mortality associated with acute PM exposure have been observed in over 60 cities throughout the world. In addition, similar quantitative estimates of the morbidity outcomes have been reported in multiple cities and/or have been conducted in California. Therefore, generalizing these results appears reasonable. There is still some uncertainty, however, concerning the choice of the specific studies and concentration-response functions used in this risk assessment. In this case, we used concentration-response functions that had been reviewed and judged as acceptable by U.S. EPA's Science Advisory Board. For example, although we used the results of single-day exposures in the short-term exposure-mortality studies, application of studies using multi-day averages would have generated higher effect estimates. As another example, the prospective cohort studies using the results from the ACS (Pope et al., 1995) and Harvard Six-Cities (Dockery et al., 1993) cohorts could have been pooled, producing a higher estimate than relying on only the Pope et al. study.

A second major uncertainty relates to the existence of a threshold. This is discussed in detail earlier, with the conclusion that there is no evidence for a threshold in the studies that have explicitly examined the issue. In addition, studies have demonstrated effects at very low concentrations of PM (see Table 7.1 and Figure 7.1, for example).

A third uncertainty involves the issue of co-pollutants. Specifically, it is possible that some of the estimated health effects include the effects of both PM and other correlated pollutants. Many of the daily exposure studies isolated an independent effect of PM and/or tested for possible interactions or joint effects with other pollutants. However, given inherent errors in measurement of exposure to ambient pollutant, it is possible that PM is serving as an index for a mix of combustion-related pollutants or other sources of pollutants. It should be noted, however, that SB25 requires OEHHA to consider possible effects of exposure to multiple pollutants in evaluating ambient air quality standards. Thus, insofar as the PM concentration-response association may include effects of other pollutants, this is in accordance with the statutory requirements. Related to this issue is the lack of a clear understanding of the relative effects of fine versus coarse particles. In addition, there is uncertainty related to the use of the existing network of monitors to represent current ambient concentrations. There will be some error in these measurements, depending on the location of these monitors and the spatial pattern of the pollutants.

Finally, estimates for only a subset of adverse outcomes are provided. For example, estimates of the effects of PM on cancer incidence and infant mortality are not provided. In addition, no estimates on averting behavior are provided. This would include measures that are taken to prevent symptoms from occurring in the first place, such as avoiding strenuous exertion on days with high PM, staying indoors, use of prophylactic medication, purchasing of air filters, and so forth.

7.10.6 Summary

In summary, the epidemiologic evidence and risk assessment support the likelihood of significant mortality and morbidity effects related to current exposure to PM. Although the relative risk per unit is low, the large number of people exposed suggests the existence of a potentially major impact on public health. A precise measure of risk, however, is difficult to determine. Given the above uncertainties, it is more likely that we have underestimated rather than overestimated the effects of PM.

7.11Recommendations for Standards

This chapter presents the staff recommendations for the Board to consider in promulgating the PM Ambient Air Quality Standards (AAQSs) for California. The section begins with findings on the overall adequacy of the current standards for PM with respect to protecting the health of the public, including infants and children. It continues with recommendations for the pollution indicators, averaging times, forms, and concentrations adequate to protect public health.

The recommended concentrations for the PM standards should be based on scientific information about the health risks associated with PM, recognizing the uncertainties in these data. With this in mind, the numerous studies of PM-associated morbidity and mortality indicate that, within the concentration ranges reported, there is no identifiable "bright line" or threshold PM concentration for either short- or long-term exposures, below which health effects would not occur. However, the Children's Environmental Health Protection Act [Senate Bill 25, 1998 Legislative Session, Escutia; specifically California Health & Safety Code Section 39606(d)(2)] does not require setting a given AAQS at a level that ensures zero risk. Given the current state of the science, it would not be possible to set such standards for particulate matter. Rather, the statute requires a standard that "adequately protects the health of the public, including infants and children, with an adequate margin of safety."

The governing statutory language indicates that California's ambient air quality standards should also protect other vulnerable populations, in addition to infants and children, and the general public [(H&SC sections 39606(d)(2) and 39606(d)(3)]. This legislative directive is consistent with historical practice in California, where ambient air quality standards have been formulated to protect identifiable susceptible subgroups, as well as the general population. For instance, the one-hour sulfur dioxide standard was developed in order to protect the most sensitive recognized subgroup, exercising asthmatics. Nonetheless, even with standards tailored to shield vulnerable populations, there may be exquisitely sensitive individuals remaining outside the ambit of protection.

Although both the California Health & Safety Code (section 39606) and the federal Clean Air Act (section 109) refer to an adequate margin of safety, no specific legislative definition of "adequate" is provided. This judgment is left to the responsible regulatory agencies. As described in the preceding chapters, the current epidemiological data suggest linear relationships between adverse health outcomes and ambient PM concentrations, with no clear demarcation of a level of PM exposure below which no adverse health effects would ever be expected to occur. The incorporation of a safety margin has been recognized by the California Supreme Court as integral to the process of promulgating ambient air quality standards [Western Oil and Gas Association v. Air Resources Board, 22 ERC 1178, 1184 (1984)]. To the extent that health effects associated with ambient PM have occurred at relatively low levels of exposure, and that there is substantial inter-individual variability in response to environmental insults, it is unlikely that any PM standard will provide universal protection for every individual against all possible PM-related effects. Thus, in this instance, applying the notion of an "adequate margin of safety" for PM standards becomes somewhat challenging. Nevertheless, taking into account the limitations of the scientific data, we have operationalized the concept of an adequate margin of safety by recommending standards that, when attained, should protect nearly all of the California population, including infants and children, against PM-associated effects throughout the year.

7.11.1 Adequacy of Current California AAQS for PM in Protecting Public Health

The extensive epidemiologic data on the health effects of PM, supported by clinical and toxicological evidence, suggests that in combination the current annual average standard for PM10 of 30 $\mu g/m^3$ and the 24-hour average of 50 $\mu g/m^3$ do not offer sufficient protection of public health, including that of infants and children (ARB, 2000). Chronic exposures to ambient PM appear to be especially deleterious, and may influence responses to shorter-term (usually daily) exposures. As reviewed in the above sections, there are strong and consistent associations between daily exposure to PM (measured as PM10, PM10-PM2.5, or PM2.5) and a range of adverse outcomes, including premature mortality, hospital admissions, emergency room and urgent care visits, asthma exacerbation, chronic and acute bronchitis, restrictions in activity, school absenteeism, respiratory symptoms, and reductions in lung function. These studies have been conducted in a wide range of cities on five continents, with differing PM sources, climates, seasonal patterns, co-pollutants, and population characteristics. The more severe outcomes are experienced primarily by the elderly and by people with pre-existing chronic heart or lung disease. However, several epidemiological studies suggest that children under age five may also experience serious adverse outcomes from exposure to PM10, including premature mortality and hospitalization for respiratory conditions (See Section 7.7.3.2).

As indicated in Section 7.3, many of the epidemiologic studies demonstrate associations between PM10 and the risk of premature mortality. The extent of early mortality or life shortening may be from days to years. Although it is possible that associations between PM10 and adverse health effects may occur throughout the range of concentrations reported in each study, these occurrences are more likely when particle levels are elevated. Therefore, for purposes of these recommendations, the staff has identified the mean PM10 concentration in a given study as representing the most likely minimum effects level. This approach is consistent with that taken in the recommendation for the California 24-hour standard for sulfur dioxide. At higher mean concentrations however, the probability increases that adverse health outcomes will occur below the mean, in contrast, as concentrations decrease, the associated risks incorporate a larger range of uncertainty (see Section 7.3). In view of the current state of the science, it is not possible to identify specific levels at which no PM-related adverse effects will occur; however, the strength of the association of interest in any given study is likely to be greatest at the mean PM concentration.

Analyses of mortality (summarized in Sections 7.3 and 7.4, Table 7.1 and Figure 7.1) and morbidity (summarized in Sections 7.5 and 7.6) demonstrate that numerous epidemiological investigations have found associations of adverse health effects with PM10 when the long term (i.e., months to years) study mean concentrations are at or below the annual average standard of 30 $\mu g/m^3$. Both of the studies reporting associations between long-term exposure and mortality have mean concentrations of PM10 or its equivalent at or below the current annual average (Pope et al., 1995; Dockery et al., 1993). In the report by Dockery et al. (1993), the long-term average for PM10 ranged from 18 to 46.5 $\mu g/m^3$ in the six cities studied, with an overall mean of 30 $\mu g/m^3$. A stronger association was found for PM2.5, which ranged from 11 to 29.6 $\mu g/m^3$, in which the overall mean concentration was 18 $\mu g/m^3$. Likewise, Pope et al. (1995) reported effects from PM2.5 in the analysis of the American Cancer Society cohort, with an overall study mean of 18 $\mu g/m^3$. If the ratio of PM2.5 to PM10 is approximately 0.65, as it was in many urban areas included in the American Cancer Society study, this would convert to a PM10 average of about 28 $\mu g/m^3$. Therefore, it appears that the current annual ambient standard does not incorporate an adequate margin of safety against the occurrence of mortality associated with long-term exposures.

Although numerous epidemiological studies have demonstrated small, but consistent, relationships between health outcomes and daily variations in PM concentrations, the impacts associated with the underlying chronic exposure cannot be separated from the health effects attributed to daily PM10 or PM2.5 exposures. In other words, the daily peaks are superimposed on this underlying chronic exposure. The notion that chronic exposures exert a dominant influence on health outcomes is reinforced when one examines the mortality risks associated with daily versus chronic exposure. Most of the time-series studies demonstrate a 0.5 to 1% increase in total mortality per 10 $\mu g/m^3$ change in PM10 (Section 7.3). In contrast, based on the American Cancer Society cohort study, the estimated mortality effect of chronic PM10 exposure is in the range of four to seven percent per 10 $\mu g/m^3$ change in the long-term average of PM10 (Pope et al. 1995; Section 7.4). These results suggest that longer-term exposures (i.e., several days to several years) account for most PM10-related mortality.

An additional complication is that, over time, the average daily PM10 concentration in a given location will be similar to the annual average PM10 concentrations. While relationships between health outcomes and daily exposure measurements can still be identified through time-series analysis, it is not possible to disentangle the influence of low-level chronic exposures with published data. Therefore, assessing the impact of occasional low-level PM peaks (e.g., at or below the level of the current 24-hour average) becomes problematic. Nonetheless, recognizing the limitations of the existing epidemiological data, the literature suggests that, when long-term mean PM10 concentrations are within the ranges reported in the published literature, it is possible to document a variety of adverse health outcomes in relation to day-to-day PM fluctuations.

Long-term mean PM levels near and below that of the current ambient California 24-hour standard have been consistently linked with respiratory symptoms and exacerbations of asthma in children. Although there are a few studies linking infant mortality to ambient PM, it is not clear, based on existing data, whether infants and children are more or less susceptible to PM-associated premature mortality than older adults with chronic heart and lunch disease. For example, it is possible that children who die of sudden infant death syndrome may have physiological abnormalities that render them unusually susceptible to the effects of PM; however, the database of published studies is too sparse for causal inference. As indicated in Section 7.7.3.2, most studies of infant mortality consist of either: (I) cross-sectional study designs, in which statistical control for all potential confounders is difficult and causal inference problematic, or (ii) time-series studies conducted in cities outside of the United States in which the PM levels are much greater than in California. In the latter group of studies, factors related to infant nutrition, health care and exposures may not be generalizable to the United States. Thus, given the current state of knowledge, it is uncertain whether infants and children represent an additional susceptible subpopulation with respect to air pollution-associated mortality at current ambient concentrations of PM. However, childhood respiratory morbidity does appear to be consistently linked with different measures of PM, within the same concentration ranges as those associated with mortality in adults with chronic heart and lung disease (See Sections 7.3 and 7.5).

The voluminous published data suggest that together, the current PM10 AAQSs are probably not adequately protective of public health particularly for the elderly and individuals with pre-existing heart or lung disease. From the perspective of public health protection, the principal shortcoming appears to be chronic PM exposures. The quantitative benefits assessment (Section 7.10) suggests that significant mortality and morbidity benefits will result from reducing population exposures to PM10.

7.11.2 Recommended Pollution Indicators

The scientific evidence suggests a need for standards to encompass fine particles as well as PM10. We therefore recommend that the PM10 indicator be retained and that a long-term standard for PM2.5 be promulgated as well. These recommendations are predicated on the following rationale:

- PM10 and fine particles are both associated with a wide range of serious adverse health outcomes, including premature mortality, hospitalizations, and asthma exacerbation, among others.

- Dosimetry studies indicate that both fine and coarse particles deposit throughout the respiratory tract (See Section 7.1). Fine particles are more likely to deposit in the alveolar region (or gas exchange zone) and may initiate inflammatory responses, with both local and systemic effects. Coarse particles (PM10 – PM2.5) can also deposit in significant quantities in the conducting airways and, to a lesser extent, in the gas exchange region of the lung. Moreover, multiple studies in which the health impacts of PM2.5 and coarse mode have been examined have reported adverse effects associated with both metrics.
- Particles larger than 10 µm in median aerodynamic diameter, which have limited deposition in either the alveolar or tracheobronchial region, are not likely to cause serious health impacts. Therefore, staff does not recommend an ambient air quality standard for particles larger than 10 µm.
- Ultrafine particles (particles with aerodynamic diameters between 0.001 and 0.1 µm), which can deposit in significant quantities throughout the respiratory tract, have been linked with serious health impacts, including premature mortality and asthma exacerbation. There is a small but growing toxicological database suggesting that ultrafine particles may be more toxic, on a mass basis, than fine particles of similar composition. However, there are few epidemiologic studies of ultrafine particles and findings are mixed. Therefore, there are insufficient data available to judge whether or not an ambient air quality standard for ultrafine particles is needed. Staff does not recommend an ambient air quality standard for ultrafine particles at this time.
- While recent toxicological research suggests potentially important roles for transition metals (e.g., iron, nickel, or vanadium) and PM-associated organic compounds in PM toxicity, there is insufficient evidence to develop ambient air quality standards for metals or any other specific chemical constituents of PM10 or PM2.5, with the exception of sulfates (see below). Therefore, staff does not recommend promulgating any other ambient air quality standard for any specific constituent of either PM10 or PM2.5. Ambient concentrations of most of the identified fine particulate constituents of potential concern, including sulfates, particulate acids, metals, and organic compounds, will be reduced by control strategies targeting PM10 and PM2.5 mass.
- Serious health effects have been associated with exposure to ambient sulfates, particularly in areas rich in strongly acidic sulfates, such as the eastern United States and Canada (See Sections 7.3, 7.4, 7.5 and 7.6). The results of such studies, however, have not been as consistent as for PM10, PM2.5 or the coarse fraction. Some studies (Gwynn et al., 2000) suggest that particle-associated hydrogen ion (H^+) and strong acidic sulfates are associated more with respiratory effects than other particle metrics, including PM10. However, in other studies, sulfates are highly correlated with the fine mode in which they predominantly occur, such that independent effects of these correlated co-pollutants cannot be reliably estimated. In a third set of studies, no association was reported for sulfates or strong particle acidity, while associations were found for PM10 (for example, Lippmann et al., 2000, Schwartz et al, 1994). In contrast to the results of some of the epidemiological studies, controlled exposure studies involving high levels (up to 1,000 $\mu g/m^3$) of strongly acidic sulfates have demonstrated little, if any, effect on volunteer subjects, including those with asthma (e.g., Aris et al. 1991). Though daily sulfate excursions in epidemiological studies have been linked with a variety of adverse health events, the nature of the study data does not allow for segregation of outcomes related to chronic low-level exposure from those associated with acute (daily) elevations in sulfate concentrations. Thus, though the mean concentrations of some multi-year studies are lower than the current 24-hour sulfate standard in California (Burnett et al., 1994; Gwynn

et al., 2000), these do not directly address the adequacy of the current 24-hour sulfate standard because it is difficult to separate the impact of a single 24-hour exposure. In this light, staff believes that the current scientific database is insufficient to use for revision of the existing sulfate standard.

In California, acidic sulfates (principally sulfuric acid and ammonium sulfate) constitute a small fraction of the PM mass relative to the areas in which sulfates have been found to be associated with adverse health impacts. For instance, in Long Beach, where the fixed-site monitor consistently shows the highest sulfate levels in the South Coast Air Basin, sulfates constitute about 13% of PM10 mass and 22% of PM2.5 mass on an annual basis, and about 16% of the maximum 24-hr PM10 mass (15 μg/m^3 sulfates/93 g/m3 PM10) and 21% of the maximum PM2.5 mass (13 μg/m^3 sulfates/61 μg/m3 PM2.5), respectively. In the San Francisco Bay Area and in Bakersfield, the percentages are much lower (California Acid Deposition Monitoring Program, 1994). In the ongoing Children's Health Study in Southern California, data on sulfates have been collected, but not yet analyzed as predictors of children's respiratory morbidity or lung function growth and development. According to ARB staff, these data should be analyzed over the next couple years.

In general, sulfates detected in California are less strongly acidic than those commonly found in the eastern United States and Canada. Though a time-series study linked sulfate concentrations in 1978-79 in Azusa, California with respiratory symptom reporting in adults, ambient levels during that study period exceeded the standard (Ostro et al., 1993). Sulfate concentrations in California have been lower, typically far lower, during the past few years than the level of the existing standard. Although a mortality time-series study undertaken in Santa Clara County (1989-1996) involving very low 24-hour average sulfate values (mean = 1.8, range 0-7.9 g/m^3) suggests an association with daily respiratory mortality, staff believes this finding can be attributed principally to the strong covariation of sulfates with PM2.5 (Fairley, 1999). Based on an assessment of current scientific evidence and ambient air quality data, staff believes that exposures to sulfates in California do not appear to pose health risks distinct from or greater than those associated with exposures to particulate matter generally. In view of the mixed evidence in the sulfates health effects literature, the paucity of recent data examining sulfates and health in California, the low likelihood of health risks in relation to ongoing trends in sulfate emissions and ambient levels, staff recommends the current standard be retained until the next review of the PM standard.

In the review of the adequacy of the California AAQS to protect public health mandated by the Children's Environmental Health Protection Act (ARB 2000), much of the evidence regarding the health impacts of sulfates was based on considerations of the PM epidemiology. Revisions of California's PM standards as recommended (below) will likely further reduce sulfate concentrations. In addition, based on discussions with ARB staff, the differences in sulfate composition and levels between California and the eastern United States are sufficient for OEHHA staff to recommend further studies in California prior to a full review of the sulfate standard. In particular, OEHHA staff recommends analysis of the sulfate data in relation to health indicators in the Children's Health Study, as well as time-series analyses of health outcomes and daily sulfate data being collected at the two California particulate matter Supersites in Los Angeles and Fresno. OEHHA recommends that ARB ensure that these analyses be conducted in such a manner as to provide optimally useful data for a full review of the sulfate standard.

- PM2.5 can infiltrate directly into residences, with greater penetration than the coarse fraction, and therefore individuals are likely to have more consistent indoor exposure to ambient PM2.5 than to the coarse fraction. Nevertheless, the coarse fraction also demonstrates substantial indoor infiltration, particularly in older buildings, or those in which windows or doors are kept open. Evidence from studies in California, indicate that 75% of indoor PM2.5 and 65% of indoor PM10 may originate outdoors (Ozkaynak et al., 1996b; see Chapter 6). Therefore, outdoor, ambient concentrations of PM2.5 and PM10 will play a significant role in total, personal exposure.

- Fine and coarse particles, in general, originate from different sources and have different lung penetration and deposition characteristics, but are both linked to adverse health effects. In most California cities, mobile sources are a significant source of PM10. In these cities, there are strong daily correlations between PM2.5 and PM10 throughout much of the year, such that a substantial fraction of PM10-associated health impacts can be reasonably ascribed to PM2.5.
- In contrast, PM2.5/PM10 ratios are lower in many parts of California than those observed nationally (Chapter 6). In some parts of the state, particularly in the inland air basins in Southern California, high PM10 concentrations are driven by the coarse mode. However, at this time, the current research database regarding coarse particles' health impacts is not as well developed as that for PM10. Therefore, staff recommends that PM10 standards be used as a basis for protection from exposure to coarse particles.

Taking into account all of the above factors, therefore, staff recommends the Air Resources Board promulgate new annual standards for PM10 and PM2.5, while retaining the existing 24-hour standards for PM10 and sulfates.

7.11.3 Averaging Times and Forms

The current PM10 AAQSs for California include both an annual standard based on the geometric mean concentration, and a 24-hour averaging time, not to be exceeded during the calendar year. These joint standards were developed to protect the public from both long-term and short-term exposures. Studies published since the California PM10 AAQSs were developed in the early 1980s support earlier findings and report associations between adverse health outcomes and both long-term (i.e., a year or longer) and short-term (i.e., from less than one day to several months) exposure to both PM10 and fine particles. Therefore, staff proposes standards using annual averages for PM10, PM2.5 and sulfates, and a shorter-term average for PM10. The foundations for the annual averages are relatively straightforward, as explained in the subsections below. Identifying a shorter-term average based on the existing epidemiological database is somewhat more difficult conceptually due principally to the intermingling of effects related to chronic and acute exposure, as described in Section 7.11.1, above.

While there is evidence of health effects associated with other averaging times (e.g., 4-hour and multi-year averages), staff believes that proposed averaging times will provide a satisfactory basis for setting PM standards and directing subsequent pollution control efforts.

Attainment of the annual standards described below will shift the current distributions of PM10, the coarse fraction, and PM2.5 to levels substantially lower than currently exist. Therefore, 24-hour averages of ambient concentrations of these particle measures will also decline. This implies that the current 24-hour average standard for PM10 should, unlike today, only occasionally be exceeded in most air basins. However, data developed by ARB staff indicate that even if the proposed annual PM10 standard is attained, some parts of California will sporadically experience PM10 excursions well above the current standard. Therefore, short-term standards will function primarily to address intermittent seasonal exceedances (e.g., from residential wood combustion during the winter holiday season or prolonged summer temperature inversions) that might occur in air basins otherwise in attainment with the annual averages.

For the annual averages, OEHHA staff recommends using the arithmetic rather than the geometric mean because the former is: (1) more directly related to cumulative exposure; (2) more sensitive to repeated peak concentrations; and (3) more consistent with other annual standards.

7.11.4 Recommended Concentrations

Although individual epidemiologic studies are subject to some uncertainty, particularly with respect to exposure assessment, the overall body of evidence (including toxicologic, dosimetric and human clinical studies, in addition to the epidemiological investigations) particularly the consistency and coherence of results, provides compelling evidence of causal relationships between exposure to ambient PM and a variety of adverse health outcomes (See Section 7.9). These studies provide a sound, scientific basis for the establishment of standards for both PM2.5 and PM10.

While several indicators of morbidity have been associated with exposures to ambient PM, including hospital admissions, emergency room visits, exacerbation of asthma, work loss, school absenteeism, bronchitis and respiratory symptoms, and changes in lung function, the choices of levels for the annual average standards set forth below are based primarily on studies of mortality. This is clearly the most definitive and serious of all the health events associated with exposure to PM. The mortality exposure-response relationship appears to be linear, at least for cardiorespiratory deaths, with no evidence of a threshold of effect within the range of the long term means of 24-hour average PM10 concentrations reported in the daily mortality studies (i.e., Daniels et al., 2000). PM-associated mortality has been observed at long-term average ambient concentrations comparable to those at which morbidity outcomes have been detected in other populations (See Sections 7.3 – 7.6), which suggests that it would be reasonable to base the standards principally on studies involving the most serious outcome. To our knowledge, there is no evidence that morbidity effects would occur at PM concentrations lower than those associated with increased risks of mortality. This may be due to the different populations at risk examined in the various studies. That is, associations between 24-hour averages and mortality have been detected primarily in the elderly who have a high prevalence of chronic cardiac and respiratory disease. In contrast, time-series or panel studies of children, who are not at high risk of mortality, have examined a variety of respiratory morbidity outcomes in relation to daily changes in PM. Though the initiation of biological reactions may overlap (i.e., airway and alveolar inflammation), the downstream pathophysiological consequences will vary. As there does not appear to be a gradient of exposure concentrations related to increasing health outcome severity, standards premised on providing protection against mortaility should also, *a fortiori*, protect the public, including infants and children, against the occurrence of morbidity outcomes.

To the extent that the annual standards for PM10 and PM2.5 are attained, the distributions of 24-hour and other short-term averages of PM10 and PM2.5 will shift downward markedly throughout the year. The likelihood of adverse health events occurring after acute exposures will also therefore be substantially reduced. Nevertheless, there may well be areas that will attain the annual PM standards, yet still experience seasonally high PM excursions associated, for instance, with prolonged winter air stagnation combined with residential wood combustion or with summer temperature inversions. The plethora of time-series and panel studies cited in this document make it clear that short-term elevations of PM are associated with increased morbidity and mortality, though again, the impacts of the ongoing chronic PM exposure have not been identified. Therefore, though downward revisions to the annual PM standard will enhance protection of the health of the public, including infants and children, it is appropriate to limit shorter-term PM exposures.

7.11.4.1 Annual Standard for PM10

Considering the weight of evidence from the literature reviewed in prior sections, staff recommends the annual average standard for PM10 should be revised from 30 to 20 µg/m^3. Consideration of an annual standard at this level would place significant weight on the studies of mortality related to long-term PM exposure using the Harvard Six-Cities data (Dockery et al. 1993) and the American Cancer Society cohort (Pope et al., 1995), both reanalyzed by Krewski et al. (2000). In the study by Dockery et al. (1993), the long-term average for PM10 ranged from 18 to 46.5 µg/m^3 in the six cities, with an overall mean of 30 µg/m^3. Visual inspection of graphs of this study's results suggests a continuum of effects down to the lowest levels, with no evidence for a threshold, (although it would be difficult to ascertain a threshold graphically in this set of six data points corresponding to the six cities). However, the city with the lowest long-term average PM10 concentration (Portage, Wisconsin) was, for purposes of analysis, designated as the reference category, against which the other cities were compared. In other words, it was assumed in the analysis that there was no increase in risk in this city. Thus, it would *not* be appropriate to infer, for standard-setting purposes, that PM-related effects on mortality occurred at the long-term mean PM10 concentration of 18 µg/m^3 in Portage. In addition, while there appears to be a graphic exposure-response relationship by city, no clear increase in the risk of mortality is evident in Topeka, KS (which had a long-term annual PM10 concentration of 26.4 µg/m^3) relative to Portage. Finally, the relevant periods of exposure associated with long-term effects are unknown (other than those likely to be associated with short-term exposures within each year). In the absence of better information, it is reasonable to select the mean long-term PM10 level as a starting point for recommending the annual standard. In the Six-Cities study, the mean long-term PM10 level was 30 µg/m^3.

Likewise, Pope et al. (1995) reported effects on mortality associated with PM2.5, but not PM10, in the analysis of the American Cancer Society cohort, with an overall PM2.5 study mean of 18 µg/m^3. The recent re-analysis of the ACS study also suggests effects of PM2.5, but not PM10, related to long-term exposures (Krewski 2001). If one assumes that fine particles are driving the associations between PM and mortality in the ACS study, and that the ratio of PM2.5 to PM10 is about 0.65 for most of the urban areas included in that study (see Chapter 6), this would convert to an overall long-term average PM10 concentration of 28 µg/m^3.

Several investigations, including the Children's Health Study (McConnell et al. 1999) and the Harvard Six-Cities Study (Dockery et al., 1989), have also reported associations between long-term PM exposures and morbidity outcomes, including bronchitis, exacerbation of asthma, and reductions in lung function (See section 7.6). In these studies, the long-term (one- or multi-year) mean PM10 concentrations ranged from about 21 to 35 µg/m^3. Some of the morbidity studies, however, may be capturing the effects of exposure to multiple pollutants. For instance, in the Children's Health Study, the associations of adverse health outcomes with PM10 and PM2.5 could not be statistically disentangled from the co-pollutants NO_2 and acid vapors. Therefore, selection of a target concentration of 20 µg/m^3 puts greater likelihood on a PM-specific effect in these morbidity studies, and provides a margin of safety, assuming that there may be interactions among co-pollutants.

As noted above, the epidemiological studies of daily exposure and mortality have reported mean or median PM10 concentrations from 14 to 115 µg/m^3 (see Table 7.1 and Figure 7.1). However, the degree of uncertainty regarding the results generally decreases as the average or median concentration increases. As can be seen in Figure 7.2, almost all of the studies with means or medians below 25 μg/m^3 have point estimates suggesting an association with PM10, but the confidence intervals include the null value, indicating weaker associations that are more uncertain. The annual averages of these short-term exposure studies are relevant, since effects are observed throughout a wide range of exposures and not only at the extreme values. In addition, some of the PM-associated mortality captured in the cohort studies above would include the modest increments in the short-term risks described in the time-series studies, recognizing that larger long-term increments in risk appear to be related more to chronic than to short-term exposures. Finally, all of the time-series studies conducted at these lower concentrations were undertaken outside California and the United States. Studies more relevant to California (i.e., those conducted in California or other parts of the United States) reported long-term PM concentrations in the range of 25 to 35 μg/m^3 (see Table 7.1). Consideration of a standard of 20 μg/m^3 would, therefore, provide a margin of safety by placing significant weight on some of the time-series studies conducted outside of California and the U.S. This recognizes the generalizability of the results of these studies, although the sources and mix of PM constituents, the underlying population health characteristics, and the exposure patterns may differ from those in California. A standard set at 20 μg/m^3 would protect against mortality effects related to long-term exposure in adults and morbidity effects (such as acute bronchitis in children). The quantitative benefits assessment suggests that attainment of this standard could result in the avoidance of an estimated 6,500 (95% CI=3,200-9800) cases of premature mortality per year associated with the difference between this proposed level and the current annual averages of ambient PM10 concentrations throughout California (a population-weighted average exposure of 33.1 μg/m^3).

7.11.4.2 24-hour Average for PM10

Staff recommends that the 24-hour average for PM10 of 50 μg/m^3, not to be exceeded, be retained. This standard would offer protection primarily against peak concentrations of both fine and coarse particles in areas that otherwise attain the annual standards for PM10 and PM2.5. For many urban areas in California, attainment of the annual standards will mean infrequent PM excursions, which would typically be associated with seasonal air stagnation. Thus, the 24-hour standard would is intended to prevent occasional elevated PM10 levels. Staff believes that the existing PM10 24-hour standard proscribing any single day concentration above 50 μg/m^3, in concert with attainment of the annual average standards for PM10 and PM2.5, provides substantial protection of public health, including that of infants and children, as described below.

The 24-hour PM10 standard was first promulgated in California in 1983, based primarily on an analysis of daily mortality in London in relation to changes in PM. At that time, there were no epidemiological studies in which PM10 had actually been measured. Rather, critical PM10 concentrations had estimated from other PM metrics, including TSP and British Smoke. Since then, a voluminous literature has appeared linking fluctuations in short-term or daily measurements of PM10 with a variety of adverse health outcomes, as reviewed in Sections 7.2, 7.3 and 7.5. Complemented by recent toxicological and controlled human exposure studies, the epidemiological foundation linking variations in ambient PM10 and daily morbidity and mortality has been firmly established.

Nonetheless, translating the results of these epidemiological studies into a short-term standard remains problematic. As noted in prior sections, multi-city analyses in Europe and the United States suggest exposure-response relationships between daily variations in ambient PM10 and fluctuations in cardiopulmonary mortality and other health effects that are essentially linear and without an observable threshold. To the extent that this is an accurate characterization of PM10-mortality associations, and that the latter represent causal relationships, there is little guidance on where to draw a "bright line" in recommending a short-term standard. Moreover, in time-series studies it is difficult to identify and separate the influence of chronic low-level exposures in contributing to individuals' susceptibility to daily PM elevations. Cumulative exposures over several days or longer, rather than during a single 24-hour period, may represent a more relevant time frame of exposure. Consistent with this hypothesis, numerous epidemiological studies report morbidity or mortality effects of greater magnitude associated with multi-day moving averages compared with single-day lags (Hajat et al., 2001; Schwartz, 2000b; Schwartz et al., 1993; Pope et al., 1992).

Recognizing the limitations of the epidemiological data available for standard-setting purposes, OEHHA recommends retention of the 24-hour standard in consideration of the following factors: (1) the apparent linearity of dose-response; (2) the greater uncertainty of effects at the lower concentrations; (3) the paucity of epidemiological data documenting the impact of a single 24-hour exposure at low ambient (i.e., non-occupational) concentrations; (4) the dominance of the effects associated with chronic exposures and the impact of chronic exposure on the response to short-term elevations in PM concentration; (5) the likelihood of effects occurring at concentrations above 50 $\mu g/m^3$ and (6) the interrelationships of alternative averaging times.

<u>Linearity of Dose-Response</u>

As discussed above (Section 7.3.5), time-series studies of morbidity and mortality indicate that the exposure-response relationships for 24-hour average PM exposures are linear and show no evidence of a threshold. The latter observation makes it difficult to identify where a "bright line" representing a single-day 24-hour PM10 standard should be drawn. The historic rationale for a 24-hour standard was the presumption that significant health effects occurred only on high concentration, "episodic" days or that high pollution days generated disproportionately greater and more severe adverse health outcomes. In general, the notion that episodic peaks alone are responsible for adverse effects ignores the potential role of chronic low-level exposures, which may predispose individuals towards greater susceptibility to elevated PM concentrations. In addition, there is little, if any, evidence that the exposure-response relationship becomes steeper at higher ambient concentrations; rather, the data generally indicate a linear exposure-response relationship.

<u>Greater Uncertainty at Lower Concentrations</u>

Epidemiological studies of short-term exposure and mortality have reported mean or median PM10 concentrations ranging from 14 to 115 $\mu g/m^3$ (see Table 7.1 and Figure 7.1). As can be seen in Figures 7.2 and 7.3, however, greater uncertainty about the effects exists as one moves to studies with lower concentrations. The greater uncertainty may be due to fewer health impacts associated with exposure to lower concentrations as well as other factors, including errors in exposure measurement, confounding by co-pollutants, and the chemistry of the particle mixture. Other uncertainties related to extrapolating the epidemiological findings from many of the daily exposure studies to California may result from differences in factors such as weather, housing stock, and population characteristics. Therefore, retention of the existing 24-hour standard acknowledges the uncertainty in applying the underlying studies with relatively low PM10 levels, particularly those conducted in other countries, to urban and suburban populations in California.

<u>Impact of Single 24-Hour Exposures at Low Concentrations</u>

Exposures of 24-hours duration occur "on top of" consistent chronic low-level exposures to PM. The effects of long-term exposure to PM, as described in Section 7.4, have been documented in several carefully conducted studies using a prospective cohort design. These studies incorporate effects associated with both short-and long-term exposures (although they may not include all of the impacts associated with mortality displacement). Basically, for these study effects to be observed, individuals must be continually moving into a “risk pool” from a non-risk or lower-risk status over time. Long-term exposure to PM subjects people to an increased risk (i.e., moves then into the “risk pool”) of mortality from cardiovascular disease, whether or not their deaths are ultimately associated with a recent “acute” exposure to PM (Schwartz, 2001a; Kunzli et al., 2001). While acute daily exposures appear to exert an independent effect on mortality and morbidity, the influence of a single 24-hour exposure at a concentration relevant to the PM standards, absent any other exposure to PM, has not been (and probably cannot be) determined epidemiologically. This would require observance of weeks or months of exposure to very low background levels of PM followed by a single day peak exposure. Even for individuals exposed experimentally in chamber studies, prior exposure to ambient PM cannot be discounted. Therefore, it is difficult to completely isolate the impacts of short-term elevated PM levels from chronic background exposures. In addition, as reviewed above, there is evidence that multi-day PM10 exposures are, at least in some studies, associated with greater risks than single-day exposures.

Importance of Impacts of Chronic Exposure

Our quantitative benefits assessment (Section 7.10) as well as similar efforts undertaken recently by the U.S. EPA (U.S. EPA, 2000) indicates that the total health impacts of PM are dominated by mortality associated with long-term exposure. In addition, effects on adult cases of bronchitis and childhood acute bronchitis, both associated with longer-term exposure to PM, are significant as well. Therefore, from a public health perspective, one should focus control strategies on reducing the entire distribution of PM concentrations, which would also lower the number of peak days. Formulating a short-term index consistent with the annual average is a rational way to approach the issue of limiting peak exposures that might still occur even when the annual average PM standard is attained.

Relationship of Recommended 24-hour and Annual PM10 Standards

As discussed in Chapter 6, ARB uses the Expected Peak Day Concentration (EPDC) in determining the “design value” for the 24-hour standard. 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 conducted an analysis to determine the relationship between the EPDC and the annual average of 20 $\mu g/m^3$, the most health-protective end of the range proposed above. This analysis identified the single day peak exposure concentration that is consistent, given the current statewide distributions of PM10, with an annual average of 20 $\mu g/m^3$.

Using data from 144 sites around the state, a linear regression model was run relating the EPDC to the annual average for each site. The regression model generated an r^2 of 0.72 and indicated that statewide, the EPDC associated with a 20 $\mu g/m^3$ annual average is 48 $\mu g/m^3$ which accords quiet closely with the existing standard. For the South Coast AQMD, representing the most populous air basin in the state, the predicted EPDC is 51 $\mu g/m^3$.

Likelihood of Effects Occurring at Single Exposures Above 50 μg/m^3

As indicated by Table 7.1, several studies with study means in the range of 15 to 30 μg/m^3 PM10 demonstrate associations between daily exposures and mortality. However, as indicated above, several studies at the lower concentration had confidence intervals that included an estimate of no effect; that is where the null hypothesis of no effect could not be rejected. OEHHA staff has examined the distribution of peak concentrations (i.e., 95th percentiles or maximum 24-hour concentrations) when they were provided in the time-series mortality studies reporting study mean concentrations of less than 30 μg/m^3. Many of these studies have peak values close to or above 50 μg/m^3. Keeping peak concentrations below 50 μg/m^3 will not assure the absence of health impacts. However, peak concentrations below this level are consistent with a distribution of PM10 in which the likelihood of mortality effects are less certain. Therefore, it is reasonable, from a public health perspective, to recommend a goal of preventing days when the 24-hour average concentration exceeds 50 μg/m^3.

In summary, while it is difficult to determine the effects of a single 24-hour exposure from available scientific studies, the evidence suggests that minimizing or eliminating days when the 24-hour PM10 average concentration exceeds 50 μg/m^3 is a prudent public health goal. Taking into account all of the scientific evidence, and bearing in mind that the attainment of the annual average standard will significantly depress the entire PM10 distribution, preventing single day concentrations below 50 g/m^3 should afford additional public health protection. Therefore we are proposing that the 24-hour standard be retained 50 μg/m^3. Future research should focus on the implications of short-term exposures of 24-hours or less in the absence of cumulative or chronic exposures to PM10. Together, these standards should protect public health with an adequate margin of safety in the sense described in the introductory paragraphs of Section 7.11.

7.11.4.3 Annual Standard for PM2.5

Staff recommends that the annual average for PM2.5 should be 12 μg/m^3, as explained below. Consideration of a standard at this level would place significant weight on the long-term exposure studies using the ACS and Harvard Six-Cities data (Dockery et al., 1993; Pope et al., 1995; Krewski et al., 2000). In both studies, robust associations were reported between long-term exposure to PM2.5 and mortality. The mean PM2.5 concentration was 18 μg/m^3 (range of 11.0 to 29.6 μg/m^3) in the Six-Cities study and 18.2 μg/m^3 (range of 9.0 to 33.5 μg/m^3) in the ACS study. Thresholds were not apparent in either of these studies, although the relevant period(s) and pattern(s) of exposure could not be ascertained. If we assume, as in the PM 10 standards considered above, that health effects are more likely to be observed when concentrations are at or above the mean or median PM2.5 levels, rather than at lower levels, then a reasonable starting point for considering an annual PM2.5 standard would be 18 μg/m^3.

Targeting a long-term mean PM2.5 concentration of 12 μg/m^3 would also place some weight on the results of multiple daily exposure studies examining relationships between PM2.5 and adverse health outcomes (Table 7.2). These studies have long-term (three- to four-year) means in the range of 13 to 18 μg/m^3. It should be noted however, that many of these epidemiological investigations were conducted outside California, and may not be representative of exposures or population characteristics here. A standard set at 12 μg/m^3, well below the means of the major cohort mortality studies, would provide additional protection against mortality in adults associated with long-term exposure, as well as against a variety of morbidity effects in children (described in Section 7.6, above). In the opinion of OEHHA staff, an annual PM2.5 standard of 12 μg/m^3 would be likely to provide adequate protection of public health, including that of infants and children, against adverse effects of long-term exposure.

The quantitative risk assessment suggests that attainment of this standard could result in a reduction of 6,500 cases (95 percent CI 3,200 – 9,800) of premature mortality per year associated with the current annual averages of ambient PM2.5 concentrations in the diverse air basins of California (approximately 18.5 $\mu g/m^3$, as reported in Chapter 10.

7.11.4.4 24-hour Standard for PM2.5

Staff does not recommend a 24-hour average standard for PM2.5 at this time. Staff recognizes that PM2.5 exposures can have significant, short-term health impacts. While effects resulting from long-term exposure to fine particles are evident from the prospective cohort studies, there are fewer studies on effects from shorter exposures. As indicated in the review of the few studies of daily mortality in relation to ambient PM2.5, a consistent differential in the acute effects of fine versus coarse particles is not evident. In addition, data from California indicate that for most urban areas, days with high PM10 concentrations are associated with high PM2.5 concentrations. Therefore, the 24-hour average PM10 standard should provide control for 24-average PM2.5 peaks as well. During the next cycle of review of the PM standards, there should be a larger database of PM2.5 studies to evaluate as the basis for a potential short-term fine particle standard. At that time, staff will again evaluate the potential for short-term PM2.5 standards.

7.11.4.5 24-hour Standard for Sulfates

Staff recommends that the 24-hour average for sulfate of 25 $\mu g/m^3$, not to be exceeded, be retained. Serious health effects have been associated with exposure to ambient sulfates, particularly in areas rich in strongly acidic sulfates such as the eastern United States and Canada. The results of such studies however, have not been as consistent as those for PM10, PM2.5, or the coarse fraction. In addition, though daily sulfate concentrations have been linked with a variety of adverse health events in epidemiological studies, the nature of the study data does not allow for segregation of outcomes related to chronic low-level exposure from those associated with daily elevations in sulfate concentrations.

In California, acidic sulfates (principally sulfuric acid and ammonium sulfate) constitute a small fraction of the PM mass relative to the areas in which sulfates have been found to be associated with adverse health impacts. Sulfate concentrations in California have been far lower during the past few years than the level of the existing standard. Based on an assessment of current scientific evidence and ambient air quality data, staff believes that exposures to sulfates in California do not appear to pose health risks distinct from or greater than those associated with exposures to particulate matter generally. In view of the mixed evidence in the sulfates and health in California, the low likelihood of health risks in relation to ongoing trends in sulfate emissions and ambient levels, staff recommends that the current standard be retained until the next review of the PM standard, if not earlier.

7.11.4.6 Other Recommendations

In light of the adverse health effects observed at current ambient concentrations and the lack of a demonstrated threshold, staff further recommends: (1) that in any air basin in California that currently attains the ambient air quality standards, for either PM10 or PM2.5, the air quality should not be degraded from present levels; and (2) that the ARB, in consultation with local air quality management districts, establish a goal of continued reductions in PM10 and PM2.5 concentrations over time. We further recommend that the standards be revisited within five years, in order to re-evaluate the evidence regarding the health effects associated with particle size, chemistry, and concentration.

7.11.5 Summary of Recommendations

- Revise the current PM10 annual average standard from 30 to 20 µg/m^3. Revise the averaging method to an annual arithmetic mean from the current annual geometric mean. Based on current evidence, there are compelling reasons to be concerned about significant adverse health effects associated with exposures occurring at or below the existing standard.
- Retain the 24-hour standard for PM10 at 50 µg/m^3, not to be exceeded.
- Establish an annual average standard for PM2.5 of 12 µg/m^3, given growing evidence from epidemiological and toxicological studies of significant toxicity related to this size fraction of PM. Establish the annual PM2.5 standard as an annual arithmetic mean.
- Retain the current 24-hour average standard of 25 µg/m^3 for sulfates.

General Staff Conclusions Regarding Air Quality Degradation

- For any air basin in California that currently attains the ambient air quality standards, for either PM10 or PM2.5, that air quality should not be degraded from present levels.
- Establish a goal of continued reductions in PM10 and PM2.5 concentrations over time.
- The standards be revisited within five years, in order to re-evaluate the evidence regarding the health effects associated with particle size, chemistry, and concentration.