

The Office of Environmental Health Hazard Assessment
Response to Public Comments on
The Air Toxics Hot Spots Program Guidance Manual for
Preparation of Health Risk Assessments

July 2002

Comments of the Battery Council International

Timothy J. Lafond, Chairman, Environmental Committee of the Battery Council International (BCI) submitted comments on the Air Toxics Hot Spots Program Guidance Manual as it pertains to lead and lead compounds in a letter dated July 8, 2002. BCI is a non-profit trade association whose members are engaged in the manufacture, distribution and reclamation of lead batteries.

Comment: As the Air Resources Board's (ARB's) *Risk Management Guidelines for New, Modified, or Existing Sources of Lead* (March 2001) (hereinafter "Lead Source Guidelines") is the substantive basis for Appendix F, the Overview of Lead Risk Assessment Procedures, it should be referenced in the Guidance Manual's introduction section (1.1) along with the existing references to the Air Toxics Hot Spots Program Risk Assessment Guidelines, Parts I - IV.

Response: OEHHA staff will add a reference to the Risk Management Guidelines for New, Modified, or Existing Sources of Lead as well as a reference to the Toxic Air Contaminant identification document for lead in the section describing evaluation of noncancer risk (Section 8.3). It does not fit well into Section 1.1.

Comment: The Lead Source Guidelines, also should be incorporated into Appendix F, the Overview of Lead Risk Assessment Procedures, in its entirety. While a brief summary of the Lead Source Guidelines and, from it, Table 2 (Percentage of Children with Blood Lead Levels \geq 10 $\mu\text{g}/\text{dL}$ for Various Air Lead Concentrations at Two Exposure Scenarios) have been incorporated, missing from the Guidance Manual are important qualifying language and discussions that, if included, would provide critical background and improved balance.

Response: The Risk Management Guidelines for lead deal with risk management of stationary lead sources. As such, it is not appropriate to include them in their entirety in a Risk Assessment Guidance. We excerpted the important pieces from the Risk Management Guidelines that describe methods for estimating noncancer risk from stationary sources appropriate for the Air Toxics Hot Spots facilities. The risk assessment methods that were incorporated in the Lead Risk Management Guidelines were based on, and are consistent with the Toxic Air Contaminant identification document for lead approved by the Scientific Review Panel.

Comments by CH2MHill

Comments on the Guidance Manual for Preparation of Health Risk Assessments were submitted by John Castleberry, Air Quality Specialist with CH2MHill, in a letter dated July 8, 2002.

Comment 1. General Comment. The guidance document contains a lot of text that is extraneous, in that it is actually background information rather than guidance. Sections 4.3, 4.4, 4.9, 4.10, and 4.11 are some examples. This extraneous text makes the document a lot longer and more confusing than it really needs to be. I would suggest deleting such text.

Response: In preparing the document OEHHA staff attempted to balance the desire for a stand-alone document with the realization that much of the information was already available in the four Technical Support Documents. OEHHA staff will review the manual for additional appropriate deletions.

Comment 2. General Comment. The guidance document contains a lot of indecisive words like "may" and "can" throughout. I would suggest using more decisive text, where appropriate, to make the guidance more definitive.

Response: This is a guidance manual and there is flexibility involved. However, OEHHA staff will review the document for improved language in this area and others.

Comment 3. General Comment. Throughout the guidance document, many decisions are delegated to the local air districts (the 3rd paragraph on Page 4-17 is just one example). To simplify the coordination process between the regulated facility and the local air district, I would suggest adding a table in the guidance document that consolidates these district-needed decisions into a single place. That way, the facility can refer to that table when discussing the IRA approach with the district.

Response: In general the Districts have responsibility for emissions inventory, prioritization, criteria for notification, review and approval of air modeling protocol where formal risk assessments are required and establishing criteria and procedures for notification. The Air Resources Board (ARB) has responsibility for generating general guidance and some oversight responsibilities. OEHHA is responsible for producing the risk assessment guidance for the program and is required to review Hot Spots risk assessments and notify the District of our findings. There are suggestions to consult with the District, ARB or in some cases OEHHA scattered throughout the document. The reason for these suggestions is so that the risk assessment preparer is aware of which procedures require District or OEHHA review when the risk assessment is submitted.

Comment 4. General Comment. This new risk assessment methodology (even Tier 1) and the reporting requirements are more rigorous than the CAPCOA guidelines. In addition, cancer risks

will increase by about 30 percent. In short, facilities will be required to do more work to get a higher risk. This will come as an unpleasant surprise to many facilities.

Response: The cancer risks are increased by around 30% with the inhalation pathway. OEHHA was mandated under SB-1731 to come up with a “likelihood of risks” approach to risk assessment. During this process we reevaluating the appropriate default values for breathing rates and determined in the light of new studies that a higher default breathing rate was appropriate, particularly to protect children. The new default breathing rates were in the Part IV Technical Support Document for Exposure Assessment and Stochastic Analysis. This document underwent two rounds of public comment and mandated peer review by the State’s Scientific Review Panel on Toxic Air Contaminants. The Part IV Technical Support Document was formally adopted by the Director of OEHHA in September of 2000. The results of the breathing rate evaluation have been accepted for publication in the peer-reviewed journal Human and Ecological Risk Assessment and should appear in next few months.

Comment 5. Page 1-1, 2nd paragraph, 7th sentence - revise to say, "Only Tier-1 applies to acute exposure evaluations..."

Response: OEHHA staff will make this change.

Comment 6. Page 4-4,1st paragraph, 2nd sentence. The word "average" should be removed from the sentence.

Response: The sentence reads, “Specifically, HRAs should include both annual average emissions and maximum 1-hour emissions for each pollutant.” The annual average emissions is standard terminology.

Comment 7. Page 4-6,1st paragraph, 4th sentence. Does the guidance allow the use of hourly emission scalars (when necessary) in the dispersion model to account for diurnal emission patterns? Please clarify.

Response: Yes, hourly emission scalars are needed to best represent emissions from facilities, especially for diurnal patterns. Air dispersion models, such as ISCST3 and AERMOD, readily accept hourly emission scalars and are fully functional in the HARP software with ISCST3 (only). We will work to clarify this in the guidance manual.

Comment 8. Page 4-6, 2nd paragraph, 1st sentence. This requirement is too burdensome on large facilities. Is it not enough to reference the emission inventory report?

Response: In our experience from reviewing risk assessments, this requirement has only involved a few paragraphs of explanation. Some interested parties, such as OEHHA staff, usually do not see the emission inventory report (EIR). The Hot Spots legislation is a public-right-to-know-act and such descriptions aid public understanding.

Comment 9. Page 4-7, Sections 4.3 and 4.4. What is the point of these sections? These sections are not prescriptive and therefore should not be included in the guidance document. I would suggest simply referencing EPA's Guideline on Air Quality Models in lieu of these sections.

Response: In preparing the document OEHHA staff attempted to balance the desire for a stand-alone document with the realization that much of the information was already available in the four Technical Support Documents. OEHHA staff will review the manual for additional appropriate deletions.

Comment 10. Page 4-12, 1st paragraph. This paragraph on population exposure is very confusing until the reader gets much further along in the guidance document. I suggest adding a few sentences explaining what population exposure estimates are.

Response: The paragraph is confusing and we will revise it for clarity.

Comment 11. Page 4-12, 4th paragraph, 3rd sentence. What is the point in providing two different cancer risk zone of impact maps (one for the minimum exposure pathways, and another for all applicable pathways)? Why not just the latter? This seems unnecessarily burdensome on facilities.

Response: The information requested may be of use for risk management decisions and public notification. However, we recognize that the additional information adds to the complexity and cost of the risk assessment. We will make the minimum exposure pathway isopleths an option that the Districts may request at their discretion. Alternatively, one map could be provided with all relevant pathway cancer risk isopleths.

Comment 12. Page 4-13, 1st paragraph, 3rd sentence. What is the point in providing two different chronic zone of impact maps (one for inhalation, and another for all applicable pathways)? Why not just the latter? And why don't these maps include the same pathway groupings that are required for cancer risk?

Response: The information requested may be of use for risk management decisions and public notification. We will indicate that the Districts may require separate maps for inhalation and other pathways at their discretion but that the total risk isopleth maps are required.

Comment 13. Page 4-13, Section 4.6.2. Step 3 seems to end without achieving the population estimates. Shouldn't there be a "Step 4"?

Response: We will add clarifying language to this section.

Comment 14. Page 4-14, 1st paragraph (after the numbered items), 1st sentence. I suggest using a term other than "multi-tiered", as this can be confused with the 4 Tiers of risk assessment described in this document.

Response: OEHHA staff will substitute multi-level for multi-tiered.

Comment 15. Page 4-14, 1st paragraph (after the numbered items), 1st sentence. Is the area where "the facility could significantly impact" defined as the area inside the zone of impact? And if two different zone of impact maps are required, which zone would that be? Please clarify.

Response: We will replace "the facility could significantly impact" with "zone of impact".

Comment 16. Page 4-14, 1st paragraph (after the numbered items), 2nd sentence. The word "First" is used, but there is never a "second" later in the paragraph. This is confusing.

Response: OEHHA staff will delete the word "first."

Comment 17. Page 4-16, 5th paragraph, 2nd sentence. Why is the identification of sensitive receptor locations "crucial" in evaluating the potential impact of "the toxic effect"? What does this mean?

Response: The public is often concerned that more susceptible members of the public, such as kids at day care centers, patients in hospitals and seniors in extended care nursing facilities, have not been accounted for in a risk assessment. OEHHA considers the identification of sensitive receptor locations as crucial so as to assure the public that they are accounted for.

Comment 18. Page 4-16, Section 4.7.1. Why does the guidance document not specify minimum fine grid receptor spacing for the HRA to identify the PM1, MEIR, and MEIW? I would suggest requiring 50 meter spacing.

Response: Since these guidelines will be used by various facilities, it is inappropriate to specify a single minimum grid that must be used for all assessments. Rather, this decision is left to the assessor to determine the minimum fine grid spacing that is appropriate to illustrate the potential impacts surrounding the facility. Currently, a minimum grid spacing of 20 meters is used to identify potential impacts at a receptor in the near field.

Comment 19. Page 5-1, 3rd paragraph, 1st sentence. How is the "facility boundary" defined? The property line? The fence line?

Response: The facility boundary is defined as the property line. Often the fence is on the property line. We will add language to make this clear.

Comment 20. Page 5-3, 2nd bullet item, last sentence. Why is the dermal pathway singled out and discussed in a separate sentence from the other noninhalation pathways? Is there something unique in the way the dermal pathway must be assessed?

Response: Exposure via the dermal pathway does not occur orally. However the oral cancer potency factors and oral chronic reference levels are used to evaluate this pathway. The dermal pathway is of course a noninhalation pathway.

Comment 21. Page 5-3, last paragraph, 3rd sentence. How exactly are other, non mandatory, exposure pathways evaluated for inclusion or exclusion in the risk assessment? The guidance document offers no specific criteria.

Response: The non-mandatory noninhalation exposure pathways are included in the risk assessments only if local conditions surrounding the facility warrant inclusion. There may be no home gardens, home raised chickens, pigs or cows, impacted water bodies used for drinking water or fishable bodies or water in the vicinity of a facility. In such cases exposure to facility multipathway chemical emissions through consumption of water, fisher caught fish or homegrown produce, meat, milk, or eggs will not occur. From our experience from reviewing risk assessments, we have found that sometimes the homegrown produce and occasionally homegrown chicken and eggs among the non-mandatory pathways need to be evaluated. Only in tiny fraction of risk assessments do conditions around facilities warrant the inclusion of other non-mandatory pathways. The local air District should be consulted about the appropriate pathways for a particular facility. HARP can accommodate all the pathways of interest that are relevant to the facility. We will add clarifying language to Page 5-3 to indicate the criteria.

Comment 22. Page 5.3, last paragraph, 5th sentence. This sentence seems out of place with the rest of the paragraph. Is the point of the sentence to remind the reader not to forget about on site residential receptors?

Response: Yes.

Comment 23. Page 5-5, section 5.3.1, item "c". The guidance should allow the user to include plume depletion in the dispersion model to adjust air concentrations when particulate matter settling and deposition is occurring.

Response: The local air District should be consulted on this issue.

Comment 24. Page 5-5, section 5.3.2, item "b". What exactly qualifies a source as "controlled"? Although some sources may not be equipped with control devices, their emissions nevertheless are fine particulate matter (internal combustion engines, for example). In this case, the 0.02 m/s

settling velocity would be appropriate. The 0.05 m/s is only appropriate for uncontrolled fugitive dust sources.

Response: The guidance manual will be clarified (page 5-5 and section 8.2.4.a) to reflect the following language. Use the 0.02 m/s factor for emission sources that have verifiable particulate matter control devices or for emission sources that may be uncontrolled but only emit particulate matter that is less than 2.5 microns (e.g., IC engines powered by CNG).

Comment 25. Page 8-1, last paragraph, 7th sentence. Why can't a facility perform a stochastic approach for worker exposure or noncancer chronic evaluations?

Response: Specific distributions would have developed for worker exposure. OEHHA has not developed such distributions due to resource constraints. Usually residential exposure is more significant than offsite worker exposure, so the number of instances that a facility would be interested in doing a more complex stochastic analysis could be limited. Facilities always have the option of developing alternative risk assessments. OEHHA would review offsite worker stochastic analyses as part of our review of the rest of the risk assessment. OEHHA has looked at the issues involved in stochastic noncancer risk assessment and concluded that with current methodology such analyses do not add much useful additional insight into facility risk. However, if a facility wished to produce an alternative risk assessment involving a stochastic noncancer chronic evaluation, OEHHA would review it and provide comments to the District. Alternative risk assessments are specifically allowed by the Hot Spots legislation.

Comment 26. Page 8-1, last paragraph - I suggest inserting a table or figure that more clearly illustrates the various scenarios discussed in this paragraph.

Response: We will add a Table to clarify the information on Page 8-1, last paragraph.

Comment 27. Page 8-3, first paragraph, 5th through 7th sentences. This justification for a 70-year exposure period is not fair to the regulated facility. The facility's reported risk should not incorporate any assumptions for what a person may or may not be exposed to from *other facilities* during his or her lifetime. The facility should be required to report its own risk, and nothing more.

Response: The acceptable risk levels set by the District assume 70-year exposure duration. The theoretical cancer burden from facility emissions remains the same irrespective of residential turnover. People do not on the average live in the same residence for 70 years, however some individuals do reside at the same residence for large fraction of a lifetime. People commonly live their entire lives in the South Coast Air Basin within the isopleths of multiple facilities. The Hot Spots legislation specifically authorizes consideration of cumulative impact. OEHHA is looking into this issue

Comment 28. Page 8-5, last paragraph, 7th sentence. In this example, what exactly is meant by “impact a fishable body of water”? Please clarify that this means a fishable body of water located within the facility's zone of impact.

Response: OEHHA staff will clarify this issue.

Comment 29. Page 8-7, 2nd paragraph. The 3rd sentence, in most cases, means that the dominant pathways for cancer risk will consist of inhalation plus the single highest noninhalation pathway. The 4th sentence implies that the dominant noncancer pathways will consist of inhalation plus the two highest noninhalation *pathways*. *Why* is there a *discrepancy* between *cancer risk* (one noninhalation pathway) and noncancer risk (two noninhalation pathways)?

Response: The chronic inhalation pathway is calculated by multiplying the ground level concentrations times the chronic REL. There is no high end or average value for inhalation pathway for the chronic hazard. Therefore we decided to include an extra noninhalation high-end pathway in our calculation. We have reworded to the 2nd paragraph on page 8-10 (Section 8.3) to clarify this point.

Comment 30. page 8-7, last paragraph, 2nd sentence. Replace the words "may not be warranted" with "is not required".

Response: The facility always has the option of doing further analyses. It is unlikely that the Districts would be interested in requiring additional analyses.

Comment 31. Page 8-8, 1st paragraph, last sentence. Why are no exposure duration adjustments allowed for noncancer assessments? What about chronic noncancer assessments when the facility's daily emissions occur over a longer period of time than an exposed worker's daily schedule? In this case, the worker's dose should be adjusted downward accordingly.

Response: The cancer potency is based on a continuous 70-year lifetime exposure. Thus an adjustment is allowed for what are less than lifetime exposures. The chronic RELs are based on long-term exposure but not necessarily lifetime. For derivation of chronic RELs from human occupational studies as few as eight years workplace exposure is considered chronic. In the case where a facility's daily emissions occur over a longer period of time than an exposed worker's daily schedule, the exposure to the worker from the facility's emissions should be calculated based on the air concentration when the worker is present at work.

Comment 32. Page 8-10, 1st paragraph, 2nd sentence. Replace "annual average" with "annual or multi-year average".

Response: The annual average concentration is needed for the noncancer chronic health impacts calculation. Please see Chapter 4 for details.

Comment 33. Page 8-13, 2nd paragraph. Replace "RELs" with "hazard quotients".

Response: The suggested change has been made.

Comment 34. Page 8-15, 1st paragraph. Please clarify that the zone of impact is the area within the isopleth, rather than the area within a circle with a radius equal to the farthest distance to the isopleth. The latter is unnecessarily conservative.

Response: We will add clarifying language.

Comment 35. Page 9-2, 2nd bullet, 1st sentence. Delete this sentence, as references and methods are already provided in the emission inventory report. This is unnecessarily burdensome to facilities.

Response: As an alternative, the District could make both the EIR and the health risk assessment available to the public as a way to avoid duplicating this information.

Comment 36. Page 9-6, 1st bullet. Delete this bullet, as it is already covered by the emission inventory report. This is unnecessary burdensome to facilities.

Response: Comment noted. Unfortunately not all reviewers, including OEHHA staff, get to see the Emission Inventory Report. As an alternative, the District could make both the EIR and the health risk assessment available to the public as a way to avoid duplicating this information.

Comment 37. Page 9-6, 1st paragraph after "B. Exposure assessment", 4th sentence. If HARP is used to perform the risk calculations, then sample calculations should not be required.

Response: To the public HARP may appear to be a black box. Sample calculations are intended to show the interested person who knows general arithmetic the way that at least some of the numbers in the report are generated.

Comment 38. Page 9-6, 1st paragraph after "B. Exposure assessment," 5th sentence. Replace the words "The reader" with "The educated reader".

Response: We will make the suggested change.

Comment 39. Page 9-7, "Emission Control Equipment and Efficiency." Delete this bullet because it is covered by the emission inventory report. This is unnecessarily burdensome to facilities.

Response: We have added language indicating that the description should be brief.

Comment 40. Page 9-8, "Emission Estimation Methods." Delete this bullet because it is covered by the emission inventory report. This is unnecessarily burdensome to facilities.

Response: As an alternative, the District could make both the EIR and the health risk assessment available to the public as a way to avoid duplicating this information.

Comment 41. Page 9-8, last bullet, last sentence. The maximum target organ often changes from receptor to receptor; therefore, this sentence should be deleted.

Response: We will make the suggested change.

Comment 42. Page 9-10, "6. Air Dispersion .Modeling Results", 2nd and 3rd bullets. Unless HARP generates printouts that exactly match what these bullets are requesting, this would be an extremely burdensome exercise for facilities. Delete these bullets.

Response: The HARP program does not auto-generate this report. The information is available in HARP and can be transferred in a comma-delimited format to a text program and edited. We agree that it may be better to submit this information electronically and are considering a clarification to the guideline manual.

Comment 43. Page 9-13, 4th bullet. This item should be optional. Additionally, this guidance document should provide the discussion of the strengths and weaknesses of the risk analysis and associated uncertainty. The facility should be able to cut and paste from, or refer to, this guidance document.

Response: We have added language to make the discussion optional.

Comments from IWG Corporation

Dr. Lawrence Gratt from IWG Corporation, CA 92037, submitted comments on the Draft Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments in a letter dated July 3, 2002.

Comment: The overall document is an informative well-written guidance manual that should be useful for managing toxics in California. OEHHA and ARB are to be congratulated for producing a leading-edge regulatory tool with the HARP software to support the data compilation and analysis.

Response: Comment noted. We hope our Guidance manual will be useful.

Comment: Overall Concern of the Document. My comments involve the technical accuracy of selected statements and the misuse of terminology in the risk assessment area. Many of my previous comments have been understood and correct terminology has been used in important places. It appears that there is still a disconnection between some of the authors and my interpretation of stochastic analysis. Unfortunately, with many authors involved in the preparation of this document, it appears that several sections are still using inappropriate definitions. I will try again to present an overall explanation of stochastic risk assessment and will offer corrections to the wording that I feel is deficient. I will also recommend a list of references for those readers that may like additional information. But, you may ask, why am I making such an issue over the terminology? My experience has shown it to be very important when communicating with the public. Technical personnel using sloppy terms enforce public misconceptions. The excuse that the "public won't understand" or the "public is dumb" is not justified. If risk assessors do not use proper terminology, the alternative definitions will be reinforced.

About seven years ago a respected member of the SDAPCD described the results of AB2588 regulatory risk assessment as the "upper 95 % confidence level on the human health risk," in a public forum. I told him after his talk that his statement was incorrect. That in fact it *is an estimate of the risk based on an upper 95% confidence bound of a multistage model fit to animal toxicological data and a yearly average exposure assumed over a lifetime*. I went on to explain the assumptions and limitations of the risk estimate. Obviously, my explanation did not make an impression because the next year he used the exact same statement in another talk.

I hope stochastic risk assessment will not suffer the same fate.

I offer my definitions as follows:

Random Variable: a mapping of events to real numbers.

Stochastic Process: a random variable that is a function of time.

Hazard: a potential for harm.

Risk: the probability of an adverse event

I think the terminology problem may arise through the concept of trying to make a point estimate (deterministic) into a stochastic estimate. To properly consider a stochastic estimate, the function of concern must be defined. A point estimate of this function is usually done for simplicity and may initially be the only way to calculate an estimate. The random variables exposure and risk are both stochastic processes. Risk uses exposure but is a very different random variable. Risk can be formulated as random variable representing an exposure multiplied by the conditional probability of health impact given that the exposure has occurred. The mathematics using axiomatic probability theory calls for the convolution of the two probability distributions. The reduction to multiplying two point estimates together is the simplification to calculate the risk. Treating the exposure stochastically does not make the risk stochastic if the second distribution is a point estimate. It does give the risk manager more information about the risk based on a stochastic exposure assessment, but it is **not stochastic risk assessment**. Any claims that it is stochastic risk assessment is misleading. The bulk of the uncertainty (and variability) is unfortunately in the non-exposure part of the risk estimate for many risk assessments. Thus, if the public believes the uncertainties have all been incorporated (and the results are real), they will have a false impression. If the health impact is treated as an upper bound under the guise of "protecting the public," risk managers may be presented with improper information.

In previous response to comments the response included that statement, "Creating a distribution on the basis of very limited information implies a greater scientific precision than that which exists." Since the health damage functions are all point estimates, the exposure distribution being multiplied by a point estimate does not create a risk distribution. I must emphasize that the exposure is treated stochastically but the risk is not.

Response: OEHHA shares the commentator's concern about the lack of precise terminology in the field of stochastic risk assessment. There does not appear to be general agreement on even such basic terms such as uncertainty, which is often used interchangeably to mean variability, uncertainty (as defined as what it not known) and the two combined. There is also no general agreement on the best approach (e.g., separate or combined propagation of uncertainty and variability). There is a diversity of opinion on procedures for generating probability distribution functions (pdfs) in absence of adequate data (e.g., formal Bayesian elicitation procedures, or simple subjective opinion of the risk assessment preparer). We look forward to the maturation of this field and eventual agreement on terms and procedures. Given the general confusion, we have tried to be clear in defining our approach to stochastic risk assessment as confined to variability in exposure where the variability can be adequately characterized by scientific studies. We tried to come up with an approach that would be workable in a regulatory environment. Much additional research needs to be done in order to better define variability in risk assessment.

Comment: Previous comments have also referred to "no mathematical definition of uncertainty." If the previous definitions of a random variable and stochastic variable are accepted, the desired result of a stochastic risk assessment is the probability density function (pdf) of risk. Since a function can be represented as a power series expansion, the terms not expressed by truncation of such a power series are related to the error or uncertainty in the

function. Expressing the function as a power series using moments about the mean is useful when the science of statistics is used to estimate the pdf. The first moment about the mean is the variance. The higher order moments are related to other properties of the distribution. The use of statistics to establish the mathematical forms and parameters of distributions has been used with available data to generate useful information for decision makers using Monte Carlo simulations.

When performing a stochastic analysis where two data points are available, it is fundamentally better to use the range as a uniform distribution than to use the mean as a single estimate. To use an "upper bound" point estimate distorts the effort to generate a meaningful distribution of risk. If additional information is available, the form of the distribution can be inferred and the limited data be used to establish the parameters of the distribution and goodness-of-fit tests performed.

Hopefully my comments will convince the authors of this document the importance of the use of correct terminology. I would be glad to meet with and explain my point of view to them.

I have presented a simplified approach to stochastic risk assessment in the textbook I authored, *Air Toxic Risk Assessment and Management: Public Health Risk from Normal Operation*, John Wiley, 1996, pages 321-323. I believe that these overly simplified examples show that the major uncertainty in stochastic health risk assessments is due to the health impact portion.

The sources of uncertainty are adequately elaborated in section 1.6. I would certainly agree with the last two sentences.

Response: The commentator suggests that when performing a stochastic analysis where two data points are available, it is fundamentally better to use the range as a uniform distribution than to use the mean as a single point estimate. We do not agree with this approach. If there are only two data points, there is no scientific basis for believing that there is an equal probability for any value between the two points. We have therefore chosen to use the mean for variates lacking sufficient data upon which to base a probability distribution. There are well established and accepted procedures for calculating a mean and given limited data, a reasonably reliable estimate of the mean can be obtained.

OEHHA has selected the 95th percent upper confidence limit on the linear multistage model as the point estimate for cancer potency factors. This is the same approach that USEPA and other regulatory agencies have chosen. This approach was chosen to help ensure that the cancer potency is not underestimated in the face of model uncertainty. It is important to note that the 5th and 95th percent confidence limits are fundamentally different from the 5th and 95th percentiles of probability density functions. The 5th and 95th percent confidence limits are not in any way an expression of variability in a cancer potency factor or uncertainty (lack of knowledge). We agree that it is likely that cancer potency is in reality a distribution due to differences in population susceptibility and other factors. However, the data are simply not currently available to estimate probability density functions for cancer potency factors. Present attempts to do so have a large subjective component.

Specific Comments on the Document

Comment: Page 1-6, last paragraph, first line: "estimates of potential risk," should be, "estimates of risk." The word *potential* is redundant unless the meaning of risk is "hazard."

Response: We agree with the comment and have changed the text to read "estimates of risk" instead of "estimates of potential risk".

Comment: Page 2-2, Section 2.4, 5th line: "Cancer potency factors are expressed as the upper bound probability of..." This is unclear as the *level* of the bound, etc. (Omitting "upper bound" would be helpful.)

Response: We have changed the sentence to read, "Cancer potency factors are expressed as the 95th percent upper confidence limit of the linearized multistage model."

Comment: Page 2-4, Section 2.5.2: The second sentence refers to stochastic risk assessment. OEHHA did not do this or satisfy the requirement under SB 1731. OEHHA did "develop an approach to risk estimation using stochastic exposure estimates." The last sentence should read, "Such information provides the risk manager with an estimate of the percentage of the population at various exposure levels."

Response: There is no general agreement on terminology or procedures in the field of stochastic risk assessment. We have defined our approach to stochastic risk assessment in the Technical Support Document Part IV, which has undergone public and peer review and adoption. We have modified the last sentence to read in paragraph 2.5.2 to read, "Such information provides the risk manager with an estimate of the percentage of the population at various risk levels **based on variability in exposure**."

Comment: Page 8-2: Delete the word *potential* in front of *Cancer Risk* in the first and second equations. (Note: The second equation defines risk as cases.)

Response: Although the word "potential" in front of risk does not fit well with risk defined as the probability of an adverse event, in this context it is meant to convey the idea to the public that there is not a literal expectation of cancer cases. Another way to express this concept preferred by risk communicators at ARB is "chances per million". We have revised the document accordingly.

Comment: Page 8-6: (Same as above for Page 8-2.)

Response: Same as previous response.

Comment: I also strongly suggest adding the two references below for those that may need additional insight into stochastic risk assessment.

In conclusion, the reviewed document represents an outstanding effort. The overall descriptions and equations for multipathway risk assessment are well presented and clear. The prescriptive instructions in this document are excellent and should be standards for regulatory risk assessments in the future.

References:

Cullen, A. and Frey H.C., 1999, *Probabilistic Techniques in Exposure Assessment: A Handbook for Dealing with Variability and Uncertainty in Models and Inputs*, Plenum Press, New York.

Graft, L.B., 1996, *Air Toxic Risk Assessment and Management: Public Health Risk from Normal Operations*, John Wiley and Sons, New York.

Response: OEHHA staff thanks the commentator for the thoughtful and thorough review of our document. In response to the suggestion for inclusion of the two references, the Guidance manual is meant to cover the specifics of how to perform Hot Spots risk assessments. We are therefore reluctant to include general references on methodology. Such references are found in The Air Toxics Hot Spots Risk Assessment Guidelines Part IV, Technical Support Document for Exposure Assessment and Stochastic Analysis. We may consult these references for general ideas for future updates of our Guidelines.

Comments from the Antelope Valley and Mojave Desert Air Districts

Richard Wales sent identical sets of comments on the guidelines under the letterheads of the Mojave Desert Air Quality Management District (MDAQMD) and the Antelope Valley Air Quality Management District (AVAQMD).

Comment: Page 1-1. It is hard to call a 265 page documents "a concise description". It may be a shortened or condensed document but not a concise document.

Response: Comment noted.

Comment: Page 4-9. Insert English units in parenthesis after the metric units. Three (3) km equals 1.86 miles. The area of a circle with a radius of 3 km (1.86 mi) is 28.27 sq. km (10.9 sq mi). Population density of 750 people/km² equals 1942 people/mi².

Response: We acknowledge that risk assessors must continually convert between SI and English units, and visa versa. However for consistency, the guidelines has tried to maintain the original units of measure. Therefore, we will not change this in the guidelines.

Comment: Page 4-9. The land usage should be for development land and not as zoned. Many areas in the desert are zoned as 11, 12 or C1 but are years (if not decades) away from being developed.

Response: OEHHA staff agree with this comment. This issue is relevant to only some of the Air Districts and OEHHA staff defer to those Districts on this issue in their addressing Hot Spots issues. The District has the authority to utilize the appropriate zoning in the air dispersion modeling.

Comment: Page 4-10. Table 4.1 needs a type for 'undeveloped (open) desert'.

Response: Unfortunately undeveloped (open) desert was not addressed by Auer (1978). OEHHA staff defer to the District which has discretion in requiring appropriate terrain to be utilized in the air dispersion modeling.

Comment: Page 4-16. Section 4.6.4 Include 'nursing homes', 'residential care facilities' as sensitive receptors. Other sections list 'eldercare' as sensitive receptors.

Response: OEHHA staff will make this addition.

Comment: Page 5-6. Equation 5.3.2 C uses 9,490 days (26 year) *for nursing mother in mother's milk pathway'* and equation 5.3.2 A uses 25,550 days (70 years) *for adult in mother's milk pathway'*. Both of these numbers are extremely long for a nursing mother. Please explain.

Response: The 9,490 days is the time a 25 year old mother has been alive and accumulating lipophilic toxins in the mother's milk model. 25,500 days is 70 years, the baseline lifetime for cancer risk assessment in the current paradigm. The values are used to estimate exposure duration to specific facility emissions. For the mother, the breast milk pathway model assumes she has her child at age 25 and nurses for one year. Thus, dose to the nursing infant for lipophilic toxicants is based on the accumulation of such toxicants over her lifetime. All cancer estimates are based on a total 70-year exposure. Thus, the offspring is assumed to have a 70-year total lifetime and received contaminants via breast milk for one year and via other relevant exposure pathways for 70 years. We will modify the text to make this clearer.

Comment: Page 5-16. Equation 5.4.1 A uses 350 days per year; all other equations use 365 days per year.

Response: In Eq. 5.4.1 A, which describes dose via inhalation, it is assumed for the residential scenario that one is home 350 days per year allowing for the typical American 2-week vacation. All the pathways use this exposure duration. The term 365 days comes in when evaluating the time over which the exposure occurs relative to one year, which has 365 days. So, the 365 days ends up in the denominator representing one year.

Comment: Page 8-2. Section 8.2. A section is needed about adding the risk from background (ambient) level of air toxics.

Response: We do not typically evaluate risk of the facility on top of background in the Air Toxics Hot Spots program. This is a regulatory history issue. A key component for the Hot Spots Program is public notification of the potential health impacts from a specific facility. Therefore, it is not appropriate to add the ambient toxic background (from the monitoring network) to the facility emissions for Hot Spots purposes. Thus, we do not require facilities to evaluate risk of background and add it to risk from their emissions. Note however, the District has the discretion to perform this evaluation for other programs.

Comment: Page 8-4. Worker - Was the number of years worked being reduced from 46 years to 40 years?

Response: Yes. This was done to be consistent across OEHHA programs where the working life has been considered to be 40 years at any one facility.

Comment: Can Table 8.1 be replaced with the following equation:

$$EDA = (H_o * D_o * W_o * Y_o) / (HS * DS * WS * YS)$$

EDA = exposure Duration Adjustment
H = Hours per day
D = Days per week
W = Weeks per year
Y = Years
o = Off-site worker
s = Source of emissions

Response: Rather than assume all exposure adjustments are always used, we present appropriate adjustments in the table that can then be individually applied where appropriate. We do not see the benefit of replacing the table with this equation.

Comment: E-1. In line 5 an '8' needs to be added to 2,3,7,8, tetrachlorodibenzo-p-dioxin.

Response: OEHHA staff will correct this omission.

Comment: Glossary. Some of the terms are out of alphabetical order, such as *'California Air Resources Board (CARB); 'Urban Block Groups (BGs;)'Hot Spots Analysis and Reporting Program (HARP), etc.* Also the terms 'CEIDAR', 'CEIDAR-Lite', 'Prioritization Score', 'Significant Health Risk' and 'Significant Risk' need to be added. The term for 'UTM Coordinates' should be expanded to include the following: "The coordinates should be reported in kilometers to the nearest ten meters or meter. The easting coordinates should be 'EEEE.00' or EEEE.000 and the northing coordinates should be 'NNN.00' or NNN.000. The Zone should be either 10 or 11."

Response: OEHHA staff will add to and clarify the terms in the Glossary.

Comment: Page K-7. A form is needed for 'Area' and 'Volume' sources.

Response: Two forms, one for a volume source and the other for an area source will be added to Appendix K.

Comment: Appendix L. Where are Tables 1 and 2?

Response: Tables 1 and 2 are mislabeled as Table 3. OEHHA staff will correct this error.

Comments of the San Diego Air Pollution Control District

In a letter dated July 5, 2002 Dick Brightman of the San Diego Air Pollution Control District submitted comments on the Guidance Manual. The District finds it to be a very useful and well-organized addition to the guideline documents being developed by OEHHA and ARB. It is evident that the development of this document resulted from a tremendous effort conducted at a very high technical level. The District hopes that these comments will help to make the document even stronger.

Comment 1. Executive Summary, p.1-1. The report says it contains example output files from the HARP software, but none could be found.

Response: This reference will be deleted.

Comment 2. HARP Software, Section 1.4, p 1-5. The report indicates that the HARP software provides summary risk reports for the PMI, MEIR, and MEIW. This is true as long as those locations were identified during the modeling process and included as receptors during the HARP calculations. The HARP software does not automatically identify these points.

Response: It is up to the assessor to identify these points from the air dispersion modeling.

Comment 3. Risk Assessment Review Process, Section 1.5, p 1-5. The report states that OEHHA provides comments on the "technical accuracy" of the HRA. Perhaps it would be better to say "concordance with the guidelines" or something similar. To refer to accuracy suggests that the health risks are already known.

Response: Comment noted. We'll work on the wording to indicate we are looking for correct use of the health risk values and general concordance with the guidelines.

Comment 4. Exposure Assessment, Section 2.3, p 2-1. The report should state that air dispersion data generated separately from HARP using other air dispersion models can be imported into HARP, so long as that data is already in the format required by HARP. It is not known if HARP can do this automatically.

Response: We will change the text Sections 2.3 and 4.9.1. to indicate that air dispersion data generated separately from HARP using other air dispersion models can be imported into HARP, so long as that data is already in the format required by HARP.

Comment 5. Point-Estimate Approach, Section 2.5.1, p 2-4. While the 3rd paragraph does say that the 9-year exposure scenario is only for child exposure, it also suggests that the 9-year exposure can also be used in a study of impacts over a range of residency periods. It is not clear from the report that even in this case, the 9-year exposure is only for child exposure.

Response: The document states in several places that the 9-year scenario utilizes child-specific exposure parameters as point estimates or distributions. This is done so that the higher exposure years are accounted for in the risk estimates.

Comment 6. Stochastic Exposure Assessment, Section 2.5.2, p 2-4. The report states that the results of a stochastic analysis give the risk manager an estimate of the population at various risk levels. This may lead to an over-interpretation of the risk information. The stochastic risk estimate is for a single receptor point, whereas the population is distributed spatially around the source. Most of the variation in risk for the population arises from the location of receptors relative to the source. What the stochastic risk estimate is really providing is the probability that the risk is not higher than a given value as a result of including the population variability for the subset of the input variates for which distributions have been identified.

Response: This reviewer had the same comment as the reviewers from the South Coast Air Quality Management District (see Response to SCAQMD Comment 6). We are rewording the document to clarify this.

Comment 7. Air Dispersion Modeling in Exposure Assessment: Overview, Section 4.1, p. 4-1. Airborne pollutant concentrations are needed to calculate exposure for all exposure pathways, including the airborne pathway.

Response: OEHHA has reworded the sentence to read “ The concentration of pollutants in ambient air is needed to characterize both inhalation and noninhalation exposure pathways.”

Comment 8. Emission Estimates Used in the Risk Assessment, Section 4.2.1.1, p 4-4. The report should make it clear that a District may, at its discretion, allow facilities to base HRAs on updated emissions, and that this is not a recommendation of ARB. Districts need to balance these considerations against the public's right to know aspects of the Hot Spots Program. SDAPCD public notification and risk reduction requirements are based on the results of the initial HRA as per District Rule 1210.

Response: Comment noted. The guidelines clearly state that the facility must revise the emissions inventory report and submit that to the District prior to conducting the HRA using revised emissions estimates.

Comment 9. Emission Estimates Used in the Risk Assessment, Molecular Weight Adjustment, Section 4.2.1.1.A, p 4-5. If emissions data for metallic compounds has already been corrected for the molecular weight of the toxic metal ion, automatic application of the MWAFF could lead to erroneously low emissions used in HRAs. It is good that HARP, makes this correction. Perhaps it would be useful for HARP to warn the user of this issue.

Response: Comment noted.

Comment 10. Emission Controls, Section 4.2.1.4, p 4-6. The inclusion of description of control equipment, the emitting processes it serves, and the efficiency in reducing emissions may be an over-ambitious goal for inclusion in the HRA report. It will add to the cost and complexity of the HRA, especially for large facilities, and may detract attention from the analysis of health risks. This information is already required to be included in the Emission Inventory Report.

Response: Comment noted. Unfortunately not all reviewers, including OEHHA staff, get to see the Emission Inventory Report. As an alternative, the District could make both the EIR and the health risk assessment available to the public as a way to avoid duplicating this information.

Comment 11. Receptor Points, Section 4.7.1, p 4-16. The primary geographic data source for some Districts is in the California State Plane reference system. This means that exclusive use of UTM coordinates presents an extra data processing burden. It is possible to input source, building, and receptor locations into ISC3 using State Plane coordinates as long as location measures for inputs are converted from feet to meters and then the results converted back from meters to feet. It would be useful if the HARP software incorporated this capability.

Response: Comment noted. OEHHA staff will confer with ARB staff about this desired capability.

Comment 12. Meteorological Data, Section 4.8, p 4-18. While 5 consecutive years of representative meteorological data may be desirable, previous guidance and District practice have considered 3 years of data to be sufficiently representative, both spatially and climatologically (temporally) for performing conservative HRAs. District experience indicates that two additional years of meteorological data will not result in significant differences in calculated risk. Could ARB comment on why it should not continue to be the case that 3 sequential years of representative meteorological data are sufficient for HRAs. Additionally, 1 year of site-specific meteorological data, as determined by the local District, should be adequate to determine facility impacts for HRAs.

Response: This is a guidance manual. The District can accept an alternative to 5 years of data if 3 years of data are sufficiently representative. One year of data does not seem to be adequate to include yearly variations in meteorology, but may be the only site-specific data available.

Comment 13. HARP Dispersion Analysis, Section 4.11.1.3, p 4-27. The report states that HARP has the flexibility to calculate risk using pollution concentrations generated separately from HARP using other approved air dispersion models. We assume that this includes not only approved non-ISC3 models, but also commercial versions of ISC3 that are broadly used by Districts, facilities, and consultants. It should be clearly and specifically documented how this can be done. The structure of any output files from other models or commercial versions of

ISC3 that are needed to input to HARP should be fully described. This question is also directed at the use of monitoring data to input ground level concentrations (GLC) to HARP. Procedures for inputting or editing GLC data in HARP should be documented.

Response: Comment noted. Such documentation belongs in the HARP manual, not necessarily in this document.

Comment 14. Estimation of Exposure Through Inhalation, Section 5.4.1, p 5-16. Table 5.5 (Breathing Rate Distributions) does not match data in the equivalent tables of the Technical Support Document IV (Exposure and Stochastic Guidelines) on pp 3-35 - 3-36 for 30 & 70-year exposure duration.

Response: The data in Table 5.5 is descriptive of the shape of the breathing rate distributions and is correct except for one typo. It appears the reviewer confused the description of the adult breathing rate distribution with the simulated 70-year distribution in Part IV on pp.3-35 and 3-36. The simulated distribution, which includes the higher breathing rates of children is the appropriate distribution to use for the 30- and 70-year exposure durations. Thanks for the comment – we found a typographical error in one number.

Comment 15. Estimation of Exposure Through Ingestion, Section 5.4.3, p 5-20. Table 5.9 (Water Ingestion Distributions) does not match data in the equivalent tables of the Technical Support Document IV (Exposure and Stochastic Guidelines) on pp 8-13 - 8-14 for 9-year exposure duration.

Response: The reviewer is correct. There is a small error in one of the numbers, which we have corrected.

Comment 16. Estimation of Exposure Through Ingestion, Section 5.4.3, p 5-22. Table 5.9 (Food Consumption Distributions) does not match data in the equivalent tables of the Technical Support Document IV (Exposure and Stochastic Guidelines) on p 7-7 exposed produce.

Response: Table 5.9 is addressed above. Tables 5-11 and 5-12 on pp.5-22 are correct. The original table in the Part IV document, however, has an error which we discovered after finalizing the current version– we will be issuing an errata to correct the distribution for the exposed produce category.

Comment 17. Calculating Inhalation Cancer Risk, Section 8.2.1, p 8-2. Expressing the cancer potency in units of kg-day/mg obscures the fact that cancer potency has the units of lifetime cancer probability per unit of dose, or lifetime cancer probability per mg/kg-day. Those performing risk assessments should be sophisticated enough to know the difference and to not need the simplification of units as shown in the report which can also be misleading.

Response: We are unsure what the commenter means here. Kg-d/mg is the same thing as (mg/kg-day)⁻¹. There should be no confusion on the part of the assessors.

Comment 18. Calculating Inhalation Cancer Risk, Section 8.2.1, p 8-2. The use of the words "potential" with "cancer risk" may be problematical. First, potential and risk refer to the same concept, and so are redundant. Second, the meaning of potential is unclear. Does it mean "as high as"? Does it mean "no higher than?" Or does it mean "as opposed to actual"? Third, the term is not needed to express the concept "cancer risk".

Response: OEHHA agrees with this comment. We are striking « potential » when it is in front of « cancer risk ». We are rewording that to be consistent with ARB's risk communication language of « chances in a million ».

Comment 19. Calculating Inhalation Cancer Risk, Section 8.2.1, p 8-2. When using the expression "cancer cases per million" there is always the problem that it can get turned around to a discussion of how many actual cases of cancer there will be, which obscures the probabilistic nature of risk. Unless one is talking specifically about populations, would it not be sufficient as well as conceptually correct to simply equate "cancer risk" with "cancer probability" or "lifetime cancer probability"?

Response: OEHHA staff acknowledge the problem. Some organizations have found estimated cancer cases per million a useful risk communication tool. It may not be appropriate in some situations. And it must be put in context. Other comments have lead us to change the wording to "chances per million", the preferred language used in risk communication by ARB.

Comment 20. Calculating Cancer Risk Using Different Exposure Durations, Section 8.2.2, p 8-3. Regarding exposure duration corrections, the report says "it is useful for a person who has resided in his current residence for less than 70 years to know that his or her cancer risk is less than the 70 year risk". We are concerned with the phrase "risk is less". We are concerned at the level of certainty implied by that statement. We suggest using instead "risk may be less". We were under the impression that cancer risk or probability of cancer being proportional to dose usually refers to lifetime dose, since animal bioassays are usually lifetime exposures and human data is similarly based on outcomes over a lifetime. Since information is generally lacking on how early or late in an observation period initiation of a cancer-causing event occurred, and since, as we are informed, there is evidence that some chemicals can cause cancer after only one exposure, it seems that reducing the exposure dose by reducing the exposure duration rather than the exposure rate may be insufficient to prevent the end effect. Thus, it seems that there is no guarantee that risk will be reduced by an exposure duration correction factor, and there could be some (unknown) probability that the risk will not be reduced by this factor. Another way to say this is that while it may be plausible that a shorter exposure time might reduce the risk, data are lacking to specify the probability of this. Is this the reason that the 70-year lifetime risk estimate is the one suggested for risk management decisions?

Response: We agree to an extent with this comment. In calculating estimated cancer risk, the calculated value will be lower for a shorter exposure duration. It does not necessarily mean that all life-stages are equally sensitive since this is not yet included in cancer potency factors, but the point is the paradigm for calculating risk results in a lower estimate for shorter duration exposures (lower cumulative dose). One way to address the commenter's concern is to reword the paragraph to indicate that we mean the actual value of the estimate of the cancer risk is less with shorter exposure durations.

The reason that the 70 year lifetime duration is suggested for risk management is that we want to make certain the risk estimate reflects lifetime risk; that is the basis for the "acceptable" risk levels set by the Districts for Air Toxics Hot Spots risk management. In addition, it is important to realize that people do not move from one location near a facility to a pristine location with no cancer risk. Allowing a facility to pose a lifetime cancer risk of 10^{-5} within a period of 9 years results in individual cancer risks greatly exceeding 10^{-5} for a given individual. In addition, for the population risk as a whole, individuals who move from a community are replaced by others; thus, the cancer risk might be spread over more than one person but in terms of population risk it is still the same.

Comment 21. Determination of Non-inhalation (Oral) Cancer Risk, Section 8.2.4, p 8-6. Same as comment 17 above with reference this time to Oral Slope Factor.

Response: We do not understand the confusion. The units are the same. We can just use the term $(\text{mg}/\text{kg}\text{-day})^{-1}$ to avoid any undue confusion.

Comment 22. Risk Characterization for Stochastic Risk Assessment, Section 8.2.6, p 8-9. The second paragraph states that an overview of a stochastic analysis follows in the next paragraph, but it does not.

Response: The sentence was misplaced and has been struck.

Comment 23. Outline for a Health Risk Assessment Report, Section 9.2, p 9.8. Please provide reasoning behind including elevation contours on HRA result maps. Adding elevation contours to an already feature-rich map may result in confusion. Some practitioners will likely use GIS for map presentations. For them, adding contours may not always be straightforward. We suggest a separate map showing facility, significant geographic features, and elevation contours.

Response: Comment noted. We can change the wording to indicate we prefer elevation contours but they are not necessary.

Comment 24. Outline for a Health Risk Assessment Report, Section 9.2, p 9.13. The report suggests including a discussion of the strength and weakness of the risk analysis and associated uncertainties. This section is often used to editorialize on the risk assessment process, and to tie a specific risk assessment with known weak points of risk assessment generally. What is not often found in these sections is a discussion of the strength and weakness of the input data that were used to produce the HRA report, including a discussion of uncertainties in the emissions

and the input data used to calculate them. Comments which serve only to diminish the risk assessment process belong under separate cover or in an appendix.

Response: Comment noted. We agree that many risk assessments turned into the Districts have been accompanied in the body of the report with much editorializing designed to minimize the results. We do want to provide an opportunity for the reader of the risk assessment, however, to understand there are uncertainties in estimating risks. Perhaps a good solution is to have the District require wording that can be taken from Section 1.6 of the Guidance Document that describes some of the sources of uncertainty in risk assessment.

Comments of the South Coast Air Quality Management District

Comments on the Guidance Manual were submitted by Mike Nazemi, Planning Manager for the South Coast Air Quality Management District (SCAQMD) in a letter dated July 5, 2002. District staff appreciate OEHHA's continued efforts to develop improved and simplified health risk assessment (HRA) assumptions and methodologies and to defer risk management to the air districts. However, these tools must be useful in the regulatory arena for decision making and policy development. As such, they have the following concerns.

Comment 1: More Complex and Time Intensive. The addition of a 9-year, 30-year, childhood inclusive, adult exclusive, average, derived, and stochastic calculations would not expedite the preparation and review of HRAs nor would it be more cost-effective. (One should keep in mind that the derived risk will require two rounds of calculations: the first with high-end assumptions to identify the two peak pathways and the second to recalculate the contribution from the other pathways using average assumptions.)

"[E]xpediting the preparation and review of HRAs...", page 1-2, paragraph 1 (P1-2p1). Apart from the routine residential cancer risk calculation (70-year high-end point-estimate), the introduction of 9- and 30-year; childhood inclusive and adult exclusive; average and derived; and stochastic risk calculations complicates the preparation and review of HRAs. What used to be one calculation (70-year high-end point-estimate) is now 20 calculations: 70-year high-end point-estimate, 70-year average point-estimate, 70-year derived point-estimate, 70-year stochastic, 9-year high-end point-estimate (child assumptions), 9-year average point-estimate (child assumptions), 9-year derived point-estimate (child assumptions), 9-year stochastic (child assumptions), 9-year high-end point-estimate (adult exclusive), 9-year average point-estimate (adult exclusive), 9-year derived point-estimate (adult exclusive), 9-year stochastic (adult exclusive), 30-year high-end point-estimate (childhood inclusive), 30-year average point-estimate (childhood inclusive), 30-year derived point-estimate (childhood inclusive), 30-year stochastic (childhood inclusive), 30-year high-end point-estimate (adult exclusive), 30-year average point-estimate (adult exclusive), 30-year derived point-estimate (adult exclusive), and 30-year stochastic (adult exclusive).

"[C]ost-effective implementation of HRAs and the Hot Spots Program", P1-2pl. The added time and effort needed to prepare or review the 9-year, 30-year, childhood included, adult only, average, derived, and stochastic risk calculations would not be cost-effective.

Assuming that they are all significant and distinct calculations, SCAQMD staff is not opposed to preparing, requiring, or reviewing these calculations. However, OEHHA should provide more guidance on the significance and value of each risk calculation, especially as they may contribute to the determination or assignment of further regulatory action. Are they all really necessary? If not, what instances would trigger or require these calculations? When would one calculation be used or selected over the others? Which calculation yields the "best" health-protective estimate? What risk value should serve as the ultimate threshold for decision making by SCAQMD staff or the general public?

Response: The comment is correct that other options besides the standard 70 year risk assessment have been introduced into the risk assessment paradigm for facilities subject to the Air Toxics Hot Spots Act. However, these calculations are not all required. What is absolutely required, and it is clearly stated in the guidelines, is estimation of lifetime (70 year) cancer risks using a point estimate approach. The point estimate approach does require one additional calculation which is readily done by the HARP software, a public-domain software developed by the ARB for the Air Toxics Hot Spots program. Thus, there is not a lot of extra work in using these new guidelines, and the required calculations amount to basically two computer runs. Furthermore, the point estimates (and the distributions if one chooses the stochastic route) include the higher exposures experienced by children. These do not need to be separately calculated. We have provided point estimates and distributions for alternative exposure durations of 9 and 30 years, so that shorter exposure durations can be assessed and the information provided to the risk manager. The 9 year scenario must be done using children's exposure parameters as described and provided in the document. We continue to suggest that the 70 year exposure duration be utilized for risk management because the "acceptable" risk levels set by the Districts for cancer risk are all based on lifetime exposure.

Comment 2: Risk Communication. It is hard enough to explain a 70-year high-end point-estimate to the general public. Now, more values and variables would ensure that risk communication fails. The general public is simply overwhelmed with too many numbers and factors. Again, OEHHA should provide more guidance on the significance and value of each risk calculation, especially as they may contribute to the determination or assignment of further regulatory action. Are they all really necessary? If not, what instances would trigger or require these calculations? When would one calculation be used or selected over the others?

Response: As noted above, we continue to suggest using lifetime exposure duration in evaluating risk management decisions because the acceptable risk criteria set by the Districts are based on lifetime exposures. The additional exposure duration scenarios described in the guidelines are informational in nature. It is not appropriate in the Risk Assessment Guidance Manual to provide Risk Management Guidelines in any detail. Furthermore, risk management is a function of ARB and the local districts. We would be happy to participate in any activity such as re-opening the ARB's Risk Management Guidelines but are not responsible for providing this information.

Comment 3: Other Exposures. With the introduction of 9- and 30-year exposures, it is inevitable that other exposure durations (1-, 5-, 10-, 20-, 25-year, etc.) will be offered for consideration or "for informational purposes only". As previously mentioned in oral discussions, the 9- and 30-year exposures were intentionally designed to coincide with USEPA protocol. - This fact should be included in the Guidance Manual. -All other exposure durations would NOT have the same foundation and should therefore NOT be offered for consideration or "for informational purposes only".

Response: We will add in a brief explanation of the origin of the 9 and 30 year exposure scenarios (U.S.EPA Risk Assessment Guidelines for Superfund), as it appears in Part IV into these guidelines. The existing text in Part IV reads as follows: “ OEHHA is recommending that point estimates and stochastic risk estimates be conducted for 70-year exposure durations. This will ensure that a person residing in the vicinity of a facility for a lifetime will be included in the evaluation of risks posed by that facility. In addition, the assessor may want to present the risk estimates for 9-year and 30-year exposure scenarios using the duration-appropriate point estimates and distributions recommended in the chapter. The 9-year scenario point estimates and distributions reflect children’s exposure parameters. The 9- and 30-year exposure durations are the figures that U.S. EPA has recommended for the central tendency and high end estimates, respectively, of residency time at one address. The U.S. EPA’s estimates may not apply to all populations. However, the 9- and 30-year estimates appear to fall into a range of possible residency time estimates that may be useful to the risk manager and the notified community.”

Comment 4. Basic Calculation. SCAQMD staff concurs that the basic calculation (70-year high-end point-estimate) should continue to be the foundation for any and all HRAs, public notification, and risk reduction. Using the same equations and assumptions places all facilities on the same playing field and allows for fair comparisons. One does not have the option of "buying" better HRA results or delaying the process with more detailed studies.

"[A]11 HRAs must present the results based on 70-year exposure.", P24p3.

"Note, for the Hot Spots Program, the 70-year exposure duration should continue to be used for estimating risk." P8-lp1.

"For the Hot Spots Program, the 70-year exposure duration should be used as the basis for public notification and risk reduction audits and plans." P8-2p3 and P9-5p1, bolded and underlined.

"Tier-1 evaluations are required for all HRAs prepared for the Hot Spots Program." P2-5p2 and P8-lp5.

"NOTE: When presenting the following information, potential cancer risk should be presented for a 70-year, Tier-1 analysis." P9-4, bottom of the page, bolded and underlined.

"For the Hot Spots Program, the 70-year exposure duration should be used as the basis for residential public notification and risk reduction audits and plans." P9-1 lp2, bolded and underlined text.

Response: OEHHA staff concur that the 70-year high-end point-estimate should be the foundation of risk in an HRA. This is particularly important since the acceptable risk levels set by the Districts for risk from stationary sources are based on lifetime exposure durations.

Comment 5. Use an Appendix. As the foundation for the HRA and all decisions thereafter, the basic calculation (70-year high-end point-estimate) should be contained in the heart of the HRA. All other calculations should be stored in an appendix to the main document.

Response: OEHHA staff agree that use of an appendix for cancer risk calculations based on other than 70 years is reasonable.

Comment 6. Stochastic Approach. The stochastic approach (Tier-3 and Tier-4) does not directly yield the percentage of the population exposed to various levels of risk. The second mechanism suggested under population-level risk estimates would be a better approach to indicate the percent of the population exposed to various levels of risk.

"Tier-3 and Tier-4 analyses show a distribution of cancer risk indicating the percent of the population exposed to various levels of risk." P8-8p3. It is unlikely that any single person or and given percentage of the population will bear all of the traits of 0.95 (for example) of the cumulative probability density function, and therefore, the distribution of risk resulting from stochastic modeling fails to yield population based information or risk values. "2. An estimate of the number of people exposed at various potential cancer risk levels..." P8-14p3, from 8.4 Population-Level Risk Estimates. The second approach (either by geographic areas or concentric circles) would better indicate the percent of the population exposed to various levels of risk.

Response: OEHHA realizes now that the wording of this sentence is ambiguous. The District staff interpreted it in a way it was not meant. What we are really saying is that when you use a distributional approach, at any given receptor location you can see what the percentile of the risk is. This loosely translates into what percentage of the population would be protected at that concentration level by any risk management option. In terms of population-wide risk estimates, the District is correct that the population-level risk estimates which look at the number of people exposed to given concentrations and therefore given levels of risk is a better measure of population-wide risks. This can be done with point estimates of risk at each concentration or receptor as well as by using a distribution of risk at each concentration or receptor (the stochastic approach). In either case, you would need to look at the numbers of persons impacted within a given concentration/risk isopleth to evaluate population-wide risks. This gives you an idea of the population-level impacts (is it one resident or 100,000 residents impacted). We are rewording the section to make clear what we mean.

Comment 7. Worker Population. 8.4 Population-Level Risk Estimates, P8-14. The exposed population for population-level risk estimates should include the worker population.

Response: The analysis of population-level risks can include the worker population where the offsite impacts occur to people working at a different facility. One would need the data to estimate the number of offsite workers impacted.

Comment 8. Sample Calculations. Sample calculations may be problematic in several instances. "Sample calculations should be provided (in an appendix) for each step to indicate how the reported emissions data were used. The reader should be able to reproduce the risk assessment without the need for clarification." P9-6p2, bolded text. Will HARP produce this documentation? Are people expected to use HARP and then re-calculate risk by hand? Is it satisfactory to provide the HARP inputs in lieu of the sample calculations? (The sample calculation should represent one of the MEIs.)

Response: HARP will produce tables of results. We do not want assessors to have to re-calculate etc. OEHHA is rethinking this requirement as it appears to be "make-work" when HARP is used, and the HARP output should suffice for review. If HARP is not used, we need to see how the calculations were done when we review the risk assessment.

Comment 9. Zoning. P9-6. Zoning details, especially the residential areas (as all other areas would be treated as non-residential), of the entire zone of impact should be provided on a map. This detail validates the peak MEIR or MEIW, and, in some case, assists in the re-run or re-designation of the modeled receptors.

Response: We will add a requirement to provide zoning details of the entire zone of impact on the maps, where data are available. In some areas of the state, such data may not be available.

Comment 10. Maps. P9-8. The maps must provide street level detail or resolution. This level of detail must identify the significant streets or blocks and define where notification should be provided. (The USGS 7.5 minute maps do not provide street names. And, sometimes, maps have been shrunk to the point where the street names are no longer discernable.)

Response: OEHHA believes that the public should be informed as to specific street locations where the risk impacts them. However, for facilities with large zones of impact, the maps could provide the names of major streets within a block enumeration group.

Comment 11. HARP Training Needed. It appears that HARP will be the only available tool to prepare risk assessments under the Guidance Manual. Since the tool will be new to the health risk assessment community, "hands-on" training is critically needed not only for local district personnel but also for industry personnel and their consultants. It is unreasonable to expect facilities and their consultants to be able to apply HARP without some kind of training.

Until HARP training has been made available to a significant portion of the risk assessment community, a phase-in period where both ACE2588 (with updated URFs and RELs) and HARP are acceptable may be necessary. A phase-in period may help to avoid the development of a permitting back-log that could result from an abrupt transition to a new risk assessment tool.

Response: HARP training was provided to personnel from several air districts in June 2002 and additional training is being planned by ARB for district personnel and initial training for interested industry personnel and their consultants. A users manual will be available with the HARP Program. Other models may be used to prepare risk assessments as long as they are

documented, transparent, and utilize the inputs outlined in the OEHHA Part IV TSD and the Guidance Manual.

The HARP Program replaces the ACE2588 and HRA Computer Programs. The ACE2588 Program is not maintained or supported by ARB or OEHHA and does not contain the current OEHHA algorithms. Your recommendation that ACE2588 be maintained and supported should be directed to CAPCOA.

Comment 12. Using HARP to Only Generate Risks. HARP consists of three modules: emission inventory, dispersion model, risk assessment and mapping. The Guidance Manual states that "air dispersion data may be generated separately from HARP using other dispersion models, then imported into HARP to generate risk estimates." (P2-lp4) SCAQMD staff is interested in this capability since we require a risk analysis for equipment permitting. Facilities may object to being forced to use the emission inventory module just to estimate risks from a lone piece of equipment. Therefore, it would be convenient to import outputs from a current dispersion models into HARP and to use HARP to estimate the toxic risks. Again training on the use of this option is needed.

Response: OEHHA staff agree. We have discussed your concern with ARB staff.

Comments of the Western States Petroleum Association (WSPA)

Michael Wang, Manager, Operations and Environmental Issues of WSPA submitted comments on the Guidance Manual in a letter dated June 28, 2002. WSPA is a trade group representing about 30 companies that explore, develop, refine, market and transport petroleum and petroleum products.

Comment 1: Applicability of the "High-End" Breathing Rate for Facility Risk Assessments. OEHHA has developed a breathing rate distribution for the population and recommends the use of the "high-end" breathing rate for estimation of exposure, risk and risk-based decisions on notification under AB2588. However, OEHHA also requires that the most exposed individual remain at home for essentially 70 years to obtain a high-end exposure scenario. The two assumptions are in conflict. The point of maximum impact for many sources, particularly small sources, is quite small. It may only extend over a few hundred square meters and the concentrations fall off exponentially from the point of maximum impact. For example, if the offsite impact affects a house or apartment building across the street from a small source, the modeled concentrations will only affect the area of the residence. However, the breathing rate assumption for a high-end individual is that they lead a very active life. It is difficult to imagine a credible scenario for a lifetime of physical labor and active exercise in which one remains within the confines of a very small impact zone. If one were to derive a breathing rate distribution for residence bound individuals, it would likely look very different than the distribution used by OEHHA.

It is important to differentiate between a regional air toxics risk assessment and a point source or facility-based risk assessment (the kind required under AB2588). For a regional risk assessment we might pose the question "If the region has a given level of toxic air contaminant, what is the high-end dose and risk that some individuals might experience." Here we can consider the full range of human activities throughout the region. The distribution developed by OEHHA can be useful in addressing this question. However, for a facility-based risk assessment we ask the question, "What is the high-end exposure and risk that may result from the emissions from this facility?" If the footprint of the facility emissions extends only over a few hundred meters (declining exponentially away from the peak concentration), then the range of activities for the exposure scenario becomes more limited. One cannot run a marathon and remain at home. One cannot be a laborer in a factory and never leave one's apartment.

It is quite likely that the high end point estimate for the breathing rate that has been used in previous AB2588 risk assessments (and is still used by EPA) of 20 m³/day is sufficiently conservative to address this scenario of lifetime residence in a small impact zone. Perhaps, a statement should be inserted into the Risk Assessment Manual that would indicate to risk managers that alternative breathing rate assumptions may be used, and can still be considered health protective, in situations where the area of facility impact is geographically limited and the range of activities that is likely to take place in that area would also be somewhat limited (such as the situation described above). It is not sufficient to merely refer users on to higher tiers of risk assessment since this will not provide sufficient guidance.

In developing any risk assessment manual, it is important to recognize the context in which the risks are being assessed. The goal of AB2588 is to evaluate risk from specified facilities, not regional risk, and not the total air toxic risk to individuals from a multitude of sources (as inferred on page 8-3). The risk scenarios should be conservative, but not to the point of being extremely unlikely.

Response: The guidance manual has assembled the best scientific data available on variability in exposure and health values in order to give a best available estimate of health risk. The breathing rate distributions and point estimates used for the Hot Spots program risk assessments were publicly and peer reviewed prior to adoption by OEHHA for use in the Air Toxics Hot Spots program in 2000. The methodology can be used to estimate risks from individual facilities and compare the risks to other facilities with the same measuring tool. Many people exercise vigorously at home, do laborious projects, and are continuously in motion. Children expend much of their energy at or near home, and their higher breathing rates were not previously considered in the traditional risk estimation methods. Farmers often work near home. Thus no measuring tool can capture every scenario and address every exception. Also, it should be noted that the authorizing statute discusses evaluating cumulative risk from multiple facilities. However, we do agree that use of the 95th percentile might be overly conservative, especially in cases where the risk isopleth is quite small. We will add the following language to the text of the Guidance Manual:

“The risk assessment guidelines require the use of the 95th percentile breathing rate for all assessments of cancer risk by the inhalation route in Tier 1 risk assessments, in order to avoid underestimating risk to the public including children. In general, the risk management of facilities in the Air Toxics Hot Spots program is based on the 70-year risks at the highest exposed receptor point using high-end estimates of breathing rate. Some facilities subject to the Air Toxics Hot Spots Act (e.g., some in the industry-wide categories) have very small zones of impact. In some of these instances, there will be very few receptors within the zone of impact. It isn't possible to develop special recommendations for all possible exposure scenarios. Alternative breathing rates (point estimates or distributions) may be used as part of a Tier 2 or Tier 4 risk assessments. Thus, the risk manager should take this into account during any risk management decisions. OEHHA is willing to work with risk managers at ARB and the Districts on this issue. Further examination of the issue is warranted.”

Comment 2. Risk Communication. On page 8-2, it is recommended that multiplying a cancer risk (as chances per million) by 10^6 results in "cancer cases" which is a useful risk communication tool. This is not appropriate in many situations. From a risk communication standpoint, "cancer cases" creates the idea that a certain number of individuals will get cancer from a given facility. This is not the case. The majority of facilities have cancer burden estimates below one. The "cancer case" calculation that is recommended would only be valid if a million people were forced to live at the point of maximum impact for a lifetime. For risk communication purposes, the term cancer cases should only be used when referring to the cancer burden estimate for AB2588 facilities. The risk communication reference on page 8-2 should be changed or deleted.

Response: The Air Resources Board uses the term “chances per million” in expressing risk of cancer. Therefore, we have reworded that portion of the document to indicate that multiplying the cancer risk by one million results in chances per million of contracting cancer from the exposure. This conveys better that there is a risk of cancer rather than a certainty of cancer from exposure.

Comment 3: Extension of the Comment Period. While the separate pieces of this document have been previously put out for comment, the risk assessment manual makes it apparent how the changes in the exposure assessment will affect the notification under AB2588. Many facilities that will be affected by this change are unaware of the future impacts and more time is needed to inform these facilities. In addition, WSPA is requesting more time to develop the concepts that we have outlined here with regard to the residential "high-end" exposure scenario and its relevance to facility-based risk assessments under AB2588. We request that the comment period be extended for these reasons.

Response: The enabling legislation for these guidelines was passed in 1992. The impetus for the legislation was for affected facilities to have more flexibility in assessing risk. OEHHA has had many formal and informal meetings and discussions with representatives of facilities and with experts in the various areas of risk assessment while developing these guidelines, and one or two public comment periods for each of the technical support documents. It is time to come to closure. Therefore, we do not think it is appropriate to continue the public comment period.