

or to areas that are now in attainment with the 1-hour NAAQS.<sup>38</sup>

#### *b. Risk Assessments*

The EPA conducted an assessment of health risks for several categories of respiratory effects considering the same population groups, alternative air quality scenarios, and urban areas that were examined in the human exposure analyses described above. The objective of the risk assessment was to estimate to the extent possible the magnitude of risks to population groups believed to be at greatest risk either due to increased exposures (*i.e.*, outdoor children and outdoor workers) or increased susceptibility (*e.g.*, asthmatics) while characterizing, as explicitly as possible, the uncertainties inherent in the assessment. While different risk measures are provided by the assessment, EPA has focused on "headcount risk" estimates which include: (1) Estimates of the number of people likely to experience a given health effect and (2) estimates of the number of incidences of a given health effect likely to be experienced by the population group of interest (*n.b.*, some individuals likely experience that given health effect more than once in a year). While the estimates of numbers of people and incidences of effects are subject to uncertainties and should not be viewed as demonstrated health impacts, EPA believes they do represent reasonable estimates of the likely extent of these effects on public health given the available information.

This risk assessment builds upon earlier O<sub>3</sub> risk assessment approaches developed during the previous O<sub>3</sub> NAAQS review. The risk models produce estimates of risk by taking into account: (1) Exposure-response or concentration-response relationships used to characterize various respiratory effects of O<sub>3</sub> exposure; (2) distributions of population exposures upon attainment of alternative standards resulting from the exposure analyses described above; and (3) distributions of 1-hour and 8-hour daily maximum O<sub>3</sub> concentrations upon attainment of alternative standards, developed as part of the exposure analyses. The assessment addresses a number of adverse lung function and respiratory symptom effects as well as increased hospital admissions, as discussed below.

#### *(i) Adverse lung function and respiratory symptom effects. Risk*

estimates have been developed for several of the respiratory effects observed in controlled human exposure studies to be associated with O<sub>3</sub> exposure for which sufficient quantitative dose-response information was available. These effects include lung function decrements (measured as changes in FEV<sub>1</sub>) and pain on deep inspiration (PDI).<sup>39</sup> More specifically, these effects, or health endpoints, are defined not only in terms of physiological responses, but also the amount of change in that response judged to be of medical significance (as discussed in section II.A.3 above). For decrements in FEV<sub>1</sub> responses, risk estimates are provided for the lower end, midpoint, and upper end of the range of response considered to be an adverse health effect (*i.e.*,  $\geq 10$ , 15, or 20 percent FEV<sub>1</sub> decrements), while for PDI responses, risk estimates are provided for moderate and severe responses. Although some individuals may experience a combination of responses, risk estimates could only be provided for each individual health endpoint rather than various combinations of functional and symptomatic responses.

The exposure-response relationships used to characterize these functional and symptomatic effects were based on the controlled human exposure studies, and were applied to "outdoor children," "outdoor workers," and the general population.<sup>40</sup> These exposure-response relationships were combined with the results of the exposure analyses, which provided distributions of population exposures estimated to occur upon attainment of alternative standards, in terms of both the number of individuals in the general population, outdoor workers, and outdoor children exposed and the number of occurrences of exposure.

Following from the results of the exposure analyses showing outdoor children to be the population group experiencing the greatest exposures, this population group also has the highest estimated risk in terms of the percent of the population, and the numbers of children, likely to experience the health

effects included in the assessment. As expected, the risk estimates exhibit the same general patterns in comparing alternative standards as was observed in the results of the exposure analyses. Estimated risk varied significantly across the urban areas examined, with greater variability associated with the 1-hour NAAQS than with alternative 8-hour standards, and, within any given urban area, the differences in risk estimated for the various 1-hour and 8-hour standards analyzed were statistically significant.

In looking more specifically at a comparison between 8-hour standards at the 0.09 ppm and 0.08 ppm levels, aggregate estimates of the number of outdoor children in the nine areas likely to experience moderate ( $\geq 15$  percent) and large ( $\geq 20$  percent) FEV<sub>1</sub> decreases and moderate or severe PDI are summarized in the 1997 final rule.<sup>41</sup> For example, for large FEV<sub>1</sub> decreases ( $\geq 20$  percent), approximately 2 percent of outdoor children (58,000 children) would likely experience this effect one or more times per year (100,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 3 percent of outdoor children (97,000 children and 220,000 occurrences) at the 0.09 ppm standard level. Based on this assessment, a standard set at 0.09 ppm would allow approximately 40–65 percent more outdoor children to experience these functional and symptomatic effects than would a 0.08 ppm standard, and approximately 70–120 percent more occurrences of such effects in outdoor children per year.

In considering these observations, the Administrator and CASAC have recognized that there are many uncertainties inherent in such assessments, not all of which can be quantified. Some of the most important caveats and limitations in this assessment include: (1) The uncertainties and limitations associated with the exposure analyses discussed above; (2) the extrapolation of exposure-response functions, consistent with CASAC's recommendation, that projects some biological responses below the lowest-observed-effects levels to an estimated background level of 0.04 ppm; and (3) the inability to account for some factors which are known to affect the exposure-response relationships (*e.g.*, assigning children the same symptomatic response rates as observed for adults and not adjusting response rates to reflect the increase and attenuation of responses that have been

<sup>38</sup> A more complete discussion of uncertainties and limitations is presented in the Staff Paper and technical support documents (Johnson *et al.*, 1996a,b; Richmond, 1997).

<sup>39</sup> Each of the effects is associated with a particular averaging time and, for most of the acute (1- to 8-hour) responses, effects also are estimated separately for specific ventilation ranges [measured as equivalent ventilation rate (EVR)] that correspond to the EVR ranges observed in the studies used to derive exposure-response relationships.

<sup>40</sup> While these studies only included adults aged 18–35, findings from other clinical studies and summer camp field studies in several locations across the U.S. and Canada indicate changes in lung function in healthy children similar to those observed in healthy adults exposed to O<sub>3</sub> under controlled laboratory conditions.

<sup>41</sup> Based on the supplemental analyses that used the third-highest concentration-based form of the standards (Richmond, 1997).