Updating BC Provincial Air Quality Objectives – An Options Discussion Paper

Prepared by:

Robert B. Caton, PhD, RWDI West Inc.
and
David V. Bates, MD

Prepared for:

BC Ministry of Water, Land & Air Protection
Water, Air & Climate Change Branch
Victoria, BC

Vancouver, BC
May 2002

Preface

The ministry's New Era Service Plan, which was announced in January, 2002, outlined the ministry's vision for a clean, health and naturally diverse environment. It further identified the strategic shifts required to improve business methods and focus resources where there is the greatest risk to the environment, while reducing costs to government, industry and other stewardship partners.

To implement these strategic shifts, the ministry is putting more emphasis on core 'planning' and 'checking' functions or activities, and less emphasis on the administration of direct service delivery or 'doing' functions. One of the key planning functions is the development of clear environmental standards, including air quality objectives.

Current provincial air quality objectives were largely developed in the 1970s or earlier. As a result, they are based on science that is decades old, with few links to modern health-based targets.

This scoping paper will be used to help define a process for reviewing and updating BC's air quality objectives in light of the new science on the effects of air pollutants on human health and the environment. Updated air quality objectives and guidance on their application are viewed as important foundation pieces in the development of an improvement plan for threatened airsheds in this province -- a key project identified in the ministry's Service Plan.

An electronic version of this paper is available through the ministry's website at: http://wlapwww.gov.bc.ca/air.

Hu Wallis
Acting Director
Water, Air and Climate Change Branch
Ministry of Water, Land and Air Protection

Updating BC Provincial Air Quality Objectives – An Options Discussion Paper

CONTENTS

Updating BC Provincial Air Quality Objectives – An Options Discussion Paper

Prepared by: Robert B. Caton, PhD, RWDI West Inc. and David V. Bates, MD

May 2002

1. Background

The purpose of this paper is to help define a preliminary scope for reviewing and updating BC's air quality objectives (AQOs). The objectives are benchmarks for determining whether concentrations of pollutants in ambient air (or in emissions from sources of pollution) ought to be of concern to regulators or the public. Criteria on which objectives are based may be defined in terms of human health effects or other environmental impacts. Air quality objectives in BC are used for (quoting from the Terms of Reference for this work):

- reporting on the state of the environment
- reporting on hourly air quality through the Air Quality Index (AQI)
- establishing approval conditions for permitting new or modified sources
- assessing compliance for permitted sources
- developing and instituting episode management strategies
- developing long-term air management strategies and evaluating progress.

Some of the air quality objectives listed in the compilation currently published on the Ministry of Water, Land and Air Protection (MWLAP) website (wlapwww.gov.bc.ca/air/codes.html#objectives)[1] are relatively recent, while others have remained unchanged since the 1970s. The BC Objectives are expressed as Level A, Level B and Level C, roughly corresponding to the Canadian National Ambient Air Quality Objectives (NAAQOs) "Maximum Desirable," "Maximum Acceptable" and "Maximum Tolerable" levels, respectively. Pollution Control Objectives (PCOs) issued under the Pollution Control Act (since superseded by the Waste Management Act) in 1974-1979 addressed Level A, B & C emission criteria and incremental ambient impacts for several industrial sectors: chemical & petroleum industries, agricultural and miscellaneous industries, municipal waste discharges, forest products industry and mining, smelting and related industries. The PCOs are no longer considered current, although those that refer to ambient air are still used in permitting. Their ranges of air quality objectives are included in the current Ministry compilation.

The BC AQOs address, essentially, acute exposures to pollutants for which detailed health impact criteria have been developed ('criteria pollutants'), rather than long-term or chronic, cumulative exposures. Some of the pollutants that appear in the older PCOs, such as metals, are important in a cumulative context, but for the most part, the focus of the BC AQOs has been the criteria pollutants.

There is currently no initiative to carry out a comprehensive revision of the NAAQOs (in deference to the Canada-Wide Standards (CWS) development process or other priorities). Consequently, the NAAQOs are also getting dated. Under the Canada-Wide Standards process, ambient air quality standards have been promulgated for $PM_{2.5}$ and ozone.[2] These CWSs are accompanied

[1] See Appendix A for the current compiled list of BC "Air Quality Objectives and Standards."

[2] The CWSs for mercury, benzene and dioxins & furans focus on emission reduction targets or emission criteria. That is, these pollutants are treated

by an implementation procedure and initial requirements for the signatory provinces (which include BC). In this context, BC needs to respond to the CWS mandate, and there is a strong suggestion that it is time to carry out a comprehensive review and update of all of the BC Air Quality Objectives.

Health Canada, which has co-responsibility with Environment Canada for the NAAQOs under the Canadian Environmental Protection Act (CEPA), considers that the three-tiered NAAQO system was replaced in 1998 by the single-level approach that is available as a parallel track to complement the CWS process. Both the CWS and the NAAQO tracks are portrayed by Health Canada as the risk management conclusion of a risk assessment/risk management process. The NAAQOs as confirmed in 1989 when they were rolled over into CEPA remain available for provinces to use as the basis for developing their own objectives and are still published on the Health Canada website. The evolution from the three-tiered system to the single-tiered system is said by Health Canada "... to reflect current understanding of the continuum of health and environmental effects caused by air pollution."

Recognition of such a continuum of effects and associated risks has led Health Canada to develop a risk management framework for air pollutants, which forms the basis of its health protection strategy. A risk assessment approach to development of air quality objectives is described in a later section.[3] Health Canada identifies hazards, assesses their risks and develops standards and objectives; Environment Canada designs and implements risk management programs to complete the framework.

How BC's AQOs are applied

BC's AQOs are applied as discretionary criteria for Ministry Regional Managers (or Regional Waste Managers) in permitting processes under the Waste Management Act and in project review referrals under the BC Environmental Assessment Act. The AQOs are also applied by the Ministry and other agencies in the Province for other purposes as indicated in the list at the beginning of this paper. That is, the objectives serve multiple purposes as benchmarks for both short-term assessments and long-term air quality management programs.

Once pollutant emission criteria or ambient monitoring requirements are written into an air permit under the Waste Management Act, demonstrated exceedences of emission rates or the ambient AQOs at permit-mandated monitoring stations in the vicinity of the source become violations of permit conditions for enforcement purposes. The latter process breaks down if the permitted source is located in industrialized or urbanized areas, where many sources contribute to ambient conditions and impacts of individual sources ('source apportionment') is difficult.

The older PCOs vary as indicated in Appendix A from sector to sector and take into account the feasibility (at the time of formulating the objectives) of meeting them depending on the control capability of the respective processes. That is, although expressed in terms of ambient concentrations, the PCOs were source emission-oriented. For the criteria pollutants, the BC PCOs are at least as stringent as the NAAQOs, with the

much like the US EPA's approach to hazardous air pollutants (HAPs) under the US Clean Air Act, which address effects of chronic exposures to genotoxins and neurotoxins rather than the acute exposure to pollutants covered by the NAAQOs.

[3] See "Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks," August 2000 and the Health Canada webpages on air quality objectives and standards: www.hc-sc.gc.ca/hecs-sesc/air_quality/naaqo.htm.

exception of total suspended particulate matter. The PCOs are generally no longer applied to new facilities, but reference may be made to them in older permits under the Pollution Control Act or the Waste Management Act.

In general practice, in recent years, the most stringent guideline or objective, whether BC, Canadian or from another jurisdiction, has been applied for environmental impact assessment purposes. In permitting processes, professional judgement has been exercised by Ministry Regional Managers (or Regional Waste Managers) and their staff in writing permit conditions, often based on best available control technology determinations (or more recently, 'best available practice') from other jurisdictions (generally, as documented by the US EPA or agencies in California). The BC Guidelines and Standards Procedure (MELP, 1997) defines 'best available practice' in terms of:

- adherence to the pollution prevention hierarchy
- success under similar conditions for a minimum of six to twelve months in BC or other comparable jurisdiction
- commercial feasibility, and
- prevalence of use among comparable jurisdictions.

This procedure has not yet been exercised formally in the development of any current emission or air quality objective.

Regulatory authority

MWLAP has authority under several acts to develop standards, objectives and guidelines for protection of air quality, notably, *The Ministry of Environment Act* and *The Environmental Management Act*. Thus, there is no issue with respect to the Ministry's authority to review and revise objectives as necessary, as new information about the level of protection that existing objectives provide becomes available or new management situations present themselves.

2. Risk Assessment Approaches to Establishing Objectives

Most current air quality objectives (standards, guidelines) are developed in a risk assessment and risk management framework.[4] Most standards are expressed in terms of an ambient air concentration that, either implicitly or explicitly, is believed to correspond to a reasonably well-defined level of risk. Few standards, however, are expressed in terms of an explicit detrimental level of risk. That is, objectives that result from a risk assessment/risk management process need not be expressed in explicit risk terms. This distinction is important in thinking about how MWLAP might proceed to update BC's AQOs. The Ministry's current *Service Plan, 2002/3-2004/5* (February 2002) indicates that the Ministry should be focusing on standards development and risk analysis in its approach to environmental management requirements, hence, the specific interest in considering risk assessment approaches to establishing air quality objectives.

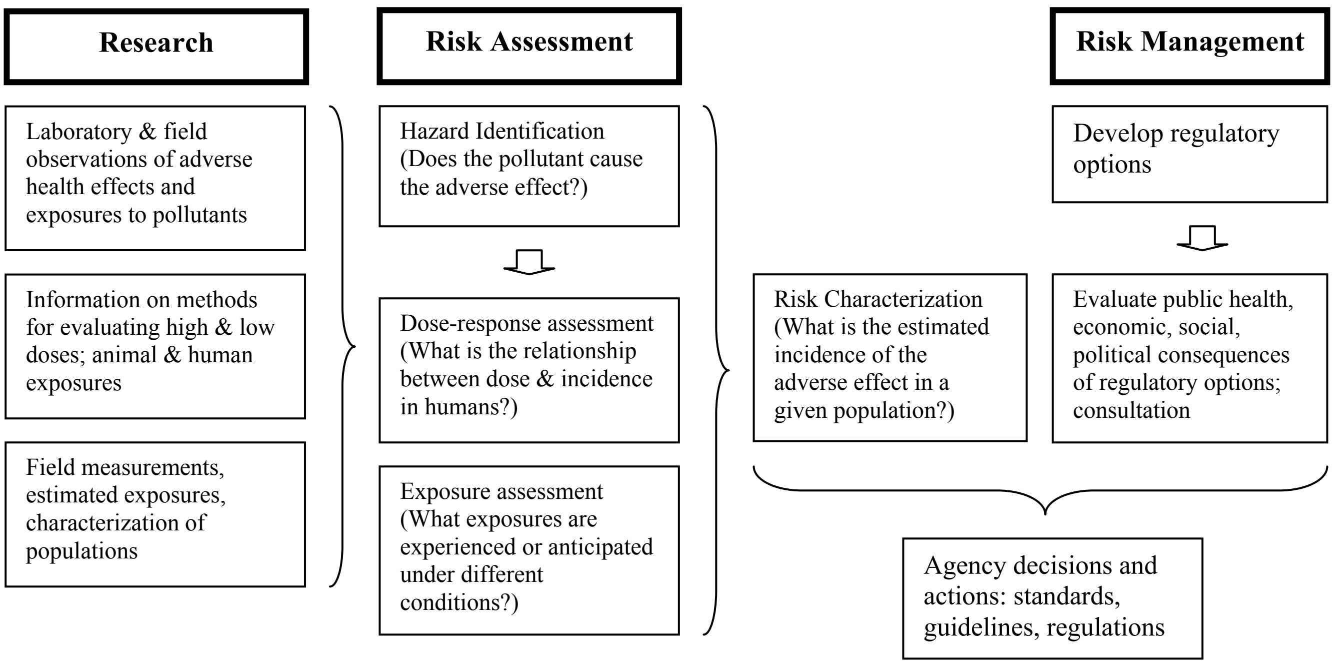
The Canada-Wide Standards (CWS) for $PM_{2.5}$ and ozone, for example, were developed within Health Canada's Risk Management Framework. See footnote 3 and additional discussion below.

[4] A formal definition of 'risk' is the potential for realising unwanted, negative consequences of an event – in this case, exposure to air pollutants. The potential may be expressed quantitatively (a numerical probability) or qualitatively (e.g., 'high' or 'low'). Risk analysis has often been used to assess chronic effects of long-term exposure to pollutants (such as cancer), but acute effects of short-term exposures can equally be addressed in such terms (such as day-to-day exposure to respiratory irritants).

Risk Management Models

Most regulatory risk assessment processes in North America are based on a model that was articulated by the US National Academy of Sciences in the early 1980s and adopted for use by the US Federal Government (including US EPA). The current Health Canada and Ontario Ministry of Environment standard development processes are similar in structure to that used by the US Government. The CWS development led by Health Canada and Environment Canada followed a risk assessment model. See footnote 3. A risk-based standard development process has the following steps (adapted from *Risk Assessment in the Federal Government: Managing the Process*, US National Academy of Sciences, 1983):

Depiction of the Risk Assessment/Risk Management Process



The analogous steps in Health Canada's Risk Management Framework are –

- Identify the problem and its context
- Assess potential risks and benefits
- Identify and analyze options
- Select a strategy
- Implement the strategy
- Monitor and evaluate results
- Involve interested and affected parties.

An issue for MWLAP is how the risk assessment framework may influence both how a review of BC's AQOs might be carried out (the process) and how the Ministry might organise itself to manage such a process. The Ministry must address a number of issues, such as –

- the Ministry's role in the research stage of the framework
- whether the risk assessment stage is carried out in-house or externally
- presuming that the Ministry will continue to develop the regulatory options in the risk management stage, whether the appropriate resources will be available

- the process by which the risk evaluation or risk acceptability determination in the risk management stage will be made.

Suggestions of how the Ministry might address these and other issues are made in the remainder of this paper.

Individual or Societal Risk?

An important risk characteristic for developing objectives is whether the AQOs are deemed to be for managing individual risk or societal risk. The former is the probability that an individual person who is exposed to a certain level of air pollution (either in an acute episode or over a long time period) will experience a health-related outcome (or some other valued ecosystem component will experience a similarly detrimental outcome). For example, exposure to 1 $\mu g/m^3$ of diesel exhaust particulate over a lifetime has been estimated by California agencies to create a risk of about 300 in a million (0.0003 or 0.03%) of a person's contracting lung cancer by the time he or she reaches age 70. That may appear to be a relatively small risk for that individual, considering that the total probability of contracting cancer of any sort (mostly due to diet, smoking or other non-air pollution-related lifestyle choices) is about 25% (250,000 in a million). The DEP risk is also small compared with the overall risk in BC of contracting lung cancer in a lifetime of about 8.8% for men or 5.3% for women (probability of 0.088 or 0.053, respectively, dominated by exposure to tobacco smoke, according to many experts).[5] If we consider the population of the Lower Fraser Valley as a whole, however, and assume that everyone is exposed to about 1 $\mu g/m^3$ of diesel exhaust particulate (which appears to be approximately so), we would estimate that about 65 people per year over the age of 65 would contract lung cancer attributable to diesel exhaust particulate.[6] What appears at first to be a small number for the individual extends to an appreciable number for the whole population of the region. A person might find that sort of risk acceptable in the context of other factors that lead to his or her own illness or death, but how is society – as represented by its public institutions and agencies – to interpret and manage such a risk? Such risk management issues are addressed in the next section.

Objectives expressed in risk terms

Although a risk assessment-based process is used to derive most air quality objectives for common or criteria air contaminants, as noted previously, they are seldom expressed in risk terms. Objectives are almost always expressed as ambient air concentrations that have an implied rather than explicit protection level against detrimental effects. The level of protection may be related to incremental risk, but most often AQOs are based on epidemiological observations of large populations from which levels of observable or non-observable effects may be determined.

Risk concepts have been more commonly used in developing acceptable exposure levels for hazardous air pollutants (HAPs) – most often associated with the cancer risk that they may pose. For example, the State of Washington's Acceptable Source Impact Levels (ASILs) are point source

[5] Canadian Cancer Statistics estimate for 2001.

[6] The exposure estimate is from *Diesel Particulate Matter and Associated Environmental Concerns, Health Risks and Tradeoffs*, The Onroad Diesel Emissions Task Force, March 2000. Since the cancer risk factor for DEP refers to a lifetime exposure (nominally, 70 years), the population at risk in the GVRD can be approximated by the fraction of people ages 65 and older. Currently, there are about 220,000 people 65 or older in the GVRD (GVRD population statistics, based on the 1996 census of 216,425, 11.8% of the population). Thus, if those people have been exposed to 1 $\mu g/m^3$ of DEP for their lives to-date, 300 in a million of them, or about 65 people, would have a new lung cancer today attributable to their exposure to DEP.

impingement standards for toxic air pollutants defined, in part, by levels corresponding to a one-in-a-million risk of cancer (or other illness outcome). Application of the HAPs management clauses of the US Clean Air Act (Section 112, etc.) has become bogged down in debates over levels of acceptable risk that might determine control actions, so that very few contaminants have been regulated under this authority. Such debates are often founded in uncertainty about extrapolating animal toxicological data to human exposures, since, in most cases, the true risk cannot be determined reliably in studies of human populations. Even when occupationally exposed human populations exhibit detrimental effects of an air contaminant, there is debate as to whether the dose-response functions are meaningful at ambient exposure levels.

A recent departure from this pattern is the only example known to the authors of objectives for a criteria air contaminant being expressed in risk terms: the World Health Organization's (WHO) recommended approach to developing national guidelines for airborne particulate matter. In its current listing of globally applicable air quality guidelines, WHO provides relationships for estimating percentage increase in various illness outcomes or mortality as functions of PM concentration. WHO suggests that it up to each nation using these data to establish objectives to determine an "acceptable level of risk for some health endpoint in the sense of a risk consideration."[7] Dose-response or exposure-response functions, such as recommended by WHO for PM, are needed if a risk-based approach is to be used for other pollutants. That is, if the public or public agencies are to assess an acceptable level of risk for a given pollutant or emission source-receptor situation, a functional relationship between exposure and risk has to be known. Whether there is a threshold of response also enters into such considerations, since the shape of an exposure-response function is different when a threshold exists.

Whether objectives are based on more conventional treatment of observations of exposure-response effects or on risk assessment principles, the process still involves professional and societal judgement about the acceptability of exposure to any given amount of a pollutant. Both benchmark or 'bright line' objectives that suggest a threshold of acceptability and risk-based functions that suggest a continuum of risk levels lead to the same kind of value judgements that regulators and the affected public need to make. These judgements take into account, for example -

- whether the hazard to which a person or a community is being exposed to create a level of risk is experienced voluntarily or involuntarily
- whether it is avoidable or unavoidable
- whether the risk is commensurate with the benefit that the exposed group or greater society may realise
- how the risk compares with those from other hazards to which the person or community is exposed (including cumulative effects).

These issues have been addressed in recent environmental assessment proceedings, such as the Port Alberni Generation Project Application to the BC Environmental Assessment Process or the Sumas Energy 2 Application to the Washington State Energy Facility Site Evaluation Council (in which BC held intervener status and gave extensive testimony on assessing health risk relative to existing air quality objectives). These are examples of the public dialogue on addressing public health risk having

[7] See the WHO website at www.who.int/peh/air/.

advanced beyond the purview of expressed public policy in BC.

The expression of objectives in health risk terms depends on the type of health outcome that is being addressed. Epidemiological studies, for example, may address health outcomes with the following characteristics–

- outcomes with non-specific implications that may be difficult to evaluate (e.g., school absences due to asthma or bronchitis)
- definitive outcomes that may have non-pollutant specific associations but which have a definite endpoint that can be evaluated (e.g., excess urban lung cancers)
- definitive outcomes that have strong association with specific pollutants and a definite endpoint (e.g., myocardial infarcts with exposure to measured concentrations of fine particles in a daily time series).

Objectives that are defined to avoid any of these (or other) morbidity or mortality outcomes need to be accompanied by an explanation of which outcomes the objectives are intended to be protective against. Because of the difficulty of doing this reliably, current objectives for common air contaminants address the most definitive and severe outcomes – premature death – with the presumption that less severe outcomes will also be avoided.

Expressing AQOs in risk terms, or based on specific risk criteria, will require not only that the Ministry develop the capacity to formulate risk-based objectives, but at least as importantly, the capacity to ensure that the risk framework and its implications are communicated effectively to stakeholders. Risk communication is a discipline on its own and requires expertise to be done properly.

Implications for BC of adopting a risk management approach

In order for a risk assessment/risk management approach to work, standards or objectives must be expressed in terms of exposure and consequent risk over a range of exposures (ambient concentrations), so that risk management decisions about what constitutes acceptable risk in a given situation can be made. As discussed below, exposure-risk information for ambient air concentrations of pollutants is seldom complete enough to provide the basis for a reliable choice. If BC is to adopt a more formal approach to air quality objectives and their application in practice based on risk principles, resources will need to be devoted to developing and implementing the regulatory framework and the objectives themselves. Given the scarcity of reliable information about risks of mortality and morbidity outcomes with exposure to ambient levels of most pollutants, a flexible and adaptive approach is necessary. A risk-based approach is in principle more flexible than the 'pass or fail' application of standards 'not to be exceeded,' because each situation is judged on its merits in terms of acceptable risk to the affected population or ecosystem (see also below, *Who or what are we trying to protect*?). The advantage of a risk-based approach is that debate is avoided over whether a standard is expected to be exceeded, or over the number of expected exceedences. The disadvantage is that consensus on risk acceptability value judgements is difficult to achieve.

BC may wish to consider exposure-based targets to address the individual and societal risk aspects of air quality objectives for project-oriented assessments. That is, it may be appropriate to gauge impacts based on the actual populations being exposed to emissions from a specific project or, in a more general context, to air quality in a community. Guidelines for the application and interpretation of existing or future

AQOs (including the CWSs) in assessment proceedings are essential if clarity on these issues is to be assured.

In practical terms, if a valid risk-exposure relationship is available over a range of personal or community exposures to an ambient air pollutant, value judgements can be made by agencies or by affected people as to what point (or range of points) along the risk-exposure relationship is generally acceptable. The choice of the acceptability point may differ from situation to situation, depending on the nature of the risk and the importance of the other risk factors listed above in this section, including socio-economic factors. For example, if a proposed emission source were directly upwind of an elementary school, it is likely that all involved in deciding on its acceptability would apply more stringent risk criteria than if the same source were to be located in a remote area. 'Bright-line' standards are not particularly helpful in such situations. Risk-based standards can lead to a more informed discussion of the important factors.

In summary, if BC were to adopt a risk-based approach to managing emissions and air quality, careful guidance would need to be provided to enable appropriate application of such a framework. Resources would be needed to develop and support risk-based objectives and to assist communities and proponents in preparing and interpreting the information. The benefit of adopting such an approach, if properly introduced, would be better public dialogue on the real issues attached to projects or air quality management programs, once the focus were taken away from standards or objectives as lines in the sand. Returning to an earlier point, the relative importance of human health and ecosystem risks would also need to be addressed.

3. Key Questions to be Addressed

With the foregoing as background, a number of key questions arise that need to be addressed in thinking about how BC might proceed to update its AQOs.

What is BC's policy framework within which air quality objectives are to be considered?

As indicated in the brief descriptions of risk management frameworks above, the process of setting standards or objectives is driven by basic public policy. Policy provides direction for deciding the purpose of establishing objectives. The recent *Service Plan* for MWLAP provides guidance on this issue. Part of the Ministry's mission over the next three years will be to implement a plan to improve air quality in threatened airsheds. Reviewing air quality management systems, including objectives, will contribute to developing such a plan. Before embarking on a process to review and update BC's air quality objectives, it is advisable to make sure that regulators and the public are clear on overarching policies and purpose.

Who or what are we trying to protect?

All clean air legislation in all jurisdictions embraces general protection of public health without excluding any groups who might be especially sensitive (such as asthmatic subjects). Sometimes there is a qualification that it should be recognized that whatever level that is proposed might still involve effects on some individuals. In the light of modern knowledge about the adverse effects of air pollutants, elderly individuals whose cardiovascular systems are compromised by disease (perhaps particularly those who are under treatment for congestive heart failure), and younger subjects with asthma (which affects as many as 8-16% of the public) have been recognized as being at risk from both particulates and ozone. There are data that indicate that exposure to air pollutants during a pregnancy may have some adverse consequences on the fetus [1]; but it is not known what specific pollutants might be responsible for this, nor what exposure levels might be detrimental. Hence it is difficult to take account of this information in setting a standard.

The general answer to this question is that public health protection is the aim, and no specific groups are excluded. Nor is it usually stated whether outdoor exercise, which in children might represent a risk in communities with photochemical air pollution [2], should be taken into account when setting exposure levels. It should be stated that whatever standard is proposed is designed to avoid adverse effects during normal human activities, which include exercise out of doors.

Review of BC AQOs also needs to consider how important is protecting sensitive ecosystems (for example, against acidic precipitation) compared with human health. The standards setting process in Ontario[8] is based on a risk assessment framework similar to those already described. An important feature of the Ontario process, which has been in place for 30 years, is the co-equality of several types of impacts in setting standards. Ontario air quality standards (short-term point of impingement standards for sources or longer-term standards for air quality management) are generally set at the most stringent level for the different types of receptor impacts (the 'limiting effect'):

- human health
- odour
- impacts on vegetation and crops
- impacts on soils and water quality
- soiling or corrosion of materials
- specific regulatory requirements (e.g., CWS)

For example, if vegetation happens to be the most sensitive receptor for a given pollutant, the standard is set on that basis – similarly for the other receptors. This type of consideration of what should be protected might enter into BC's determination of how to proceed.

A particularly important aspect of the answer to this question is whether the BC AQOs as they are to be applied in practice are intended to protect each individual (or each sensitive group of people) who may be impacted by emissions from a project or by general community air quality, or whether the AQOs are intended to be protective of the general population in a statistical sense without consideration of individual circumstances. This issue has not been thoroughly addressed in BC and has caused considerable confusion in regulatory proceedings in the province. This leads directly into the next question.

How protective need the objectives be?

It is known that sensitivity to air pollutants varies widely in the normal non-asthmatic population. If a group of normal subjects is exposed to controlled exposures of ozone, before there has been a statistically significant change in some measured parameter of function, one or two individuals will show a significant change from control values. There is therefore no such thing as a 'threshold' for a group, only for an individual [3]. A corollary is to ask whether the objective is protective against illness (morbidity) or premature death

[8] Ontario Ministry of the Environment, *Setting Environmental Quality Standards in Ontario: The Ministry of the Environment's Standards Plan*, 1999; *Summary of Point of Impingement Standards, Point of Impingement Guidelines, and Ambient Air Quality Criteria (AAQCs)*, Standards Development Branch, Ontario Ministry of the Environment, September 2001.

(mortality). The acceptable degree of protection may depend on whether morbidity or mortality is the issue.

Whatever exposure standard is adopted, therefore, a claim cannot be made that no individual will ever show an adverse effect from exposure, under certain circumstances.

For any pollutant, the higher the exposure the greater is the number of people that will be impacted. A 'standard' or 'guideline' is some number for a general exposure that would be considered 'unacceptable' if exceeded. As noted earlier, this may be expressed as an ambient air concentration, but it may or may not have a specific level of risk of illness or death associated with it. It should be protective of all except a very small minority of subjects; in some cases (as with the exposure of asthmatic subjects to SO_2) data exist which enable a reasonably reliable forecast to be made of what percentage of asthmatics would experience some airflow obstruction for an exposure for a given period of time [4]. In such cases, a level for a short-term exposure can be set which would ensure that, if not exceeded, fewer than 1% of susceptible subjects would be affected (without meaning to imply that this level is an acceptable one). For many pollutants, such as particulate matter, no data exist that permit a standard to be derived in this way.

Should an objective be risk-based, at a no observable adverse effect level (NOAEL), or at a lowest observable adverse effect level (LOAEL)?

Analyses based on risk estimates can be used in relation to some exposures. The risk of lung cancer as an outcome can be evaluated in terms of the total pack/years of cigarette smoking, and although such estimates in some cases have wide confidence limits, they are useful indicators. The widespread (or almost universal) use of such indicators in terms of lifetime cancer risk as an outcome, based both on occupational and environmental exposures (as for example in the case of radon exposure), led to proposals that all standards should be based on a strict "risk estimate" basis. This however is not feasible since the epidemiological data usually do not permit strict risk estimate methodologies to be applied, because the assumptions and judgements that have to be made in developing them are themselves subject to relatively wide confidence limits (uncertainty ranges). Also, many epidemiologic study designs do not result in a precise "dose-response" conclusion, which is needed for risk estimate analysis. Certainly risk estimates can be developed as a guide to acceptable levels of exposure – an example of this are the WHO recommendations in relation to particulate exposure [5], as noted above, in which no specific numerical value is proposed, but the implications of increases in exposure in terms of short-term mortality and hospital admission effects are set out in tabular and graphical form. WHO recommends that each agency using this information as the basis for setting a standard or guideline exercise judgement as to an appropriate acceptability point on the risk-exposure function.

Goldman has recently reviewed the use of epidemiological data in establishing risk estimates for pollution exposure, and identified the inherent difficulties in deriving precise enough dose-response functions [6]. Courts in the US have wrestled with the problem of dealing with epidemiological evidence and efforts to establish definitive criteria are in the legal record [7]. These mostly lack credibility, as they have included requiring that at least a twofold increase in risk be demonstrated before epidemiologic data are accepted, that some statistical "p" value be established as a requirement, or that any study in which the confidence limits of an "odds ratio" included a value of 1.0 be automatically excluded from consideration.[9]

It is useful to consider "No Observable or Lowest Observed Adverse Effects Levels" if such data exist. Unfortunately in the case of air pollutants, this is rarely the case. An instructive recent example of how difficult it is to define whether an effect has been observed is the detailed analysis of PM epidemiological data in major US cities under the auspices of the Health Effects Institute (HEI).[10] The analysis of US cities for PM_{10} in terms of mortality [8], which showed that of 20 major urban areas, only Atlanta failed to show the usual relationship between PM_{10} level and time-series mortality, might be taken as a case that demonstrated a NOAEL. However, it is likely that some factor, possibly the influence of blowing crustal dust (which is not believed to lead to significant changes in daily mortality) is responsible for the difference; hence the data cannot be used to derive a 'No Observable Effects Level'. Some other US cities (about one-third) in the larger, but less detailed, 90-city HEI study also showed weak or no association between PM levels and mortality. Many of the latter were in the west, where windblown dust may also be a factor, but the large majority of the 90 cities (65%) showed significant exposure-response relationships for mortality of similar magnitude. It is the general uniformity of the data associating PM_{10} with daily mortality that provides the foundation for concluding that the relationship between PM_{10} and premature mortality is causal. Efforts to identify a threshold value from the large data banks that exist have not proved successful [9]; hence no lower limit can be defined in general.

The attempt by Health Canada to propose "Health Reference Levels" on the basis of identifying lower values below which adverse effects cannot be identified, was a feature of the CWS development for PM and ozone. The statistical bases for the determinations of the Reference Levels proposed in the Science Assessment Documents for PM and ozone are unclear. The authors of those reports are careful to emphasize that the CWS Reference Levels should not be interpreted as thresholds, rather as LOAELs, being levels below which statistically significant mortality or morbidity effects had not been observed to the time of preparing the documents. The scientific literature on the subject of the existence of thresholds of exposure-response for PM and ozone indicates that, with exceptions in some urban areas,[11] the large majority of epidemiological studies has shown statistically significant exposure-response relationships down to the lowest ranges of ambient exposures that have been monitored. In this context, the CWS Reference Levels are arbitrarily selected points on continuous risk-exposure (linear) functions. They were not intended by the authors to suggest either thresholds of risk or public acceptability.

[9] The "p" value is the probability that a statistically derived factor is significant at a specified level of uncertainty. For example, $p = 0.01$ specifies certainty at the 99% confidence level. The "odds ratio" is the ratio of the probability of an outcome in a test population relative to the probability in a control group. A value of 1.0 indicates no excess occurrence of the effect being tested.

[10] Samet, J.M., S.L. Zeger, F. Dominici, F. Curreiro, I. Coursac, D.W. Dockery, J. Schwartz and A. Zanobetti. *The National Morbidity, Mortality and Air Pollution Study, Part II: Morbidity, Mortality and Air Pollution in the United State*s, Health Effects Institute, June 2000 (90 largest cities).

[11] See a series of reports from the Health Effects Institute on re-analysis of older epidemiological datasets and results of new studies for PM exposures for the largest US cities, for example, as cited in footnote 10 and reference [8].

How should objectives address short-term protection vs long-term management?

Consideration has to be given to both long-term and short-term aspects when standards are being reviewed. The need for short-term protective standards is illustrated by the question of what should be considered acceptable levels of one-hour exposure to NO_2 as a consequence of emissions from a natural gas-fired generating plant. The WHO has revised its one-hour guideline for NO_2 to 200 $\mu g/m^3$ (compared with the Canadian NAAQO of 400 $\mu g/m^3$). Impact assessments in BC have generally used the NAAQO for NO_2, but it is now apparent that if an asthmatic child living or attending school downwind from a facility that emitted NOx were exposed to more than 200 $\mu g/m^3$ of NO_2 for as much as an hour (commonly predicted by models for some sources), a response might be expected. Also, since the data associating $PM_{2.5}$ levels with the occurrence of myocardial infarct cases in Boston [10] showed that the recorded level of $PM_{2.5}$ during the 48 hours prior to the event was what was important, there is a need for a short-term standard for this pollutant. This case has recently been cogently argued by the Staff of the California Health Department in relation to proposed $PM_{2.5}$ standards in that State [11]. Similar considerations apply to situations in which exposure to large point sources is a possibility.

It is also clear that long term levels of air pollution have implications for non-acute or chronic outcomes. This appears to be the case in relation to the incidence of chronic respiratory disease death rates, and also in relation to lung cancer [7,12]. In these examples, it is particularly difficult to decide on the level of risk in relation to annual levels of a specific pollutant. The recent re-analysis of the longitudinal data [12] from the American Cancer Society involving twenty years of follow-up of 500,000 adults, showed that "Each 10 microgram/m^3 elevation in fine particulate air pollution was associated with approximately a 4%, 6% and 8% increased risk of all cause, cardiopulmonary, and lung cancer mortality, respectively." Present examples confirm these conclusions by indicating an association between levels of PM_{10} in different communities and survival rates (life expectancy) [13].

These examples suggest that both short-term protective levels and long-term issues have to be addressed. It is inevitable that the adverse health outcome data that have to be considered are likely to be different in these two instances. Further, the level of risk may be easier to identify in the case of short-term exposures.

This question may be especially important in a context of planning management strategies for the Province's threatened airsheds.

How should objectives be applied: not to be exceeded vs an acceptable number of exceedences – or as targets for continual improvement to reduce overall risk?

First, the old categories of the National Ambient Air Quality Objectives, "maximum tolerable", "maximum acceptable" etc. should be discarded, as they are confusing and provide no meaningful descriptive information. No other jurisdiction has adopted them. Similarly, the BC designations of Level "A", "B" and "C" are not helpful in describing their meaning or intent.

Second, it is important to establish a level that should be characterized as "detrimental" (the word currently used in the Australian jurisdiction). This level should be set to represent the first limit of generally "acceptable" pollutant levels. They should cover both short exposures; 24-hour maxima; and annual mean values, since all three of these are needed. They should be used as criteria in relation to current or possible future exposures. In the case of new projects, if modeling showed that exceedences would occur, it would follow that such a project would be deemed not acceptable from a health perspective. If current levels exceeded such values, it should be inferred that adverse health impacts are probably already occurring (but if the exposed population is small, it might not be possible to demonstrate this by epidemiological studies). In such instances, the Provincial policy should plan for continuous improvement to reduce the overall risk.

A possibility for establishing objective criteria for expressing AQOs in risk terms from epidemiological data might be to establish specific statistical criteria relating the exposure-response results. For example, if epidemiological studies show that exposure to an air pollutant (e.g., $PM_{2.5}$) over a well-characterised range of ambient concentrations leads to morbidity or premature mortality outcomes with a statistically reliable exposure-response risk, the statistics of the mean value of the concentrations at which the effect was found could be used to define a "detrimental" level. Such a level might be definable in terms of a specified number of standard deviations above the mean, or in terms of a specified level in the measured distribution of ambient concentrations (e.g., the 98th percentile). A recent staff paper submitted to the Air Quality Advisory Committee of the California Environmental Protection Agency proposes such an approach to setting a new $PM_{2.5}$ standard for California.[12] See also the next section and reference [11]. The detailed statistical definitions are beyond the scope of this document, but objective criteria are important in creating confidence in the resulting objectives or standards. If possible, one would want to select as the basis for setting a "detrimental" level studies of populations in similar geographic and demographic contexts to those to which it would be applied in BC.

Once the "Detrimental" levels have been established, "Policy Target Levels" should be established and promulgated. The "Policy Target Level" could be defined similarly as one or two standard deviations (or other appropriate statistical criterion) below a mean ambient level at which effects are generally found in epidemiological studies. For example, such a target might be the basis for reducing PM_{10} and $PM_{2.5}$ levels from combustion particles in the BC Interior cities to those that are found on the coast. In the case of ozone, a policy target level might be, for example, one that had been shown not to induce lung inflammation in those exercising for several hours in it. These levels for PM and ozone might be low enough that aggravation of asthma would be unlikely to occur except in a very few cases. A policy target has already been established by the Ministry in its specification of its only air quality performance indicator - achieving and maintaining at least 55% of monitored BC communities meeting the BC AQO for PM_{10} through 2005. The long-term goal for this indicator is to achieve the CWS for $PM_{2.5}$ in all monitored BC communities by 2010 (the CWS required timeline).

"Policy Target Levels" would not involve statutory responsibility to prosecute pollutant emitters, but might form a basis for some specific actions – such as closing down "beehive burners" for example.

[12] *Draft Proposal to Establish a 24-hour Standard for $PM_{2.5}$*, Report to the Air Quality Advisory Committee, Public Review Draft, California Air Resources Board (CARB) and Office of Environmental Health Hazard Assessment, March 12, 2002. An appreciable body of Canadian data is used in this assessment. Attached as Appendix C and available on the CARB website: www.arb.ca.gov/research/aaqs/std-rs/pm25-draft/pm25-draft.htm.

Third, sometimes the public is accused of expecting that they will be exposed to zero risks from air pollutants. In general, they are more sophisticated than this, and understand that any activity, such as driving a car or crossing the road, is associated with some level of risk; they also understand that risks they cannot avoid by choice – such as those induced by an elevated PM_{10} level – are in a special category.

4. Options for development and implementation

The basic options are –

- Do nothing; work within the context of current policy and the existing BC AQOs and CWS requirements.
- Keep the existing BC AQOs, but clarify the policy and application framework.
- Within the framework of existing BC and Canadian legislation, undertake a fundamental review of BC AQOs in light of contemporary science and technology.
- Review the legislative and regulatory framework within which the BC AQOs have been developed for adequacy to deal with current issues, prior to revisiting the AQOs themselves.
- Revise the legislative and regulatory framework for addressing air pollutants in BC, and simultaneously undertake a comprehensive evaluation of existing BC AQOs; identify gaps in pollutant coverage and needs for AQOs for additional pollutants.

Experience in recent Environmental Appeal Board proceedings (e.g., Campbell River or Dawson Creek), BC EAO/Environmental Assessment Act proceedings (e.g., Port Alberni, Prince George or Ft. St. John) and other regulatory proceedings, such as BC's Sumas Energy 2 application intervention in Washington State, suggests that the current framework lacks clarity – for all parties. Thus, the 'do nothing' option is not feasible, if clarity, efficiency and equity are desirable in public consideration of new projects and management programs. The following points assume that some action is necessary to address the confusing situation that project proponents and the public alike face in trying to address issues associated with new or existing sources of air pollution in BC.

Relevant findings

1. Different jurisdictions adopt different procedures before deciding on "standards." In free and democratic societies, following the lead of the US EPA, the following components are generally perceived to be important:

- a complete review of the existing relevant database; the most difficult part of this assessment is to decide how much weight should be placed on different epidemiological studies;
- public overview and access to all minutes and documents; a clear separation between what a standard might have to be to protect public health, and the modifying influence of economic and sociopolitical factors. The influence of these is accepted, but only if a clear differentiation is made between conclusions based solely on scientific criteria and the modifications required by these factors.

The procedures and processes now used by the US date from 1980; a useful review of the chronology of the decision-making for standards has recently appeared [14]. A process for reviewing and updating BC's AQOs should not necessarily copy another jurisdiction, but it should reflect some of the elements of the more open and accountable process followed in the US (short of adopting the litigative aspects of the US system, which have not always served the interests of stakeholders, the public or the environment).[13] A clear policy and decision-making framework needs to be in place so that accountability and transparency can be realised in BC.

2. Review and evaluation processes can become very drawn out, and timelines have to be set for various stages. The following sequence and timing of steps is an illustration of a possible review process:

- conduct a review (probably about 2 months' duration) of controlled exposure and epidemiological data, and the same period for a review of animal data, if that is appropriate, to begin the process.
- discuss the document resulting from such a review openly at a convened public forum.
- prepare an in-house staff paper to summarise possible levels for the two-tier standards proposed above (another one-two months).
- convene another public meeting for further discussion, and
- propose a standard within a short time after the second public meeting (say, no more than four weeks later).

The public forum (consultation) held in 1991 on developing a new clean air policy and program framework for BC might serve as an example of structuring a consultative approach. More specific options for structuring an approach appear in a later section of this paper.

3. All relevant documents, including particularly US EPA Criteria Documents and WHO guidelines/standards should be considered in the development process. See footnote 7. The WHO documentation contains a useful discussion of air quality management in general in addition to the pollutant-specific guidelines and rationale. Useful documents are also published from Sweden [15], and the conclusions reached by the Australian authority (NEPM) should also be considered. British and European Union documents should also be available. Documentation prepared for the Canada-Wide Standards consultations on PM and ozone standards, should be included in the review, as well as for other pollutants prepared under the CWS process and the related multi-pollutant emission reduction strategy (MERS) processes for various sectors. The latter include assessments of important pollutants in addition to PM and ozone. A number of pollutant assessment reports under the Canadian Environmental Protection Act (CEPA) toxic substances control provisions also provide useful information on effects of a variety of substances.

The Air Quality Advisory Committee in California has very recently (March 2002) recommended a standard for 24-hour $PM_{2.5}$ of 25 micrograms/m^3 not to be exceeded. This is far more stringent than the currently proposed EPA standard of 65 micrograms/m^3, 98th percentile, which allows 7 exceedences a year. The wide gap between these recommendations illustrates the present disarray of the standard setting process in relation to $PM_{2.5}$ – emphasizing the need for BC to take an independent look at the available information. It is also more stringent than the 24-hour CWS for $PM_{2.5}$ of 30 μg/m^3 (also with an exceedences formula). Historically, BC and GVRD have followed California's lead in establishing more stringent standards and objectives than Canadian national objectives for emission

[13] See also *The Changing Character of Regulation: A Comparison of Europe and the United States*, R.E. Löfstedt and D. Vogel, Risk Analysis 21 (3), 399-416, 2001. This paper suggests that the adversarial US system is evolving toward the more consensual approach used generally in Europe (and in Canada).

criteria and air quality. Examples of the latter are early adoption of California's PM_{10} standard as a BC objective in 1995, well before the CWS process for PM concluded, or the aggressive targets in clean vehicle and fuels regulations in the mid-1990s.

Particular attention should be paid to studies that have been completed in British Columbia, such as the study of asthmatic and non-asthmatic children in Port Alberni [16], and the study of farmworkers in the Fraser Valley in Abbottsford [17]. Studies of the effect of domestic woodsmoke on asthmatic children in the valleys north of Seattle [18] should also be considered especially relevant to standard-setting in British Columbia.

4. It would be worthwhile considering the feasibility of a collaborative effort, at least in the initial stages, between the Western Provinces (Manitoba, Saskatchewan, Alberta and British Columbia). Each province would set its own standards; but the preparatory work might be shared. Pooled resources would enable a more thorough assessment of air quality objectives. Differing provincial perspectives on implementation of the CWS requirements may preclude policy congruence, but the basic literature and its scientific interpretation should be common to all jurisdictions, regardless of eventual differing paths to policy statements.

5. Any standard should have to be reviewed on the order of every five years. It is not clear what a "legally binding requirement" for this would entail. The US EPA is mandated to review certain regulations and legislation every five years, and in Canada, the Federal Government is required to review certain legislation, including the Canadian Environmental Protection Act, every five years. This locked-in process can become artificially constraining, since new information that would be the basis for revisions does not accumulate at a defined pace. A required review could be specified to take place as seen fit by an expert panel of advisors, for example, without restricting the timeline for such reviews.

6. It should be noted that in the US, court challenges can be and often are mounted against proposed standards. This requires that an EPA Criteria Document be very complete and balanced in its assessment of the evidence. The Parliamentary process in Canada is not so constrained. Public and ENGO awareness, however, will create a demand for such completeness and balance in BC deliberations, whether legally mandated and documented or not. There are many ways of approaching completeness and balance in establishing objectives that are credible. For example, WHO does not attempt the preparation of a criteria document before proposing a standard, but the credibility of its expert panels is high, and the reasons for recommending a particular guideline are open for all to debate. The current fluid status of the science of air pollution's health and environmental effects suggests that a rigid, mandatory framework is unlikely to serve BC's long-term interests in air quality management.

7. The need for Air Quality Standards should be closely tailored to air emissions and the need for protection. In British Columbia, taking account of local industrial processes, the list would include, for example -

- Particulate matter – both PM_{10} and $PM_{2.5}$, 24-hour maxima, and annual averages.
- Tropospheric ozone – one hour, 8-hour averages, and annual mean values.
- SO_2 – ten minute, one hour, 24-hour, and annual mean values.
- NO_2 – one hour, 24-hour, and annual mean values.

- Formaldehyde – one hour and 24-hour mean values
- Styrene – one hour
- CO – one hour, 24-hour mean and annual mean
- H_2S (TRS) – ten minute, one hour, 24-hour and mean annual levels.

Ontario's long list of point of impingement standards and ambient criteria has developed over the years in response to permit (Certificate of Approval) applications, so each of the pollutants listed has been identified at one time or another in actual emissions from proposed or existing facilities in Ontario. If BC decides to pursue developing objectives for a longer list of pollutants than the current one, priority should be given to those pollutants that are of current concern with respect to known sources in BC.

8. Many regulatory proceedings in BC over the past 10 years or so have addressed the meaning and interpretation of BC's AQOs. One can cite debates in the course of these proceedings that focused on pollutant emission rates, their modeled air dispersion and the interpretation of the modeling results in terms of impacts on local populations. Arbitrarily selected examples are –

- a proposed ferrochromium smelter in Port Hardy (1990/91)
- BC Hydro's application to the BC Utilities Commission for an Energy Removal Certificate (export), focused on emissions from the Burrard Thermal Generating Plant (1992)
- an appeal before the BC Environmental Appeal Board (EAB) of Louisiana-Pacific's air permit for its Dawson Creek OSB plant, and subsequent appeal by the permittee of the findings of the original panel (1994/95)
- an appeal before the BC EAB of the Island Cogeneration Project's air permit in Campbell River (2000/01)
- Environmental Assessment Process hearings for the proposed Port Alberni Generation Project (2001)
- an appeal before the EAB of the Province's failure to implement the phase-out of beehive woodwaste burners in the Bulkley Valley (2000/01)
- the Province's intervention in the EFSEC hearings in Washington State respecting the Sumas Energy 2 application (2001/02).

One or both of the authors were involved in all of the above proceedings. Each process had difficulty in coming to terms with the application and interpretation of the BC AQOs, the NAAQOs, the CWSs and supplementary information from the scientific literature provided by experts. Based on this experience, we conclude that at this point in time, the question of health protective standards in BC appears to be both complex and confused.

Some options

Assuming that the *status quo* is deemed unacceptable, based on the discussion and findings presented here, which are a sample of possible observations of recent experience in the Province, general framework options for change and the path forward can be suggested.

Implications for short- and long-term actions by MWLAP are addressed in the Recommendations which follow the summaries of options.

1. Commission MWLAP staff to prepare a policy and options discussion document for public consideration (consultation) based on updating objectives by selecting the most appropriate alternates from those already in place elsewhere (taking the lead from other provinces,

US states, US EPA and WHO for example).

The Ontario standards-setting process, which has been mentioned several times, has been until recently a staff-driven exercise. With resource cutbacks, more of the information that goes into Ontario's considerations for standards and guidelines has been outsourced, but the body that makes the ultimate choice of ambient standard levels for most pollutants is the Ministry of Environment (with input from other Ministries). Ontario has used a risk assessment approach to standards for some pollutants, such as dioxins and furans, for which chronic exposure is more important than acute exposure, but most of the pollutants on Ontario's list have been addressed by establishing standards at levels that are dividing lines between acceptable and unacceptable. A current situation in Ontario bears watching, in which Ministry staff who were involved in risk determinations at a particular site (where soil contamination is the issue moreso than air) may be engulfed in litigation respecting the findings. Such situations are a potential risk related to in-house execution of the objectives development and implementation process, if staff resources are thin. Such issues have already been addressed in BC in the development of the Contaminated Sites Regulations under the Waste Management Act over the past few years.

The in-house option is the simplest approach, but adequate resources need to be allocated.

2. Commission an external agency to undertake a comprehensive review of existing practices and prepare reviews of (a) policy, (b) human health epidemiological studies and perhaps (c) animal toxicological studies as the basis for re-formulating BC's AQOs.

   The external body could be mandated to recommend revisions and additions to BC's AQOs, or its findings could lead into a stakeholder or full public consultation. The commissioned agency might very well be a reputable foundation or institute that has the public's confidence in similar matters. A possible approach might be a BC Royal Commission similar to that on uranium mining in the Province that was chaired by one of the authors in the early 1980s. This type of forum could capture the broadest scope of professional and general input. If managed formally and rigorously, such an undertaking may be costly relative to less formal approaches.

   The recent Expert Panel to review socio-economic analysis methodology for the Canada-Wide Standards process that was convened under the auspices of the Royal Society of Canada is an example of this approach.

3. Establish a permanent expert panel or board (perhaps, such as is anticipated by the Government's recent announcement of forming an Environmental Assessment Board) to oversee and commission the necessary studies and convene deliberations. The members of such a body should be professionally expert in their fields, including expert representatives of public interests.

   Perhaps the most successful examples of this approach are the various boards and committees that have been formally mandated to advise the US Environmental Protection Agency and vet its activities. Some of these bodies have been mentioned in the discussion above. The EPA's Science Advisory Board (SAB) has broad scope to oversee and evaluate EPA's regulatory and scientific undertakings, including vetting the basis for standards and guidelines. The Clean Air Science Advisory Committee of the Board (CASAC) performs this function with respect to air quality standards. Its critical oversight of the development of the revised EPA standards for PM and ozone that were challenged vigorously in court proceedings, in part, provided the credibility that supported the science behind the standards. This led eventually to the standards being fully upheld by the courts (March 2002). SAB reports directly to the EPA Administrator (junior ministerial rank, roughly).

4. Establish a less formal independent body (compared with #3) for the purpose of carrying out a comprehensive review of BC's AQOs, but not maintained as a continuing standing body. Once this body's tasks were complete, responsibility for oversight would revert to Ministry staff.

   This approach would allow the current requirements of reviewing and updating the AQOs to be carried out, but would lack an ongoing review and oversight function. This would have the advantage of being less costly in the long-term. The advantage of continuing input from experts in option #3 would be lost.

The following table summarises some of the advantages and disadvantages of the proposed options.

Options Summary

Option	Advantages	Disadvantages
Do nothing	None in current context, except low direct cost; savings may be illusory, since resources are being wasted in current regulatory processes.	Many, since current situation needs guidance and renewal as a minimum.
Commission staff policy and options discussion paper followed by consultation; borrow 'best' objectives from other jurisdictions	Least external expenditure.	Sufficient internal staff expertise required; others' values and frameworks may not be compatible with BC's
Mandate an existing external agency (e.g., university or NGO organisation) to undertake review and update; conduct public process	Independence from government lends credibility; can be cost-effective since infrastructure already in place.	May not necessarily address government priorities, unless mandate is carefully specified.
Establish a temporary panel for the sole purpose of reviewing and updating AQOs; Ministry conduct consultation process	Independence lends credibility; can be disbanded when process complete (sunset); specific mandate controls scope (cost)	No continuing oversight function; implementation reverts to internal staff (requires adequate follow-on funding).
Establish a standing (permanent) expert panel or board	Independence lends credibility; wise counsel brought to bear on the issues; continuing oversight and advisory functions; panel available for referrals (permit applications, hearings).	Experts and secretariat function costly; timelines may be difficult to control; establishing separate entity may be costly; starting from scratch may add excessive time to completion of tasks.

5. Recommendations

Short-Term Actions

1. Standards, objectives and guidelines are important for the protection of public health from exposure to air pollutants; otherwise, there is no framework within which reasonable and supportable regulatory or professional value judgments can be made. This is true whether conventional or risk-based objectives or criteria pertain. A first step is to confirm that AQOs for BC are essential to support regulatory processes.

   Objectives are required as essential guides for decision-making on new projects which will affect local pollution levels, and in guiding policy priority decisions. They should not be treated as bright lines or hurdles that mark thresholds of acceptability.

2. It is most important that the policy drivers for the practical application of air quality objectives in BC be defined clearly as a preamble to initiating a process to review and update BC's air quality objectives. Without a policy framework, the review would not have a definable goal. Policy review should be the next step in the updating process.

3. The Ministry should develop guidelines for applying and interpreting BC's AQOs to clarify their intent for the public, regulators and assessors in permitting, permit appeals and environmental assessment proceedings – whether or not they are updated. Such guidance is more important than changing the numerical values of the AQOs. This is our principal recommendation and might take a year to complete.

4. An early task might be to undertake a review and possible updating of BC AQOs in the context of BC's response to the implementation requirements of the CWSs for $PM_{2.5}$ and ozone. An evaluation of BC's approach to these two pollutants could broaden into a more comprehensive, general evaluation of AQOs.

5. Prepare an assessment of lessons learned from the proceedings of the quasi-judicial public proceedings listed in this paper and any other relevant proceedings to develop a sense of problems that arose in interpreting AQOs and how they were addressed by the reviewing body.

6. Air quality standards, objectives and guidelines may also be desirable for protecting non-human receptors and environmental values in BC. The multi-media, 'limiting effect' approach taken by Ontario is instructive in this regard. MWLAP should address the relative priority of non-health effects compared with direct human impacts.

Longer-Term Actions

7. Two levels of standards should be defined. The top level should be designated as "detrimental" indicating that contemporary data indicate that, beyond any reasonable doubt, significant adverse health risks will be incurred if exposures exceed such a level. A second level should be designated as a "policy target objective;" these objectives would be recognised as defining a level towards which policy initiatives should be directed.

   It might take several years to build up the framework and body of knowledge necessary to implement such a system, and it will need both internal staff resources and external expert and stakeholder input.

8. The process of arriving at the two levels of standards should involve public input; specialized external reviews of contemporary literature; and open discussion of these reviews by interested parties before actual standards are promulgated.
9. BC policy should address the role of technical or economic feasibility in setting and implementing air quality objectives; public health risk should be kept as a separate consideration without technical and economic factors. A full risk management approach would include such political and socio-economic factors at the end of the assessment process. The scientific findings and policy or program decisions should consider both streams of information, placing appropriate weights on the risk and socio-economic findings. The classic risk analysis framework that separates research, risk assessment and risk management activities has proven its worth and should be recognised by BC.
10. Depending on the model that is chosen for the path forward, it is recommended that in a resource-constrained environment, priorities should be focused on the priority pollutants identified above (mostly conventional contaminants) before tackling more exotic contaminants such as trace organics or metals ('hazardous air pollutants,' HAPs). Based on the US experience, the significant resources devoted to regulating HAPs have reduced health risk only marginally compared with managing the more conventional pollutants.
11. The process of reviewing air quality objectives for BC might parallel a similar review of water quality objectives, since public health impacts through both media have some similar characteristics. BC should consider whether the joint review of air and water objectives would improve the scope and efficiency of the reviews, or whether the two media are sufficiently different that such an approach would not be beneficial.

6. Conclusion

No specific choice among the four optional approaches to addressing BC's AQOs is recommended, since this is up to the BC Government to determine, considering advantages and disadvantages of each, their relative effectiveness, the feasibility of establishing any one of them in BC's current budgetary restraint circumstances – and the expressed wishes of stakeholders and the public.

We are convinced that the public places a high priority on enforced standards that are necessary to protect public health and that it expects, therefore, that the effort for this process would command the highest priority in the departments charged with the responsibility. The options outlined here are potential approaches to addressing the public's expectations.

References

[1] Ritz, B., Yu, F., Fruin, S., Chapa, G., Shaw, G.M., & Harris, J.A., *Ambient Air Pollution and Risk of Birth Defects in Southern California*, Am J Epidemiol 2002; 155; 17-25.

[2] McConnell, R., Berhane, K., Gilliland, F., London, S.J., Islam, T., Gauderman, W.J., Avol, E., Margolis, H.G., & Peters, J.M., *Asthma in exercising children exposed to ozone: a cohort study*, Lancet 2002; 359; 386-391.

[3] Hazucha, M., *Relationship between ozone exposure and pulmonary function changes*, J Appl Physiol 62, 1671-1680, 1987.

[4] See *A Citizen's Guide to Air Pollution*, Second Edition. Edited by D. V. Bates and R. B. Caton. In press, The David Suzuki Foundation, 2002.

[5] *Update and Revision of the Air Quality Guidelines for Europe*, Meeting of the Working Group "Classical" Air Pollutants, Bilthoven, The Netherlands, 11-14 October 1994. Regional WHO Office for Europe, Copenhagen. 1995, and published version of *Global Air Quality Guidelines* for 2000 on WHO website.

[6] Goldman, L.R., *Epidemiology in the Regulatory Arena*, Am J Epidemiology 154, No.12 Supplement, S18-S26, 2001.

[7] Bryant, A., & Reinert, A., *Epidemiology in the Legal Arena and the Search for Truth*, Am J Epidemiol 154 No 12. Supplement, S27-S35, 2001.

[8] Samet, J.M., Dominici, F., Curriero, F.C., Coursac, I., & Zeger, S.L., *Fine Particulate Air Pollution and Mortality in 20 U.S. cities, 1987-1994*, New Engl J Med 343; 1742-1749; 2000.

[9] Schwartz, J., & Zanobetti, A., *Using meta-smoothing to estimate dose-response trends across multiple studies, with application to air pollution and daily death*, Epidemiology 2000: 11; 666-672.

[10] Peters, A., Dockery, D.W., Muller, J.E., & Mittleman, M.A., *Increased particulate air pollution and the triggering of myocardial infarction*, Circulation 2001; 103; 2810-2815.

[11] California Staff analysis of $PM_{2.5}$ standard. See *Review of the California Ambient Air Quality Standards For Particulate Matter and Sulfates. Report to the Air Quality Advisory Committee, Public Review Draft, November 30, 2001,* California Environmental Protection Agency, Air Resources Board and Office of Environmental Health Hazard Assessment.

[12] Pope, C.A.III., Burnett, R.T., Thun, M.J., Calle, E.E., Krewski, D., Ito, K., & Thurston, G.D., *Lung Cancer, Cardiopulmonary Mortality, and Long-term Exposure to Fine Particulate Air Pollution*, J.Am.Med.Assoc. 2002; 287; 1132-1141.

[13] Dockery, D.W., Pope, C.A. III., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris B.G.Jr., & Speizer, F.E., *An Association between air pollution and mortality in six U.S cities*. New Engl J Med 329, 1753-1759, 1993.

[14] Greenbaum, D.S., Bachmann, J.D., Krewski, D., Samet, J.M., White, R., & Wyzga, R.E., *Particulate Air Pollution Standards and Morbidity and Mortality: Case Study*, Am J Epidemiol 154, (No. 12, Supplement), S78-S90, 2001.

[15] Nyberg, F., & Pershagen, G., *Epidemiologic studies on ozone*, Scand J Work Environ Health 1996; 22 Supp 3; 72-98.

[16] Vedal, S., Petkau, J., White, R., & Blair, J., *Acute effects of ambient inhalable particles in asthmatic and nonasthmatic children*, Am J Respir Crit Care Med 1998; 157: 1034-1043.

[17] Brauer, M., & Vedal, S., *Health Effects of Photochemical Smog: Seasonal and Acute Lung Function Change in Outdoor Workers*, J Environ.Med 1: 163-170 (1999).

[18] Koenig, J.Q., Covert, D.S., Larson, T.V., Maykut, N., Jenkins, P., & Pierson, W.E., *Wood smoke: Health effects and legislation*, Northwest Environmental Journal 4, 41-54, 1988.

BIBLIOGRAPHY

Ministry of Water, Land and Air Protection, SERVICE PLAN, 2002/2003 – 2004/2005, Ministry of Water, Land and Air Protection, February 2002. Available on MWLAP website homepage: www.gov.bc.ca/prem/popt/corereview/srv_pln/wlap/.

Lipfert, F.W., *Air Pollution and Community Health: A Critical Review and Data Source Book*, Van Nostrand Reinhold, New York, ISBN 0-442-01444-9, 1994.

Guidelines for Air Quality, World Health Organization, Geneva, 2000.

APPENDIX A: Current BC Air Quality Objectives and Standards

AIR QUALITY OBJECTIVES AND STANDARDS
(μg/m³)

Contaminant	Averaging Period	Canada maximum desirable	Canada maximum acceptable	Canada maximum tolerable	B.C. level A	B.C. level B	B.C. level C
		objective	objective	objective	objective/guideline	objective/guideline	objective/guideline
carbon monoxide	1 hour	15000	35000		14300	28000	35000
	8 hour	6000	15000	20000	5500	11000	14300
hydrogen fluoride	24 hour						
hydrogen sulphide	1 hour	1	15		7.5-14	28-45	42-45
	24 hour		5		4	6-7.5	7.5-8
lead	24 hour				4	4	6
	30 day geometric mean						
	quarterly						
	annual geometric mean				2	2	3
nitrogen dioxide	1 hour		400	1000			
	24 hour		200	300			
	annual arithmetic mean	60	100				
ozone	1 hour	100	160	300			
	24 hour	30	50				
	annual arithmetic mean		30				
sulphur dioxide	1 hour	450	900		450	900	900-1300
	3 hour				375	665	
	24 hour	150	300	800	160	260	360
	annual arithmetic mean	30	60		25	50	80
total reduced sulphur	1 hour				7	28	
	24 hour				3	6	
total suspended particulate	24 hour		120	400	150	200	260
	annual geometric mean	60	70		60	70	75
Date of Reference		1989	1989	1989	several	several	several

Ambient Air Quality Objectives Established in 1995

formaldehyde	1 hour	**Action Level** = 60 **Episode Level** = 370
PM10	24 hour	50

APPENDIX B: Terms of Reference

W AC-O2-335

SCHEDULE "A" - SERVICES

SCOPING PAPER ON OPTIONS TO UPDATE

PROVINCIAL AIR QUALITY OBJECTIVES

The Contractor shall, in consultation with Ministry staff prepare a scoping paper on options to update the provincial air quality objectives. In the report, the Contractor shall:

1. Summarise the current set of provincial air quality objectives, including

- what the objectives are,
- how they are applied, and
- what the legal mandate is to update the objectives.

2. Describe the risk-based approach to setting air quality objectives. This should include:

- examples of jurisdictions where this approach is applied;
- a description of implications of a risk-based approach to the current air management system, including the impact assessment and permitting of new or modified stationary sources.

3. Identify key questions/value judgments required by the Ministry to finalise an approach to updating the provincial air quality objectives.

4. Identify options for the short-term (within 12 months) and long-term development and implementation (within 5 years) of updated provincial air quality objectives, including common air contaminants and air toxics. This summary should include but not be limited to the following:

- an assessment of options to develop air quality objectives, including but not limited to in-house development, expert panel, consultants, and borrowing from other jurisdictions, including:
    - a description of the process for developing air quality objectives associated with each option, the time required, and value judgments needed;
    - an assessment of the advantages and disadvantages of each option;
    - examples of other jurisdictions who follow these approaches, including a description of how the objectives are developed, how they are applied, how often they are reviewed, and the legal mandate to do this;
- a discussion of how often provincial objectives should be reviewed; and
- a discussion of the utility of a legally binding requirement to regularly update air quality objectives.

Project Schedule and Deliverables:

The Consultant agrees to complete a penultimate draft report on the work described above by March 31, 2002. Specific tasks will be undertaken according to the following schedule.

Task	Tentative Date
Draft report	March 21, 2002
Receive comments of draft report	March 26, 2002
Penultimate draft report	March 31, 2002

The project deliverables will include electronic files of Draft and Final Reports in a format compatible with MS Word/Windows NT.

This contract may be extended for a further term to complete Phase 2 of this project based on satisfactory service, successful negotiations and funding as per item 24 of the Terms of Service Contract (General).

APPENDIX C:

California Air Resources Board Staff Paper, *Draft Proposal to Establish a 24-hour Standard for $PM_{2.5}$*

Note: References in the attached document are to sections in the draft report cited in reference [11].

Air Resources Board
Alan C. Lloyd, Ph.D.
Chairman

State of California

Governor Gray Davis

Office of Environmental
Health Hazard Assessment
Joan E. Denton, Ph.D.
Director

Draft Proposal to
Establish a 24-hour Standard for PM2.5

Review of the
California Ambient Air Quality Standards
For Particulate Matter and Sulfates

Report to the Air Quality Advisory Committee

Public Review Draft

March 12, 2002

California Environmental Protection Agency

Air Resources Board
and
Office of Environmental Health Hazard Assessment

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see our Website: http://www.arb.ca.gov.

California Environmental Protection Agency

Winston Hickox, Secretary

Printed on Recycled Paper

Draft Proposal to Establish a 24-hour standard for PM2.5

Background

In the initial Report to the Air Quality Advisory Committee (November 30, 2001), Air Resources Board (ARB) and Office of Environmental Health Hazard Assessment (OEHHA) staff did not propose a specific 24-hour standard for PM2.5. The Committee, however, unanimously recommended that staff develop such a standard, and suggested several possible approaches. Responding to the Committee's concerns and suggestions, OEHHA staff members have formulated the following recommendation, in consultation with staff at the ARB.

As reviewed in prior sections, the epidemiological literature suggests the existence of impacts on both morbidity and mortality related to fluctuations in ambient PM2.5 on a daily basis. Morbidity outcomes associated with changes in 24-hour concentrations in PM2.5 include admissions to hospitals for respiratory and cardiac diseases (see sections 7.5.1 and 7.5.2). There is also a growing literature suggesting potential mechanistic linkages between ambient PM2.5 and exacerbations of cardiovascular disease that could result in hospitalization or death (see section 7.8). These include associations with serious cardiac arrhythmias, myocardial infarctions, and decreased heart rate variability (Peters et al., 2000; 2001, Liao et al., 1999; Gold et al., 2000; Pope et al. 1999). As noted in prior sections, the entire spectrum of adverse health outcomes associated with ambient PM2.5, including exacerbations of asthma, emergency room visits, hospitalizations, as well as mortality, occurs within the same general concentration range and also seems to be best described by a linear, non-threshold model. Such a model implies that the level(s) at which adverse effects begin to occur cannot be identified and that there are no abrupt changes in the slope of the dose-response relationship to delineate a "bright line" or threshold.

Consistent observations of health effects associated with low ambient concentrations of fine particles, however, indicate that a short-term PM2.5 standard is required to protect public health. Moreover, while state-wide attainment of the proposed annual PM2.5 standard will result in a reduction of PM2.5 peak concentrations, some areas will be able to attain the annual standard and still experience periods during which 24-hour PM2.5 concentrations associated with increased morbidity and mortality can occur (e.g., during winter inversions accompanied by widespread residential wood combustion). This phenomenon also evidences the need for a short-term standard.

Development of a short-term standard for PM2.5, however, encompasses difficulties similar to those encountered with respect to the 24-hour standard for PM10, largely because the exposure-response relationships examined appear to be linear without clear evidence of a threshold. The linear, nonthreshold model carries implications for the determination of an "adequate margin of safety" specified in the language of the Children's Environmental Health Protection Act.

In order to address the lack of a "bright line" in the exposure-response curve, OEHHA staff members propose to reduce the entire distribution of fine particles below reported the levels of distributions consistently associated with adverse health effects. The underlying principle is to reduce not only the mean concentration (represented by the annual average), but specifically the upper tail of the distribution, described by the 98th percentile of the distributions of published studies. In so doing, OEHHA has relied primarily on studies relating fine particle concentrations with daily mortality, the most serious irreversible health impact. As noted above and in section 7.5, associations of PM2.5 with morbidity have been observed to occur within the same concentration range as those linked with increased daily mortality. We have therefore assumed that a standard intended to protect against the occurrence of mortality will also protect against these other important health outcomes.

Methodological Approaches

In developing this recommendation, OEHHA staff followed several approaches. Specifically, we have: (1) used statistical methods to examine the shape of the exposure-response relationships using two California datasets, and compared the results with those reported for other non-California datasets; (2) tabulated the results of all time-series studies published in English, for which direct PM2.5 monitoring data were available, that have explored associations between low levels of ambient PM2.5 and daily mortality; and (3) examined, with technical assistance from ARB staff, the upper tail of the PM2.5 distribution in California consistent with an annual average of 12 $\mu g/m^3$, based on data collected throughout California in 1999 and 2000. Based on the results of these analyses, OEHHA recommends that the 24-hour PM2.5 standard be established at a level of 25 $\mu g/m^3$, not to be exceeded. The adoption of the accompanying recommendation for an annual PM2.5 standard of 12 $\mu g/m^3$ is an integral component of this proposal. Attainment of the recommended annual standard will help shift the entire PM2.5 distribution to the left, and will influence peak concentrations, as well. However, in itself, the annual average will not fully address the issue of brief (i.e., one to several days) increases in PM2.5 levels. Thus, the 24-hour standard is intended to protect Californians against significant short-term elevations of PM2.5.

1. Statistical approaches

With the objective of further examining the validity of the linear model between mortality and PM2.5, staff from OEHHA and the Bay Area Air Quality Management District (BAAQMD) undertook a variety of detailed analyses of data from the two published California studies involving 24-hour measurements of PM2.5 and daily mortality counts (in Coachella Valley [Ostro et al., 2000] and Santa Clara County [Fairley, 1999]). The modeling techniques used for the exposure-response functions included piecewise linear regression (e.g., utilizing several "hockey-stick" models), locally weighted smoothing in generalized additive models, trimming analysis (selectively deleting days with high PM2.5 values), and Bayesian models (comparing the likelihoods of various thresholds) to explore the evidence for a nonlinear exposure-response at low PM2.5 concentrations. In general, within the concentration range of interest for PM2.5, nonlinear models (and, in particular, models intended to identify possible thresholds) offered no improvement over a linear, nonthreshold model in fitting the data. These analyses, which are not presented in this document, are consistent with results reported by almost all other researchers (except, e.g., for Smith et al., 2000) using datasets from locations outside California. At least for mortality, others have also found that a linear nonthreshold model best characterizes the relationship between ambient PM2.5 and adverse health outcomes (Pope, 2000 and section 7.3.5). A corollary of this observation is that, in order to calculate a short-term PM2.5 standard, additional information (such as the distributions of PM2.5 concentrations in published studies examining exposure-response relationships) may be required.

2. Distributions of PM2.5 in daily mortality studies.

OEHHA staff obtained data from the authors of all recently published studies examining ambient PM2.5 concentrations in relation to daily nonaccidental mortality. Table 7.a provides information on the estimated percentage change in daily mortality associated with a 10 $\mu g/m^3$ change in PM2.5. All the point estimates of this relationship in Table 7.a are positive, though not all are statistically significant. The upper tail of the PM2.5 distribution in each of these investigations is indicated by the 98th percentile, which is somewhat less subject to the factors determining the most extreme values. Examination of the PM2.5 levels in Table 7.a indicates that, when the 98th percentiles of the fine particle distributions are $\leq$32 $\mu g/m^3$, and the mean fine particle concentrations are <13 $\mu g/m^3$, the results are characterized by greater uncertainty, since the confidence intervals for the percent change in mortality include zero. These were studies conducted in Portage (WI), Topeka (KS), and in four Canadian cities (Calgary, Edmonton, Ottawa, and Winnipeg). One partial exception to this observation is Vancouver, British Columbia, which had a 98th percentile PM2.5 concentration of 30 $\mu g/m^3$, though the mean concentration was 13 $\mu g/m^3$. These results do not imply an absence of effects when peak PM2.5 concentrations are below 30 $\mu g/m^3$; rather, these estimates may be subject to greater uncertainty potentially ascribable to several factors, including fewer health impacts associated with exposure to lower concentrations, exposure measurement error, confounding by co-pollutants or meteorological factors, differences in the composition of particle mixtures, decreased statistical power, and reduced variance in the PM2.5 values in studies with lower means. The last explanation is unlikely, however, as we examined the coefficients of variation in the studies with relatively low PM2.5 mean concentrations and found that they were generally similar to those in the studies with higher mean levels. In contrast, statistical power (i.e., the ability to detect statistically a real relationship between two variables) is likely to be reduced at lower ambient pollutant concentrations. Based on model simulations conducted by staff at the BAAQMD, the increased uncertainty between lower-level PM2.5 concentrations and daily mortality may be attributable in part to insufficient statistical power.

Published studies provide some guidance for an appropriate reduction in the distribution of PM2.5. An annual PM2.5 standard of 12 $\mu g/m^3$ would represent a level lower than the long-term means of all the studies in which significant associations with changes in daily mortality have been identified (see Table 7.a and section 7.3, above). Attainment of the annual average would, as previously noted, result in an across-the-board reduction of PM2.5, including peak concentrations. Setting a 24-hour standard level below 30 $\mu g/m^3$ would shift the upper extreme of the PM2.5 distribution to a level lower than those identified in the studies described above. Because the exposure-response relationship is characterized by a linear, nonthreshold model, such a 24-hour standard does not imply total elimination of health risks when this standard is attained. However, reduction of peak PM2.5 concentrations below those observed in studies reporting adverse effects represents a rational approach to reduce the risk of short-term PM2.5-associated mortality and morbidity and to position the entire distribution of PM2.5 below those for which there is current, published evidence of health effects.

3. Relationship of Recommended Annual PM2.5 Standards and 24-hour PM2.5 Concentrations in California

As discussed in Chapter 6, the ARB uses the Expected Peak Day Concentration (EPDC) to determine the “design value” for 24-hour standards. The development of the EPDC uses a statistical model of the highest 20% of the daily values from the previous three years, making it relatively robust with respect to fluctuations in daily meteorological conditions. Specifically, the index will not be unduly influenced by any single day, and exceptional events such as forest or urban fires can be excluded. We used a modified version of this process to examine the upper tail of the PM2.5 distribution (98^{th} percentile) rather than the most extreme values within California. With assistance from ARB staff, we conducted an analysis to determine the relationship between the 98^{th} percentile of the PM2.5 distribution in California and the proposed annual average of 12 $\mu g/m^3$. This analysis identified the 98^{th} percentile concentrations consistent with an annual average of 12 $\mu g/m^3$, given recent statewide distributions of PM2.5.

Using data from 54 sites around the state, located principally in large urban areas, a linear regression model was performed (linear models fit the data better than non-linear models) relating the 98^{th} percentile of the PM2.5 distribution to the annual average for the years 1999 and 2000 for each site. The regression model generated an r^2 of 0.79 and indicated that statewide, the 98^{th} percentile for the distribution of PM2.5 associated with a 12 $\mu g/m^3$ annual average is approximately 39 $\mu g/m^3$. For sites within the jurisdiction of the South Coast Air Quality Management District, representing the most heavily populated air basin in the state, the predicted 98^{th} percentile concentration is approximately

37 μg/m^3, while the corresponding value for three other major air basins (the San Francisco Bay Area, San Joaquin Valley, and Sacramento) is 45 μg/m^3, and that for the South Central Coast is 33 μg/m^3.

This approach to identify ambient PM2.5 98th percentile concentrations consistent with attainment of the proposed annual average indicates that, at least in some of the heavily populated air basins, predicted concentrations of PM2.5 could fall within ranges previously reported to be associated with increased daily mortality (Table 7.2) and morbidity. This modified EPDC exercise suggests the need for a lower short-term standard to limit excursions of PM2.5 to protect against increased risks of morbidity and mortality.

<u>Recommendation for 24-hour PM2.5 Standard</u>

Examining the evidence described above, OEHHA recommends that the 24-hour PM2.5 standard be 25 μg/m^3, not to be exceeded. The rationale for this recommendation is as follows:

(i) Multiple analyses of the exposure-response relationships between PM2.5 and mortality indicate that the data can be fitted most parsimoniously with linear, nonthreshold models. Given the apparent linearity of the exposure-response relationships in the epidemiological data, it is difficult to determine at what concentrations within the PM2.5 distributions in each study adverse health effects begin. Intuitively, one would expect greater biological responses and larger numbers of adverse events occurring at higher concentrations, everything else being equal. Nonetheless, in a linear exposure-response relationship, effects may be observed at lower levels as well. (Schwartz et al., 1996)

The importance of the linear, nonthreshold exposure-response relationship cannot be overemphasized in light of legislation requiring that ambient air quality standards be "established at levels that adequately protect the health of the public, including infants and children, with an adequate margin of safety." (California Health & Safety Code Section 39606(d)(2)) If a threshold in the exposure-response curve cannot be identified, then specification of an "adequate margin of safety" becomes challenging. The approach OEHHA staff members have adopted in pursuit of this objective has therefore been to: (1) identify indicators of the distribution of PM2.5 (specifically the means and 98th percentiles) in epidemiological studies that demonstrate the relationship of ambient fine particles with adverse health impacts, (2) recommend that the distribution of PM2.5 in California be reduced below the levels of these distributions, and (3) incorporate a margin of safety in the form of a standard "not to be exceeded", which will assure that the extreme values of the PM2.5 distribution in California will be lower (and in general substantially lower) than the 98th percentiles of PM2.5 distributions in published studies.

(ii) Without placing a short-term limitation on PM2.5 concentrations, recent experience in California indicates that even attainment of the recommended annual standard of 12 $\mu g/m^3$ will allow for excursions well into the range in which adverse effects, including mortality, have been identified in epidemiological studies. Notably, the modified EPDC analysis undertaken by the ARB staff indicates that for several large air basins, the estimated 98th percentile of the PM2.5 distribution consistent with attainment of an annual standard of 12 $\mu g/m^3$ would be in excess of 40 $\mu g/m^3$. Thus, adoption of a 24-hour standard of 25 $\mu g/m^3$ would be intended to limit such excursions.

(iii) As with PM10, morbidity and mortality outcomes appear to occur within the same PM2.5 concentration ranges (See Section 7.5). Therefore, we have focused on mortality as the most serious adverse health outcome. Changes in ambient air quality sufficient to protect against increases in mortality should, *a fortiori*, protect against the occurrence of morbidity, too.

(iv) Among studies examining PM2.5 and mortality, the long-term mean concentrations of those finding a significant association varied from 13 to 21 $\mu g/m^3$, while the 98th percentiles of the distributions ranged from 30 to 51 $\mu g/m^3$. Shifting the entire PM2.5 distribution downwards and limiting short-term excursions should reduce the likelihood of fine particle-associated mortality and morbidity. Recommending an annual average of 12 $\mu g/m^3$ addresses the issue of shifting the overall distribution downwards. By the same token, recommending a 24-hour PM2.5 limit of 25 $\mu g/m^3$ would place the upper extreme of the distribution lower than the 98th percentile of those identified in studies finding significant associations with mortality, thereby incorporating a margin of safety. More specifically, except for the study of Vancouver (Burnett et al., 2000), all published investigations of PM2.5 and mortality in which statistically significant effects were detected had 98th percentile PM2.5 concentrations of 32 $\mu g/m^3$ or greater. Positioning the upper extreme of the PM2.5 distribution in California at 25 $\mu g/m^3$ effectively incorporates a margin of safety into this recommendation, based on the best available scientific evidence.

Table 7.a: Distributions and Associations of 24-hour PM2.5 with Daily Mortality in U.S. and Canadian Cities with Long-term Mean PM2.5 Concentrations < 25 $\mu g/m^3$, Sorted by Reported 98 percentile Concentrations*

City	Study Period	Reference	Mean ($\mu g/m^3$)	98th percentile	% Increase (95% CI) per 10$\mu g/m^3$
Edmonton	1986-1996	Burnett et al., 2000	10	28	2.18(-1.74, 6.10)
Calgary	1986-1996	Burnett et al., 2000	10	29	0.63(-3.58, 4.84)
Winnipeg	1986-1996	Burnett et al., 2000	10	29	0.38(-3.15, 3.91)
Vancouver	1986-1996	Burnett et al., 2000	13	30	2.56(0.23, 4.89)
Topeka, KS	1979-1988	Schwartz et al., 1996	12	31	0.80(-0.20, 3.60)
Phoenix, AZ	1995-1997	Mar et al., 2000	13	32	2.22(0.00, 5.56)
Portage, WI	1979-1987	Schwartz et al., 1996	11	34	1.20(-0.30, 2.80)
Ottawa	1986-1996	Burnett et al., 2000	12	35	2.45(-0.53, 5.43)
Coachella Valley, CA	1995-1998	Ostro et al., 2000	17	38	4.44(0.00, 8.89)
Toronto	1986-1996	Burnett et al., 2000	15	41	0.91(-0.05, 1.87)
Boston, MA	1979-1986	Schwartz et al., 1996	16	42	2.20(1.50, 2.90)
Windsor	1986-1996	Burnett et al., 2000	18	43	5.20(2.24, 8.16)
Montreal	1984-1993	Goldberg et al., 2001	18	43	1.93(1.16, 2.71)
Kingston	1980-1987	Schwartz et al., 1996	21	44	1.40(0.20, 2.60)
St. Louis, MO	1979-1987	Schwartz et al., 1996	19	46	1.10(0.40, 1.70)
Santa Clara, CA	1990-1996	Fairley, 1999	13	51	3.18(0.00, 6.10)
Montreal	1986-1996	Burnett et al., 2000	15	51	1.23(0.11, 2.35)
Detroit, MI	1992-1994	Lippmann et al., 2000	18	55	1.24(-0.26, 2.83)

*Some data in Table 7.a, particularly most of the 98^{th} percentile values, were obtained directly from the authors of the published reports.

References

Burnett RT, Brook JR, Dann T, Delocla C, Philips O, Calmak S et al . (2000). Association between particulate- and gas-phase components of urban air pollution and daily mortality in eight Canadian cities. In: Grant LD, ed. PM2000: Particulate Matter and Health. Inhal Toxicol 12(Suppl. 4):15-39.

Fairley D (1999). Daily mortality and air pollution in Santa Clara County, California: 1989-1996. Environ Health Perspect 107(8):637-41.

Gold DR, Litonjua A, Schwartz J, Lovett E, Larson A, Nearing B et al. (2000). Ambient pollution and heart rate variability. Circulation 101(11):1267-73.

Goldberg MS, Burnett RT, Bailar JC III, Tamblyn R, Ernst P, Flegel K et al. (2001). Identification of persons with cardiorespiratory conditions who are at risk of dying from the acute effects of ambient air particles. Environ Health Perspect 109(Suppl. 4):487-94.

Liao D, Creason J, Shy C, Williams R, Watts R, Zweidinger R (1999). Daily variation of particulate air pollution and poor cardiac autonomic control in the elderly. Environ Health Perspect 107(7):521-5.

Lippmann M, Ito K, Nadas A, Burnett RT (2000). Association of particulate matter components with daily mortality and morbidity in urban populations. Res Rep Health Eff Inst (95):5-72, discussion 73-82.

Mar TF, Norris GA, Koenig JQ, Larson TV (2000). Associations between air pollution and mortality in Phoenix, 1995-1997. Environ Health Perspect 108(4):347-53.

Ostro BD, Broadwin R, Lipsett MJ (2000). Coarse and fine particles and daily mortality in the Coachella Valley, California: a follow-up study. J Expo Anal Environ Epidemiol 10(5):412-9.

Peters A, Dockery DW, Muller JE, Mittleman MA (2001). Increased particulate air pollution and the triggering of myocardial infarction. Circulation 103(23):2810-5.

Peters A, Liu E, Verrier RL, Schwartz J, Gold DR, Mittleman M et al. (2000). Air pollution and incidence of cardiac arrhythmia. Epidemiology 11(1):11-7.

CA III (2000). Epidemiology of fine particulate air pollution and human health: biologic mechanisms and who's at risk? Environ Health Perspect 108 Suppl 4:713-23.

Pope CA III, Verrier RL, Lovett EG, Larson AC, Raizenne ME, Kanner RE et al. (1999). Heart rate variability associated with particulate air pollution. Am Heart J 138(5 Pt 1):890-9.

Schwartz J, Dockery DW, Neas LM (1996). Is daily mortality associated specifically with fine particles? J Air Waste Manag Assoc 46:927-39.