix B. The authors should consider using a more transparent  
18 approach to presenting this data. In revising Appendix B, EPA should at least explain  
19 more clearly why the median and mean values of event to long-term release rates are less  
20 than 1. Furthermore, the figures contained in the referenced reports by Allen et al.  
21 provide an easily understandable template that could be used to present the development  
22 of the 10X screening assumption used to assess acute impacts.<sup>19,20</sup> Figures 2 through 8 of  
23 the Allen et al. paper clearly show the baseline annual hourly emission rates for VOCs,  
24 highly reactive VOCs and 1,3- butadiene, and the magnitudes of the excursions over the  
25 baseline annual hourly emission rates. The results demonstrate that the facilities in the  
26 Houston-Galveston area clearly do not have emissions that are constant and continuous.  
27 The daily emissions can vary from the annual average emissions by a factor of 10 to  
28 1000. Figure 1 of the Allen et al. paper also provides a useful conceptual illustration of  
29 the four characteristic types of emissions variability from the industrial sources in the  
30 Houston-Galveston area, which EPA might adapt.<sup>18</sup>

31  
32 Apart from our concerns about data presentation, the Panel concurred that a release factor  
33 associated with the 99<sup>th</sup> percentile value would seem to be appropriately health-  
34 protective. However, there is one significant limitation to the TCEQ database that needs  
35 to be identified in Appendix B, which is that the emissions event reporting rule only  
36 requires reporting from the time of discovery until the event was corrected. This would  
37 cause a low bias for both the event duration and quantity of emissions released.

---

<sup>19</sup> Allen D, Murphy C, Kimura Y, Visure W, Jeffries H, Kim, B, Webster M and Symons, M. Variable Industrial VOC Emissions and their Impact on Ozone Formation in the Houston Galveston Area. Available at <http://www.epa.gov/ttn/chief/conference/ei13/uncertainty/allen.pdf>

<sup>20</sup> Allen D, Murphy C, Kimura Y, Visure W, Jeffries H, Kim, B, Webster M and Symons, M. Variable Industrial VOC Emissions and their Impact on Ozone Formation in the Houston Galveston Area. (April 2004). Final Report Texas Environmental Research Consortium Project H-13. Available at <http://files.harc.edu/Projects/AirQuality/Projects/H013.2003/H13FinalReport.pdf>

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1  
2 In Appendix B, EPA attempts to address the representativeness of the Texas Commission  
3 on Environmental Quality (TCEQ) data base by filtering the data to isolate routine and  
4 allowable hazardous air pollutant (HAP) excursions from major emitters in the Houston-  
5 Galveston area (Table 2 of Appendix B). There appears to be a mixture of source types  
6 (e.g., petroleum refineries and chemical manufacturing plants) in Table 2; isolation of  
7 petroleum refinery specific allowable hourly excursion data in the manner described  
8 above would provide a more transparent justification of the conservative nature of the  
9 10X screening assumption. We are also concerned about the filter applied to attempt to  
10 remove facilities below the major threshold from this analysis. NESHAP applicability for  
11 each identified facility should be easily obtained from the current Title V permits, the  
12 EPA should revisit this filtering assumption to insure all facilities subject to the NESHAP  
13 are included in the analysis. The Panel also suggests that following the screening process,  
14 the chemicals of highest concern (drivers) be evaluated against the list of chemicals  
15 reported in the Houston area (Appendix B), to ensure they are adequately represented.

16  
17 The 10X screening assumption makes the most sense under conditions when the  
18 production facility is operating continuously (24 hrs/day and 7 days/week) for the entire  
19 year. However, adjustments may need to be made for other source categories where  
20 facilities operate during only part of the day or part of the year. Under these scenarios,  
21 which may frequently occur as demonstrated by the Allen et al. report and papers,  
22 estimates of daily releases calculated from annual release values may seriously  
23 underestimate releases occurring during production periods.<sup>18, 19</sup>

24  
25 Although the Panel generally agreed that the 10X assumption could be used for other  
26 geographic areas, it was felt that the actual releases would be dependent upon the  
27 manufacturing processes involved which may or may not be captured in the Houston  
28 example. There was limited information on the manufacturing processes in the Houston  
29 area included in the document making it difficult to evaluate its relevance to the case  
30 studies. We would recommend that a table listing the industries by Standard Industrial  
31 Codes (SIC) be included in the evaluation to allow comparisons with industries to be  
32 evaluated in the future. The report by Allen et al. (2004) reports these excursions by SIC  
33 codes, allowing for some understanding of source category-specific emissions  
34 variability.<sup>2</sup> In the case of petroleum refineries, for example, it appears there are four  
35 types of emissions points (fugitives, pipelines, cooling towers and flares) associated with  
36 the short-term excursions.

37  
38 Going beyond the Houston-Galveston data set, the Panel suggests that an estimate of the  
39 variation and peaks in short-term emission rates could be obtained by examining time  
40 trend data from continuous emission monitors. Since HAPs emitted from a stack are often  
41 controlled by the same air pollution equipment that is used for criteria pollutants, it may  
42 be reasonable to use variations in PM, SO<sub>2</sub>, or opacity as surrogates for variation in  
43 emission of HAPs. Another option may be the utilization of real-time fence-line

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1 measurements (FTIR or UV-DOAS) collected during enforcement and research  
2 investigations around facilities such as petroleum refineries.

3  
4 Refinements to acute screening assessment: For facilities with elevated acute hazard  
5 quotients, EPA used aerial photographs to ensure exposures were not occurring within  
6 property boundaries, and re-estimated maximum (off-site) exposures where this had  
7 occurred. The panel found this to be a useful refinement. In addition, however, where  
8 pollutants emerge as drivers of acute risks, EPA should also re-examine the acute toxicity  
9 reference values used in the assessment to make sure that they are correct and appropriate  
10 for the assumed 1-hr period of exposure. For example, the acute REL for benzene used  
11 in the case studies (1.3 mg/m<sup>3</sup>) appears to be based upon a 6-hour exposure period rather  
12 than a 1-hr exposure.<sup>21</sup>

13  
14 Summing acute hazard quotients: The Panel recommends that EPA examine the  
15 likelihood that a 10X release would occur under the most hazardous meteorological  
16 conditions, and how likely it would be for 10X releases of multiple chemicals to occur  
17 simultaneously. If it is concluded that simultaneous releases under adverse  
18 meteorological conditions would be very unlikely, then summing the acute hazard  
19 quotients by target organ would not be necessary. Alternatively, screening could be done  
20 using the TOSHI approach with more detailed follow-up for agents or combinations of  
21 agents that were identified as potential concerns. A primary focus of this approach would  
22 be on irritants, which are generally of most concern for acute exposures.

### 23 24 Charge Question 6

25  
26 Section 3.5 and Appendix J describe a refined, site-specific application of TRIM to  
27 conduct an ecological risk assessment for PB-HAPs emitted by the same Portland cement  
28 facility evaluated in the human health risk assessment. Appendix J also describes a  
29 nationwide facility ranking exercise that identifies Portland cement facilities with the  
30 highest potential for causing indirect ecological effects via acidification of the  
31 environment by hydrogen chloride emissions. Appendix K describes an analysis of  
32 possible direct effects on plant foliage of air concentrations of hydrogen chloride emitted  
33 from Portland cement facilities that are below human health thresholds.

34  
35 6. Is the ecological assessment case study scientifically defensible? Does it conform to  
36 EPA risk assessment guidance (*e.g., Guidelines for Ecological Risk Assessment, Risk*  
37 *Characterization Handbook, etc.*)? If not, how can we improve it? Are the elements of  
38 the ranking scheme adequate to identify the facilities most likely to be of concern? Are  
39 there better data sources or approaches for drawing conclusions for specific locations?  
40 With regard to investigating the potential for direct ecological effects at air  
41 concentrations below human health thresholds from other sources or source categories,

<sup>21</sup> OEHHA (1999) [http://www.oehha.ca.gov/air/acute\\_rels/pdf/71432A.pdf](http://www.oehha.ca.gov/air/acute_rels/pdf/71432A.pdf)

Note: This information can also be found in summary form in the reference  
(<http://www.oehha.ca.gov/air/pdf/acuterel.pdf>) cited in the text on page 2-13.

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1 what suggestions can be made for prioritizing additional HAPs for literature searches  
2 similar to that done for hydrogen chloride in Appendix K?

3  
4 **Panel Response**

5  
6 Ecological risk assessment case study: The ecological risk assessment (ERA) presented  
7 in Appendix J is an impressive effort tackling an extremely complex issue. While it is a  
8 good first step, the ERA needs to be improved, as the EPA ERA guidelines were not  
9 followed well. This would entail doing a problem formulation stage (which is perhaps  
10 the most important stage; see Dale et al. 2008<sup>22</sup>) that shows the ecological conceptual  
11 model, which then directs the study design, and subsequent linkage between assessment  
12 and measurement endpoints. In addition, the risk characterization did not show how the  
13 measurement endpoints linked back to the assessment endpoints and conceptual model.  
14 Each stage of the ERA (problem formulation, exposure/effects characterization, and risk  
15 characterization) can be improved, with specific suggestions given below.

16  
17 The selection of contaminants of concern for the ERA case study (Appendix J, section  
18 2.1) is well justified as is the choice of key ecological receptors (Appendix J, section  
19 2.3.1). However, given the paucity of information on other potential HAPs, a separate  
20 research effort is warranted to rank HAPs for analysis. This effort should consider  
21 particulate-associated HAPs, high  $K_{ow}$  compounds, and multiple exposure pathways as  
22 shown on the flow charts EPA presented to the panel to summarize its approach for RTR  
23 health assessments.

24  
25 The heavy reliance of the ERA case study on TRIM.FaTE is a concern, as this EPA  
26 model has not been well validated in the peer-reviewed literature for ERAs, and an  
27 adequate sensitivity analysis with ground-truthing is lacking. A related concern is the  
28 fact that all exposure and effects predictions are based on generalized assumptions, and as  
29 discussed in response to Charge Question 1A, there are multiple indications that  
30 emissions may be underestimated. The potential for error propagation is a concern. More  
31 transparency is needed for key parameters used in TRIM.FaTE for the ecological (as  
32 opposed to the human health) risk assessment, such as sediment concentrations of the  
33 chemicals of potential concern and whether or not (and how) their bioavailability is  
34 linked to key factors (e.g., total organic carbon (TOC), dissolved organic carbon (DOC),  
35 and hardness). Appendix I (referenced as the source of the information) is confusing in  
36 this regard. It appears virtually all TRIM.FaTE parameters for the test site have been  
37 estimated and extrapolated from other sites with a significant amount of “professional

---

<sup>22</sup> Dale, VH et al. 2008. Enhancing the Ecological Risk Assessment Process. Integrated Environmental Assessment and Management 4:306-313. [SAB report entitled, “Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board”, available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/7140DC0E56EB148A8525737900043063/\\$File/sab-08-002.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/7140DC0E56EB148A8525737900043063/$File/sab-08-002.pdf) ]

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1 judgment”, making this a truly hypothetical ERA. This raises the question of how can we  
2 assume there is no risk for this, much less other Portland cement facilities, without some  
3 degree of verification that the model’s predictions regarding food web, chemical fate and  
4 speciation, biological uptake and effects are correct?  
5

6 From the information presented in Appendix J, the case study appears to have relied on  
7 Toxicity Reference Values (TRVs) based on data that are 15 years old or older. In  
8 addition, it is difficult to determine if, or which, data from Appendix J were used. There  
9 have been a multitude of excellent peer-reviewed studies that are relevant to this process,  
10 as they have focused on mercury and highly chlorinated compounds such as dioxins.  
11 (Relevant examples are listed at the end of this response.) There are recent data for the  
12 Housatonic and Hudson Rivers for TCDD congeners (and related PCBs), that could be  
13 further employed to reinforce the assumed concentrations and feeding patterns.  
14

15 In Appendix J, section 3.2.3, EPA discusses and rejects the option of using TRVs  
16 expressed in terms of tissue concentrations instead of chemical intake. However,  
17 reporting TRVs in terms of tissue concentrations (rather than intake as commonly done  
18 for human risk assessments) would allow for more and better comparisons with the peer-  
19 reviewed literature and predictions of risk, as there are fewer peer-reviewed literature  
20 reports of intake values. The report should add tables of these values and calculate new  
21 HQs based on steady-state tissue concentrations. It would also be helpful to see predicted  
22 concentrations in sediment and sediment quality guidelines listed in the same table.  
23

24 In the case study, EPA uses a two-stage approach to characterize ecological risks from  
25 Hg and dioxin emissions, In the first stage, risks are summarized by computing hazard  
26 quotients as the exposure dose divided by the TRV (Appendix J, section 3.2.4). The  
27 Hazard Quotient approach is justifiable as a crude screening level approach in  
28 applications such as the RTR assessments, but only if very conservative values are  
29 utilized. For ground-truthing this effort, or for a refined ERA, probabilistic approaches  
30 are needed. We know Hazard Quotient-type ERAs are fraught with unacceptably high  
31 levels of uncertainty regarding exposures and their linkages to adverse effects and do not  
32 account for multi-stressor and non-chemical stressor interactions and resulting effects.  
33 The assumptions of constant exposures are of course conservative, but best used in a  
34 “reference condition” approach whereby multiple reference sites within the area of the  
35 facility are considered. This will help account for the non-facility related exposures and  
36 effects. For a more thorough discussion of these issues and others important to  
37 improving the ERA process, see Dale et al’s (2008) summary of their recent EPA SAB  
38 report (EPA-SAB-08-002).<sup>18</sup>  
39

40 For ecological risk, there are some overlapping charge questions with the human health  
41 risk assessment that should be considered. In particular, Charge Questions 2 and 3,  
42 concerning dispersion modeling and dose-response assessment, affect both risk  
43 assessments. The environmental chemistry (atmospheric chemistry) and fate are critical  
44 for ecological assessment endpoints to be determined. For example, more consideration

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1 needs to be given to how particulate matter may interact with certain types of chemicals  
2 in the emissions. In particular, coarse particulates that settle within 1 to 2 miles of the site  
3 may contain high levels of contaminants and should be considered as a potential exposure  
4 compartment. High  $K_{ow}$  compounds, such as PAHs and dioxins, will adsorb to carbon, so  
5 the presence of particulate matter may be critical in bioavailability and fate. QSAR  
6 (Quantitative structure and activity relationship) models are important in this respect, as  
7 is the nature of the ecosystem into which the chemicals and particulate matter deposit.  
8 Although the TRIM-FaTE model simulations indicate little expected risk to humans via  
9 inhalation, other receptor organisms, such as benthic macroinvertebrates and fish in  
10 waters or soil invertebrates may be affected.

11  
12 On pages J-29 through J-33, EPA presents a sensitivity analysis of how angler harvesting  
13 would affect mercury and dioxin concentrations in food web compartments for the ERA  
14 case study. This analysis should be omitted, as fish harvesting by fishermen should not be  
15 a part of an ERA.

16  
17 In characterizing the risk for the Ravena case study (page J-46), EPA discounts the  
18 finding of elevated HQ values for Ravena pond on the grounds that it is a small water  
19 body with correspondingly small wildlife populations. The rationale that no population  
20 effects will occur in a small water body because there are few individuals is flawed. In  
21 fact, small water bodies with small populations may pose special concerns, as has been  
22 shown in prior studies. Greater population effects would be expected in systems with  
23 fewer individuals, particularly with limited to no refugia for recruitment. Page J-46 also  
24 indicates no adverse effects are expected for piscivorous and insectivorous wildlife, even  
25 though they have elevated HQs. The stated conclusions cannot be justified using the HQ  
26 approach.

27  
28 The assumption that ecological receptors will be protected if human health is protected is  
29 incorrect. Recall the “canary in the coal mine” approach was derived long ago and it is  
30 well known that wildlife are good sentinels for protecting humans due to their greater  
31 sensitivity. Through literature comparisons it should be possible to develop a sound  
32 “safety/application” factor that protects species of concern (note mink/otter will likely be  
33 the species of greatest risk). This literature based factor could then be used to back  
34 calculate (via TRIM-FaTE) to an allowable emissions concentration, which would fit  
35 nicely into the existing flowchart replacing the top decision point based on no human  
36 health effects.

37  
38 Facility ranking scheme: The process to select the Portland cement facilities of greatest  
39 potential concern for HCl deposition using pH, hardness, alkalinity and soil type data was  
40 very good. For site-specific ERAs, however, other site characteristics should also be  
41 considered, such as altitude, gradient, trophic status, TOC levels, watershed location  
42 (e.g., headwaters), sensitive land uses (forested, protected areas, wetlands), and sensitive,  
43 threatened or endangered receptors (e.g., amphibians, mussels, piscivorous wildlife). For  
44 the discussions on Hg, the trophic status of the receiving lake or pond becomes important.

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1 Methylation of Hg is very site dependent. For example, it tends to be stronger in lakes  
2 with high organic matter in the sediments. Over time, much of the terrestrial primary  
3 production moves to the aquatic habitats in watersheds. Hence, the buildup of organic  
4 materials in shallow riparian habitats influences the bioavailability of chemicals  
5 deposited. If the RTR process is to establish a guide for ERAs conducted under the Clean  
6 Air Act, there may be value in adding a section on the importance of obtaining, for each  
7 site, site-specific emissions and exposure data. Otherwise, it will be difficult to account  
8 for the wide range of critical factors that will affect ecological risk and are defensible in a  
9 court of law.

10  
11 Direct-contact ecological assessments: EPA explains it has not developed criteria for  
12 HAPS for direct-contact ecological assessments (page 3-20), yet there was an RTP  
13 workshop 3 to 5 years ago [Federal Register Notice announcement published September  
14 8, 2005 (Volume 70, Number 173, Page 53360)] with the focus of bringing the ERA  
15 process into emissions of HAPs. There were a lot of good ideas put forward that should  
16 be considered for the RTR assessments. There should be a peer-reviewed effort to  
17 reevaluate other potential HAPs of ecological concern, particularly those that associated  
18 with particulates, from both petroleum refinery and Portland cement operation emissions.

19  
20 In summary, many of the above concerns and issues can be addressed by conducting a  
21 ground-truthing ERA at a site such as the Ravenna Pond, or by a comparison of  
22 TRIM.FaTE, predictions with more conventional ERA methods (e.g., using  
23 Bioaccumulation Sediment Accumulation Factors in food web models (e.g.,  
24 TrophicTrace and EcoFRAM by Frank Gobas, USEPA's AQUATOX 2.2, CATs) at a  
25 well studied site with similar CoCs (e.g., see web sites for USEPA reports on Superfund  
26 sites: Lower Housatonic River, Region I  
27 (<http://www.epa.gov/NE/ge/pcbshealthandenviro.html>); Hudson River, Region II  
28 (<http://www.epa.gov/hudson/reports.htm>); Fox River, Region V  
29 (<http://www.epa.gov/Region5/sites/foxriver/index.html>)). This could be done by a  
30 contractor experienced with ERAs and they could use more conventional fate/effect ERA  
31 models using both deterministic and probabilistic approaches with limited on-site  
32 sampling of exposure compartments and receptors. Sediment concentrations of the CoCs  
33 can be linked to food web bioaccumulation and then compared to adverse tissue levels in  
34 the key receptors. This rather simple effort would determine whether the proposed  
35 generalized approach works and is of sufficient accuracy to warrant its nationwide  
36 application. This would allow for refinement of the "nationwide" Tier 1 ERA approach  
37 and with general guidelines for site-specific, Tier 2-type evaluations.

38  
39 Some references that may be relevant as EPA reviews its approach for ERA in the RTR  
40 process are provided below.

41  
42 Bargar TA, Scott GI and Cobb GP. 2001. Maternal transfer of contaminants: Case study  
43 of the excretion of three polychlorinated biphenyl congeners and technical grade

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3
- 4 Brasson RL and Cristol DA. 2008. Effects of mercury exposure on the reproductive success of  
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7
- 8 Custer TW and Heinz GH. 1980. Reproductive success and nest attentiveness of mallard  
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- 11 Custer TW et al. 2002. Dioxins and congener-specific polychlorinated biphenyls in three avian  
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24 February 2009.
- 25 McCarty JP and Secord AL. 1999. Reproductive ecology of tree swallows (*Tachycineta*  
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28
- 29 Nosek JA, Craven SR, Sullivan JR, Olson JR and Peterson RE. 1992. Metabolism and  
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- 32 Rice CP et al. 2003. Souces, Pathways, and Effects of PCBs, Dioxins, and  
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34 CRC Press. Boca Raton FL. Pp 501-573. (a critical review article)
- 35 Tanabe S, Subramanian A, Hidaka H and Tatsukawa R. 1986. Transfer rates and pattern  
36 of PCB isomers and congeners and pp-DDE from mother to egg in Adelie penguin  
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38
- 39 Tillitt DE, Gale RW, Meadows JC, Zajicek JL, Peterman PH, Heaton SN, Jones PD,  
40 Bursian SJ, Kubiak TJ, Giesy JP, and Aulerich RJ 1995. Dietary Exposure of Mink to  
41 Carp from Saginaw Bay. 3. Characterization of Dietary Exposure to Planar Halogenated

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3  
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5 Handbook of Ecotoxicology, 2<sup>nd</sup> edition. CRC Press. Boca Raton FL. Pp 409-463 (a  
6 critical review article)

7  
8  
9 **Charge Question 7**

10  
11 The risk characterizations for these two case studies (Sections 2.3 and 3.6) represent our  
12 current practices in providing information to decision-makers responsible for RTR  
13 rulemaking. The analyses presented in the appendices are by and large illustrative of  
14 what can currently be done in the regulatory context, given time and resource constraints.  
15

16 7 Do these characterizations objectively and completely incorporate the goals and  
17 principles of EPA’s *Risk Characterization Handbook* to the extent scientifically feasible?  
18 In particular do they provide a complete and transparent discussion of uncertainties and  
19 limitations? If not, how can the risk characterizations be improved? Can you suggest  
20 where we might focus any additional efforts and resources in order to have the biggest  
21 impact on refining risk characterizations for these RTR assessments, ultimately leading to  
22 better regulatory decision-making?

23  
24 **Panel Response**

25  
26 Risk characterizations are often difficult to develop because a highly technical  
27 assessment must be communicated to decision makers and others who may lack some of  
28 the underlying technical background. As stated in the *Risk Characterization Handbook*  
29 (pg 13):

30  
31 **“Are Risk Assessment and Risk Characterization the Same?”**

32 No, they’re not the same. Risk assessment is a process comprised of several  
33 steps (see section 1.2.1 above for detail). Risk characterization is the  
34 culminating step of the risk assessment process. Risk characterization  
35 communicates the key findings and the strengths and weaknesses of the  
36 assessment through a conscious and deliberate transparent effort to bring all  
37 the important considerations about risk into an integrated analysis by being  
38 clear, consistent and reasonable”.

39  
40 The RTR report took great care in summarizing and providing justification/explanation  
41 for most of the results, including attention to uncertainties. The summary tables (tables  
42 2-7 and 3-3) were well done and provide a concise summary of the risk assessment  
43 results for the risk manager. However, a number of improvements are possible.  
44

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1 Presentation of risk characterizations: In the RTR case studies, the presentation of  
2 methods, risk assessment results, and risk characterization are intermingled, such that the  
3 purposes of the risk characterization are not met. This can be improved by focusing more  
4 on the purpose of the characterization to communicate with decision makers as the  
5 primary audience, recognizing that transparency is important and that the audience will  
6 inevitably be broad (e.g., a reporter may use it as a source for a story, the regulated  
7 source may use it for community interaction). To these ends the Panel recommends the  
8 following improvements:

- 9
- 10 1. Develop a separate methods document that contains a full description  
11 (including uncertainties) of all of the common components of the source-  
12 specific risk assessments. For example, it would include EPA RfC and  
13 cancer assessment methodologies, the National Emissions Inventory (NEI)  
14 description, AEGL methods, etc.
- 15
- 16 2. Refer back to this master document, as appropriate, in source-specific risk  
17 characterizations, while providing additional information particular to the  
18 source category at issue. For example, in a source-specific risk  
19 characterization, there is no need to repeat a discussion of mode-of-action  
20 for cancer risk if it wasn't used. On the other hand, source-specific  
21 discussions of uncertainties are far more useful than generic boilerplate  
22 about uncertainties. For example, there may be particularly strong (or  
23 weak) elements of the emissions inventory that need to be discussed for a  
24 specific source.
- 25
- 26 3. While other sections of the RTR assessments should document the  
27 technical details, the risk characterization sections should stand alone. A  
28 broad outline of the risk characterization section would include:
  - 29 a. The general background information for the RTR assessment  
30 (perhaps using flow diagrams).
  - 31 b. The risk characterization, with sections on emissions, cancer risk,  
32 non-cancer risk, and ecological risk, each of which *integrate*  
33 results and uncertainties and are written for EPA decision-makers.  
34 For HAPs that are found to drive risks, the risk characterization  
35 should include expanded discussion of the nature of the effects at  
36 issue (including qualitative cancer classification if applicable) and  
37 potential susceptibilities (e.g., children, elderly, women of  
38 childbearing age, individuals with preexisting diseases). For  
39 example, page 3-23 says that the maximum hazard index for  
40 Portland cement manufacturing is associated with potential effects  
41 of manganese compounds on the central nervous system. But what  
42 type of CNS effects are they? What groups are expected to be  
43 more susceptible? Expanded discussion is important to  
44 understanding the "real-world" risk, including dealing with health

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1                   disparities. For example, it would be important to recognize if a  
2                   risk driver for a particular facility exacerbated asthma and the  
3                   community surrounding the facility was a low-income population  
4                   with an elevated incidence of asthma.

- 5                   c. A summary with a clear description of risks of concern, using  
6                   language understandable to an educated non-technical audience.  
7                   This section should be relatively brief and balance the weight-of-  
8                   the-evidence. An example audience for this section might include  
9                   officials in the community where a facility of concern is located;  
10                  they should be able to understand the nature of and degree of risk  
11                  to human and ecological health.

12  
13 Risk characterization for facilities covered by more than one source category: The Clean  
14 Air Act requires residual risk assessment of source categories, which have a particular  
15 definition that may only include part of a facility. For example, the petroleum refinery  
16 MACT 1 standards do not cover combustion processes within a refinery facility.  
17 Although this requirement for separate assessments has practical regulatory implications,  
18 it only partially accounts for potential human health or ecological risk. Since regulators  
19 seek protection of the public health and the environment, the risk characterization should  
20 clearly explain the inherent limitations of only dealing with one source category at a time.  
21 This limitation needs to be clearly noted for the risk manager. This will not change the  
22 source risk characterization itself. However, it can change its interpretation, especially in  
23 the case of large industrial complexes. For example, the Coke Oven Residual Risk  
24 Assessment clearly identifies that it is assessing a source category (i.e., coke batteries)  
25 that is only part of an entire facility.<sup>23</sup> The risk assessment provides the estimated risk  
26 associated with emissions from the subpart and also accounts for similar emissions from  
27 different processes at the plant to provide the risk manager with an estimate of the total  
28 facility risk in the surrounding community. The risk characterization section should  
29 provide an estimate of total facility risk for facilities subject to multiple federal emission  
30 standards for hazardous air pollutants or clearly identify it as an outstanding issue that  
31 needs to be examined further.

32  
33 Characterization of aggregate and cumulative risks: Since risk will be influenced by  
34 aggregate and cumulative exposures, finding that a source category has no significant risk  
35 from a particular chemical or a mixture of chemicals does not mean that people in the  
36 area are without risk from that chemical or mixture. For example, Houston faces  
37 particularly difficult air toxics challenges due to the significant air emissions from one of  
38 the largest petrochemical complexes in the world. There are more than 100 benzene  
39 sources alone from refineries and chemical plants in the Houston area. Harris County, in  
40 which Houston is located, over 19 million pounds of hazardous air pollutants were  
41 emitted in 2003, including 750,325 pounds of benzene according to the EPA's 2003  
42 Toxic Release Inventory (TRI) report. From a public health viewpoint, personal

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<sup>23</sup> United States Environmental Protection Agency (USEPA) 2005a. USEPA Risk Assessment Document for Coke Oven MACT (maximum achievable control technology) Residual Risk – March 31, 2005

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1 exposures resulting from occupational or behavior (e.g., smoking) sources can also  
2 contribute to risk beyond that of a particular source category.

3  
4 Ecological examples where aggregate risks are important also exist. The PB-HAP  
5 methodology used for the case studies does not consider background concentrations,  
6 focusing instead on incremental risks from the source category. However, ecological  
7 resources are also influenced by aggregate and cumulative exposure that must be  
8 considered in protecting the environment. The ecological receptors, just as humans, are  
9 affected by their total environment and all the stressors to which they are exposed.  
10 Exposures to multiple stressors at sub-lethal levels can result in lethal effects. Since  
11 many of these facilities will be located in human-dominated watersheds, there is a high  
12 probability that organisms will be exposed to multiple stressors.

13  
14 Linkage of Hazardous Air Pollution Emissions and Risk Assessment: RTR assessments  
15 must provide clear documentation of the hazardous air pollutants emissions that are  
16 modeled in the risk assessment. For example, the RTR case study models actual  
17 emissions using the 2002 National Emissions Inventory (NEI) and there apparently was  
18 an adjustment of these emissions using site-specific data from 22 refineries as provided  
19 by the American Petroleum Institute. However, it is not clear what adjustments were  
20 made.

21  
22 The risk characterization for petroleum refineries includes a discussion of an ingestion  
23 pathway screen for POM emissions and indicates all 156 facilities were screened.  
24 However, one important aspect of this screening was not adequately explained. Only 70  
25 facilities reported some type of POM emissions (Table 2-6) and the POM emission rates  
26 used to assess the potential risk for 156 facilities are never explained to the risk manager.  
27 The emission summary tables should include the emissions that were modeled to estimate  
28 cancer and non-cancer risk for the inhalation and ingestion pathways.

29  
30 Identification and discussion of uncertainties: RTR assessments must proceed even  
31 though most will have a relatively long list of uncertainties. Such a list should be treated  
32 as an opportunity to identify future improvements. Insofar as possible, the Panel  
33 recommends that EPA perform a sensitivity analysis to identify the major uncertainties  
34 and then proceed to: (1) explain them clearly in the risk characterization section and (2)  
35 take steps to reduce them. For example, it appears that the NEI and paucity of up-to-date  
36 IRIS values are very likely to have a significant impact on the quality of the RTR  
37 assessments. These problems should be emphasized more, and EPA management should  
38 seek improvements so that future assessments can benefit. Action on major uncertainties  
39 that can be identified very early in the assessment of a particular source could have a  
40 substantial impact on the utility of that assessment. For example, if an apparent chemical  
41 driver has an out-of-date (or no) health value, it may be possible to rectify this problem  
42 prior to completion of the assessment.

43

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1 In the case studies, EPA has generally done a good job of investigating uncertainty in  
2 many aspects of the inputs for the residual risk assessments. The sensitivity analyses  
3 provided to the panel are extensive. However, the next step is to carry the results of these  
4 uncertainty analyses through to the final risk results and characterization. There are too  
5 many sources of uncertainty to qualitatively brush aside differences with statements  
6 discounting degrees of uncertainty because of either the risk range or that the component  
7 in question “does not introduce significant uncertainty into the risk assessment relative to  
8 other sources of uncertainty that limit reporting risk estimates to one significant figure”  
9 (page 4-7).

10  
11 As one example, on pages 2-21 and 2-27, the concern is raised that Canadian and  
12 European studies [30, 31] suggest emissions from some refineries are significantly higher  
13 than amounts estimated, but this is acknowledged almost in passing in the uncertainty  
14 section (page 2-30). This is an important issue for the human and ecological risk  
15 assessment and if it cannot be accounted for, then appropriate uncertainty factors must be  
16 used.

17  
18 Ecological risk characterization: According to USEPA ERA guidelines, the Risk  
19 Characterization should link measurement endpoint effects back to the assessment  
20 endpoints and conceptual model, which this report does not do. Furthermore, as discussed  
21 in the response to Charge Question 6, no site-specific data exist for the ERAs, with every  
22 aspect of the ERA from exposure to effects (thus the risk characterization) being based on  
23 non-site data averaging, assumptions, questionable extrapolations, averaged/steady state  
24 conditions, and literature-based values. It seems that the only ways to get past the huge  
25 uncertainties involved are to do some case studies with site specific data that would  
26 represent a Tier 1 ERA, or to compare the TRIM.FaTE predictions to those of another  
27 peer-reviewed study (e.g., studies conducted at Superfund sites such as the Lower  
28 Housatonic River, Fox River, or Hudson River). After those efforts are completed, a  
29 guidance document could be provided that explains the general ERA process for the Tier  
30 1 exercise, the most critical input parameters to determine if a site risk may exist (e.g.,  
31 sensitive ecosystems/receptors, high emissions), and suggest a more refined Tier 2 ERA  
32 process following USEPA ERA guidelines for reducing uncertainties. In addition, the  
33 public will be suspicious of the assumption that petroleum refinery emissions are not an  
34 ecological risk issue, so a more thorough justification is needed with site specific  
35 documentation.

36  
37 A few strong contentions regarding ecological risks need more discussion and  
38 justification. For example, page 3-20 (second paragraph under 3.5.1) contends that if  
39 there are no adverse effects on humans, the “potential for adverse environmental  
40 effects...was considered to be insignificant. This assumption needs some scientific  
41 justification. Also, the rationale (e.g., pages 3-22 and J12 (J-3.2.4)) that no population  
42 effects will occur in a small water body because there are few individuals is flawed, and  
43 could be the reverse. Fewer individuals (lower abundance) means the population is more

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1 susceptible to extinction, particularly if there are few to no areas of refugia for  
2 recruitment of new individuals.

3  
4 On page 2-29 it is stated that contaminant concentrations were evaluated against  
5 ecological benchmarks for sediment, soil and water. These comparisons were not found  
6 and must be reviewed. Which benchmarks (there are many for sediments)? What  
7 concentrations were used for each media? What was their associated uncertainty?  
8

9 Cancer risk characterization: In Table 2-6 on page 2-22, the blank space for toluene  
10 cancer unit risk stands out because toluene has the greatest emissions. A person scanning  
11 this table would worry that this unknown could be a great source of risk. The document  
12 should explicitly discuss toluene cancer studies (from IRIS) and risk classification in the  
13 earlier section on dose-response. It should also provide a summary in the text here about  
14 the evidence being inconclusive, but since good studies were performed carcinogenic  
15 effects would likely have been observed if the risk were high. Thus, it cannot be  
16 dismissed, but there is no current evidence for significant concern.  
17

18 In the discussion of uncertainties in dose-response relationships for cancer assessment,  
19 the most important uncertainty is probably that the upper bound is used for assessments.  
20 The discussion of this issue in the last paragraph of page 2-32 is good. Page 2-33  
21 describes the cancer guidelines accurately. However, with perhaps one exception,  
22 defaults were used. For example, on page 2-33, the paragraph dealing with  
23 pharmacokinetic models is accurate, but not relevant if none of the URE values were  
24 actually developed or modified through such an analysis. If they were not, this  
25 information should be deleted and only included in case studies where it was used,  
26 specifying the chemical for which it was used.  
27

28 Characterization of chronic non-cancer risks: This section has about two full pages of  
29 description of the RfC/D methodology (pages 2-36 on). It should be reduced by about  
30 half, only providing information pertinent to understanding which uncertainties applied to  
31 the particular source category and which were accounted for in the RfC/D derivation. A  
32 full description of the methods is more appropriate for a separate general methods  
33 document. Some of the discussion here is redundant. A simple description will  
34 communicate the process better. The focus should be on the RfC, with a brief paragraph  
35 explaining where the RfD differs. Right now, much of the text treats the RfD as the  
36 “standard”, when it doesn’t apply (e.g., dosimetric adjustment). There are also a few  
37 missing elements or errors in the description of the methodology, which are described  
38 below.

- 39 a. Insert a sentence that states that the RfC has basic data requirements (e.g.,  
40 at least a 90 day study, etc) before proceeding, to explain that an RfC is  
41 not guesswork.  
42 b. Insert a short discussion about how many of the uncertainty factors (UFs)  
43 have redundant elements and therefore are conservative when multiple  
44 UFs are used. That is why EPA has a maximum of a total factor of 3000.

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- 1 c. On page 2-37, under paragraph “1)”, note that the heterogeneity UF  
2 includes children, people with preexisting disease, and other populations  
3 that may have added susceptibility. This is implied in the word  
4 “heterogeneity,” but it is important to be direct about such a critical risk  
5 element.
- 6 d. On page 2-37, paragraph “2)” needs significant revision. The RfC  
7 methodology for extrapolation from animals to humans includes a  
8 dosimetric adjustment, resulting in the routine use of an UF of 3 to  
9 account for pharmacodynamic extrapolation. The RfD methodology does  
10 not do this routinely. This is a major difference. The paragraph implies  
11 that an UF of 10 is routinely used. Also, the paragraph talks about  
12 mg/kg/day which is only relevant to the RfD.

13  
14 Characterization of acute health risks: The discussion on page 2-38 should be expanded  
15 to cover the uncertainties involved in the values chosen (e.g., AEGLs, ERPG). This is  
16 especially important since these are levels that cause effects, rather than “safe” levels.  
17 The discussion in this section should better parallel the section on chronic risks. The  
18 difficulty is that acute did not really contribute much risk in the case study, but it still  
19 bears more discussion.

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2 APPENDIX  
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5 Editorial suggestions for risk characterization sections:  
6

- 7 1. As described in the EPA document, during the risk characterization step,  
8 information from other risk assessment steps is integrated to come to an overall  
9 conclusion about the risks involved. As a result, for the petroleum refinery  
10 discussion, Section 2.3.2 and the information in Tables 2-7 and 2-8 should be  
11 included in the Risk Characterization section. Similarly for the Portland cement  
12 discussion, Section 3.3 and the information contained in Tables 3-3 and 3-4  
13 should be included in the Risk Characterization section. The details of EPA's  
14 cancer guidelines for early-life exposure (page 2-17, last paragraph) should be  
15 moved to section 2.2.6 on dose-response assessment. The risk characterization  
16 should provide some of this information, but delete the details for the age groups  
17 and also the BaP equivalence.
- 18 2. The risk characterization should "stand alone". For example, in some cases  
19 abbreviations are used excessively for the intended audience. All but very  
20 common abbreviations (e.g. HAP) should be avoided. For example, on page 2-  
21 19, "TOSHI" should be spelled out. The abbreviation URE should be defined on  
22 page 2-17, in paragraph 3.
- 23 3. On page 2-22, in Table 2-6, in the first row, specify that the URE is the upper  
24 bound (perhaps through a footnote).
- 25 4. The footnotes often provide excessive detail for the intended audience. Perhaps  
26 they could be summarized in plain English, with references provided for those  
27 seeking the precise words. Footnote 29 might be omitted.
- 28 5. P2-18ff. Section 2.2.7.2 Mixtures. P2-19, line 1. The word aggregate should be  
29 changed to cumulative since the intent here is to look at mixtures of different  
30 chemicals.
- 31 6. P 2-26 Table 2-8. Consider adding a footnote that defines the term "refined" used  
32 in the title.
- 33 7. P2-32, Section 2.4.2. Para 1 The description of durations not used could be  
34 deleted (i.e., just keep the descriptions for 1 hr and chronic durations).
- 35 8. P2-35. Last paragraph, "Chronic noncancer..." after the word represent, delete  
36 "chronic" and insert "70-year lifetime continuous exposure". Since everyone  
37 knows that such exposure scenarios are highly unlikely, the reader will  
38 automatically sense an uncertainty in the conservative direction.
- 39 9. P2-36 paragraph 3, line 3. Delete "relevant" and insert "sensitive" after endpoint.  
40 It is the "critical" endpoint, but such language doesn't really communicate  
41 effectively.
- 42 10. P2-38 para 1. Line 4. Insert "respiratory" before irritation.  
43  
44