Overview of the Second Draft Risk and Exposure Assessment to Support the NO_2 Primary NAAQS

Presentation to CASAC

September 9, 2008

Overview of Presentation

- Timeline of current review
- Identification of potential alternative standards for analysis
- Identification of potential health benchmark levels
- Air quality analysis and risk characterization
- Epidemiology-based risk assessment
- To be discussed this afternoon: Status of exposure analysis and exposure-based risk characterization

Timeline for Review

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Integrated Review Plan	Draft Final	April 2007 June 2007	May 2007
Integrated Science Assessment	First Draft Second Draft Final	August 2007 March 2008 July 2008	October 2007 May 2008
Risk/Exposure Assessment	Plan First Draft **Second Draft** Final	September 2007 March 2008 **August 2008** November 2008	October 2007 May 2008 **September 2008**
Rulemaking	ANPR Proposed Final	December 2008 May 2009 December 2009	January 2009

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*Indicates that a single CASAC meeting will address both documents

Alternative Standards for Analysis

- Indicator: NO_2
  - Majority of information regarding health effects and exposure is for NO_2
- Averaging time: 1-hour (daily max)
  - We focused analytic efforts on endpoints for which scientific evidence (as judged in ISA) is strongest
- Form: 98th and 99th percentiles averaged over 3 years
  - Goal is to provide a balance between protecting the public from peak NO_2 levels and providing a stable regulatory target
- Levels: based on epidemiology and controlled human exposure studies
  - For key U.S. epidemiologic studies, we identified 98th/99th percentile 1-hour daily maximum NO_2 levels from highest monitor
  - For controlled human exposure studies we focused on increased airway responsiveness in asthmatics
    - ISA concludes that "transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control"
    - Findings on airway responsiveness contribute to the plausibility and coherence of epidemiologic evidence linking NO_2 and emergency department visits/hospitalizations

Identification of Alternative Standard Levels

- 0.20 ppm
  - Based on highest NO_2 levels associated with epidemiologic studies (2 studies in LA) and on 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.15 ppm
  - Based on providing margin of safety relative to 0.20 ppm and on the range of 1-hour and 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.10 ppm
  - Based on NO_2 levels associated with epidemiologic studies in several cities (NYC, Atlanta, Cleveland/Cincinnati) and on 1-hour exposure levels associated with increased airway responsiveness in asthmatics
- 0.05 ppm
  - Based on the lowest NO_2 levels associated with an epidemiologic study (Alpine, CA), of the key U.S. studies evaluated, and on providing a margin of safety relative to 0.10 ppm

Identification of Potential Health Benchmark Levels

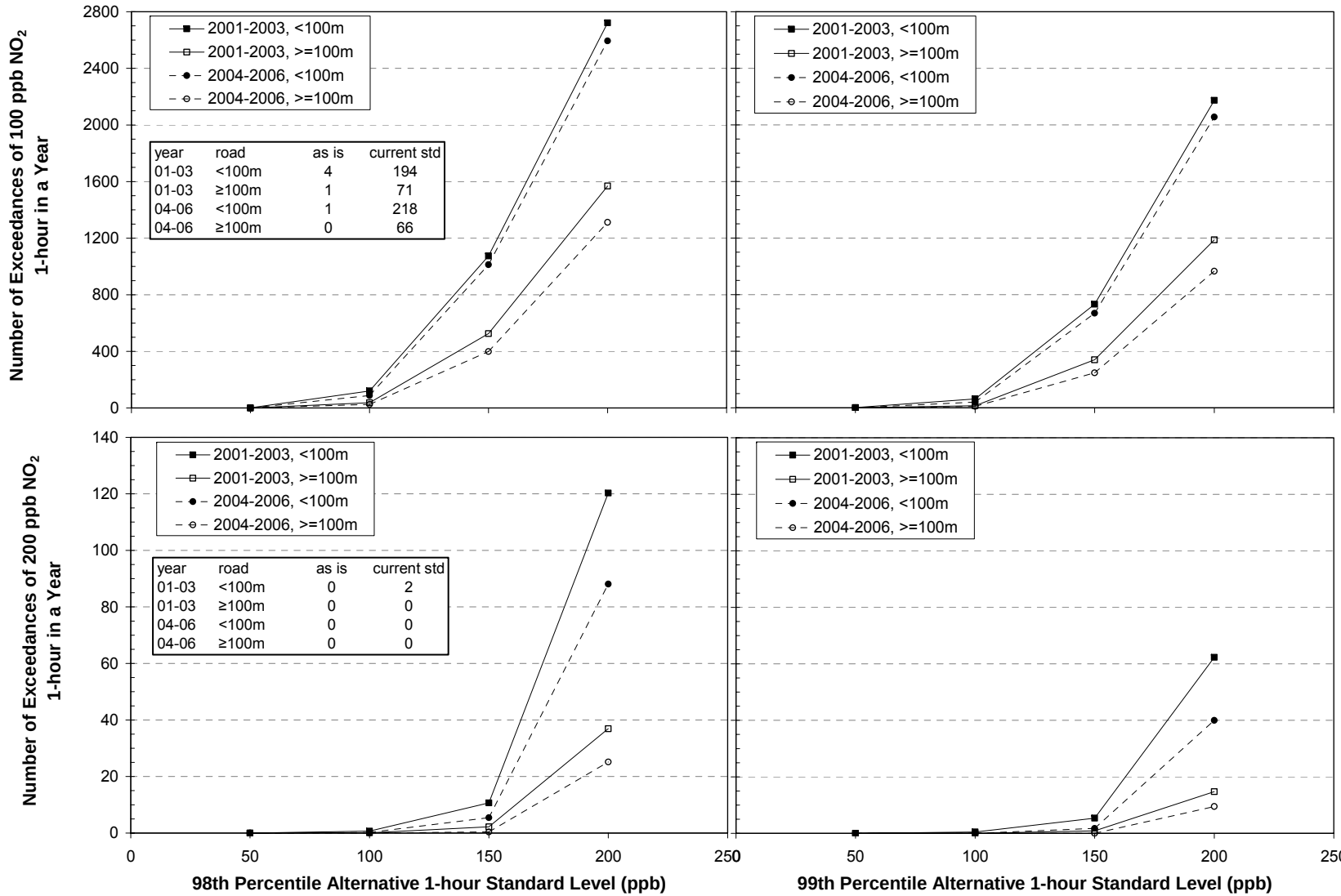
- Purpose of benchmarks:
  - Compare to air quality/exposure levels to help characterize health risks
  - Provide perspective on NO_2 health risks under different air quality scenarios
    - Current air quality
    - Just meeting current/alternative standards
- Based largely on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics
- Benchmark levels
  - 0.10, 0.15, 0.20, 0.25, 0.30 ppm

Air Quality Analysis: Overview of Approach

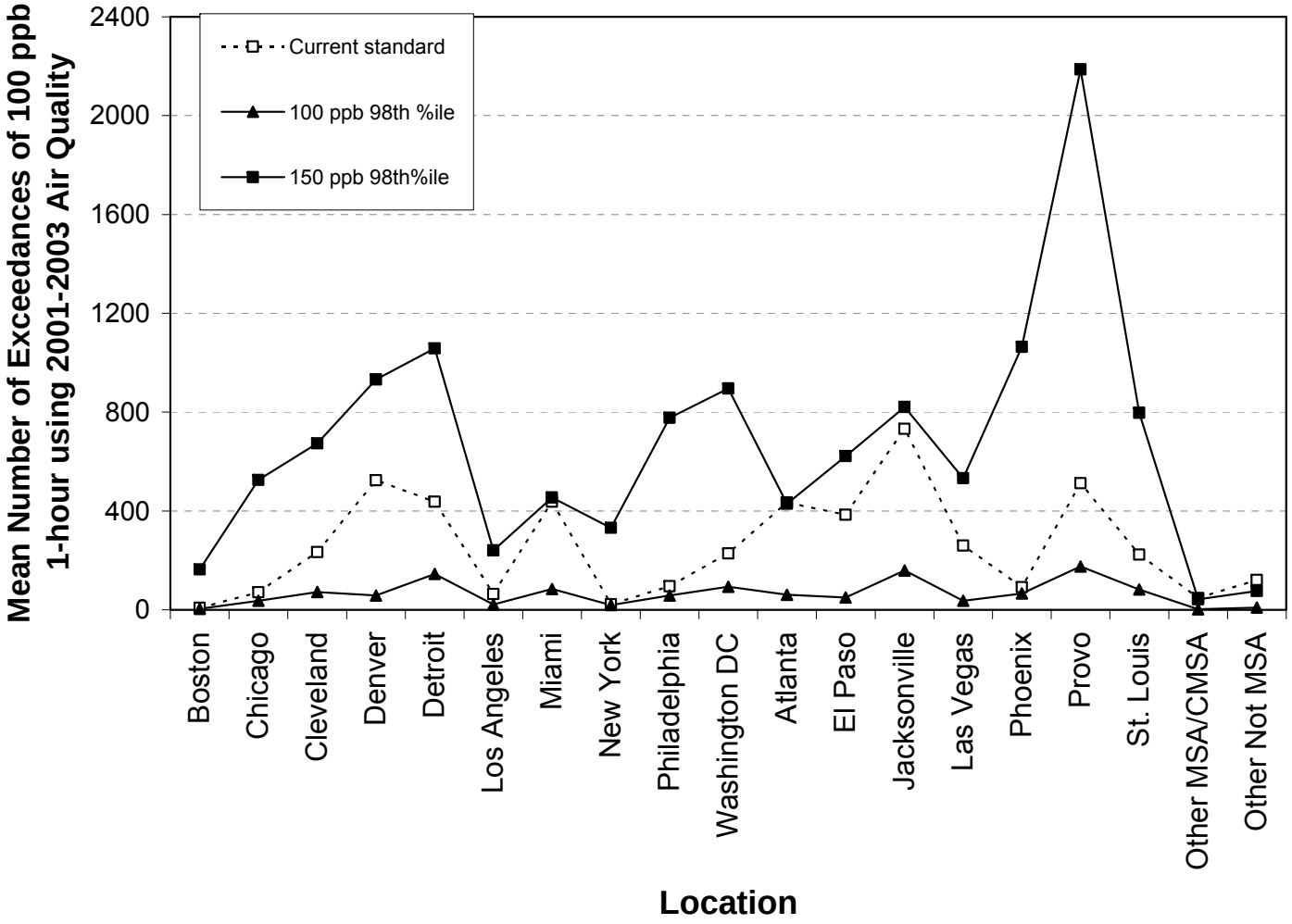
- Ambient air quality data from monitors across U.S. were screened
- 18 specific locations were identified for analysis based on NO_2 levels
  - Rest of U.S. was grouped together into 2 non-specific categories
- 1-hour NO_2 levels exceeding health benchmarks were estimated in each location
  - Exceedances were estimated for ambient and on-road levels of NO_2
  - On-road NO_2 estimates were based on literature-derived ratios of ambient levels to roadway levels
- Scenarios considered…
  - Air quality as-is
  - Air quality adjusted to simulate just meeting current annual standard
  - Air quality adjusted to simulate just meeting potential alternative standards

Air Quality Analysis: General Trends for Alternative Standards and Monitor Siting

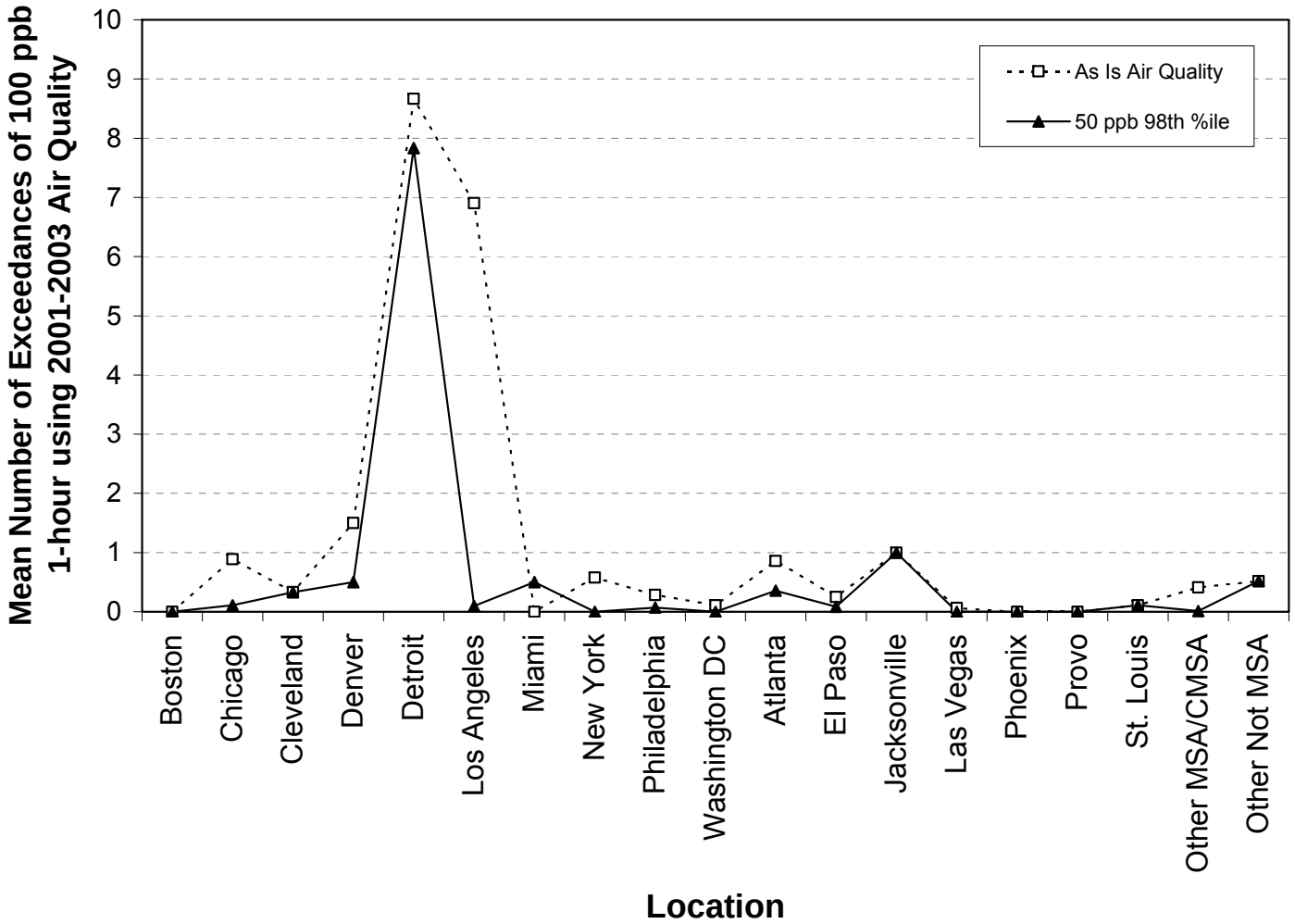
Figure 7-2. Estimated **mean** number of exceedances of potential health effect benchmarks (100 ppb, top; 200 ppb, bottom) in **Chicago** given just meeting alternative 1-hour standard levels (**98th percentile, left; and 99th percentile, right**) using recent air quality data from monitors sited **< 100 m** of a major road and sited **≥100 m** of major roads.



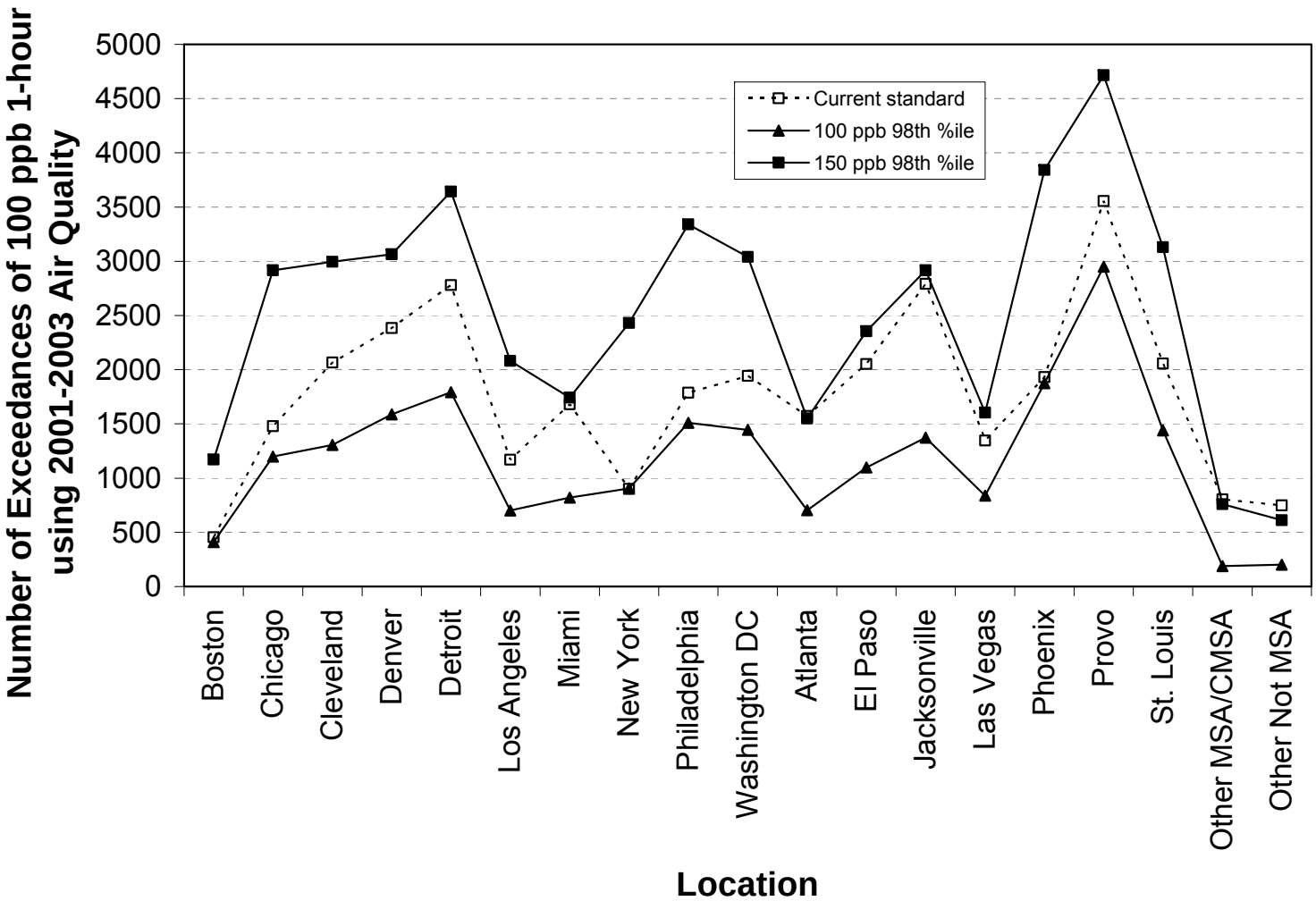
Air Quality Analysis: General Trends - CS Monitors ≥ 100m or major road



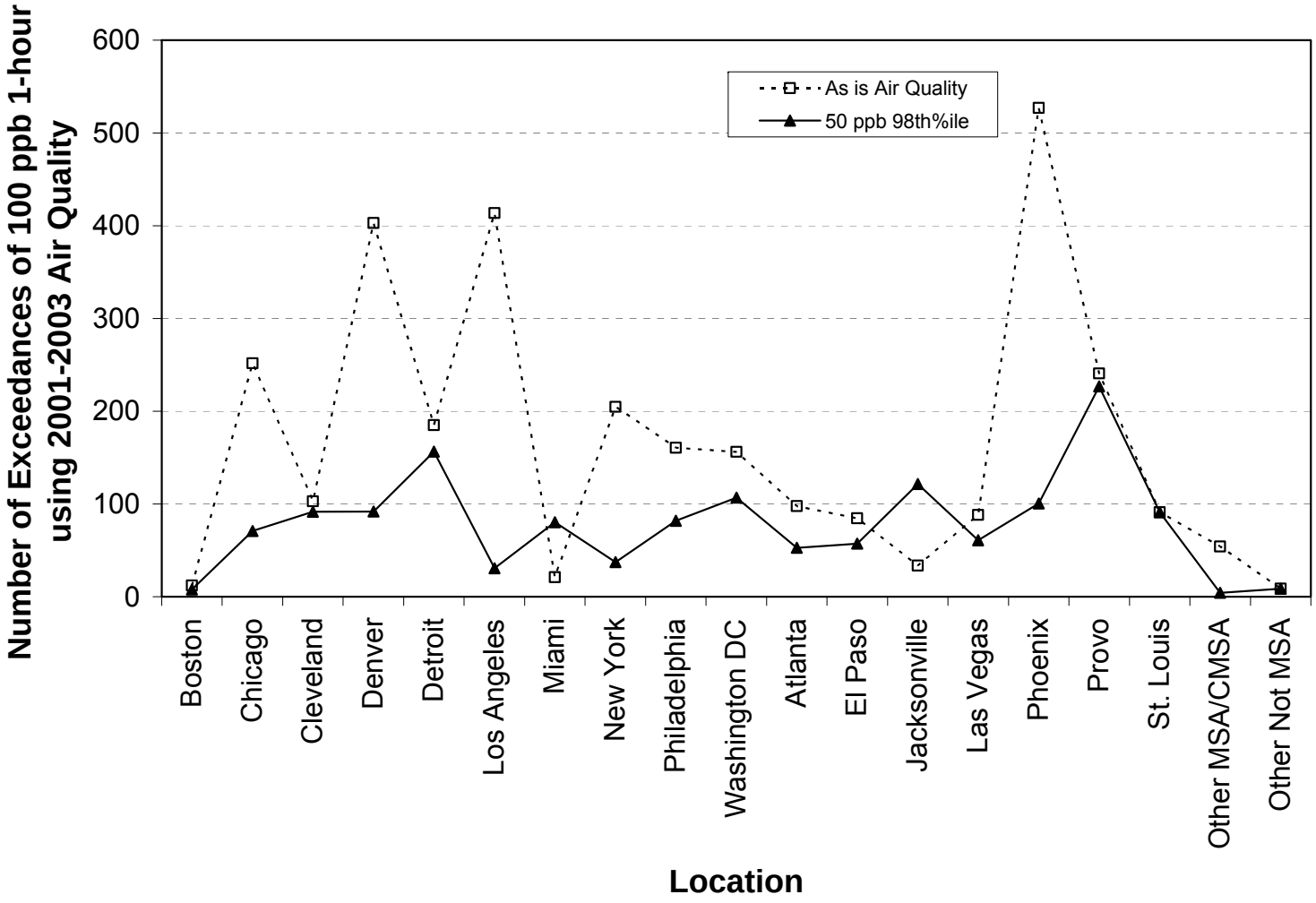
Air Quality Analysis: General Trends - As Is Monitors ≥ 100m or major road



Air Quality Analysis: General Trends - CS On-Road Estimation



Air Quality Analysis: General Trends - As is On-Road Estimation



Quantitative Risk Assessment: Overview of Approach

- Focused assessment of NO_2-related respiratory ED visits for the Atlanta urban area

  - Case study to illustrate magnitude of changes in NO_2-related health impacts associated with recent air quality, just meeting the current standard, and just meeting alternative 1-hr standards

  - Agency's views on policy options considering the assessments and the scientific evidence in the ISA to be presented in ANPR
- General approach to estimating risk illustrated in Figure 9-1

Quantitative Risk Assessment: Overview of Approach

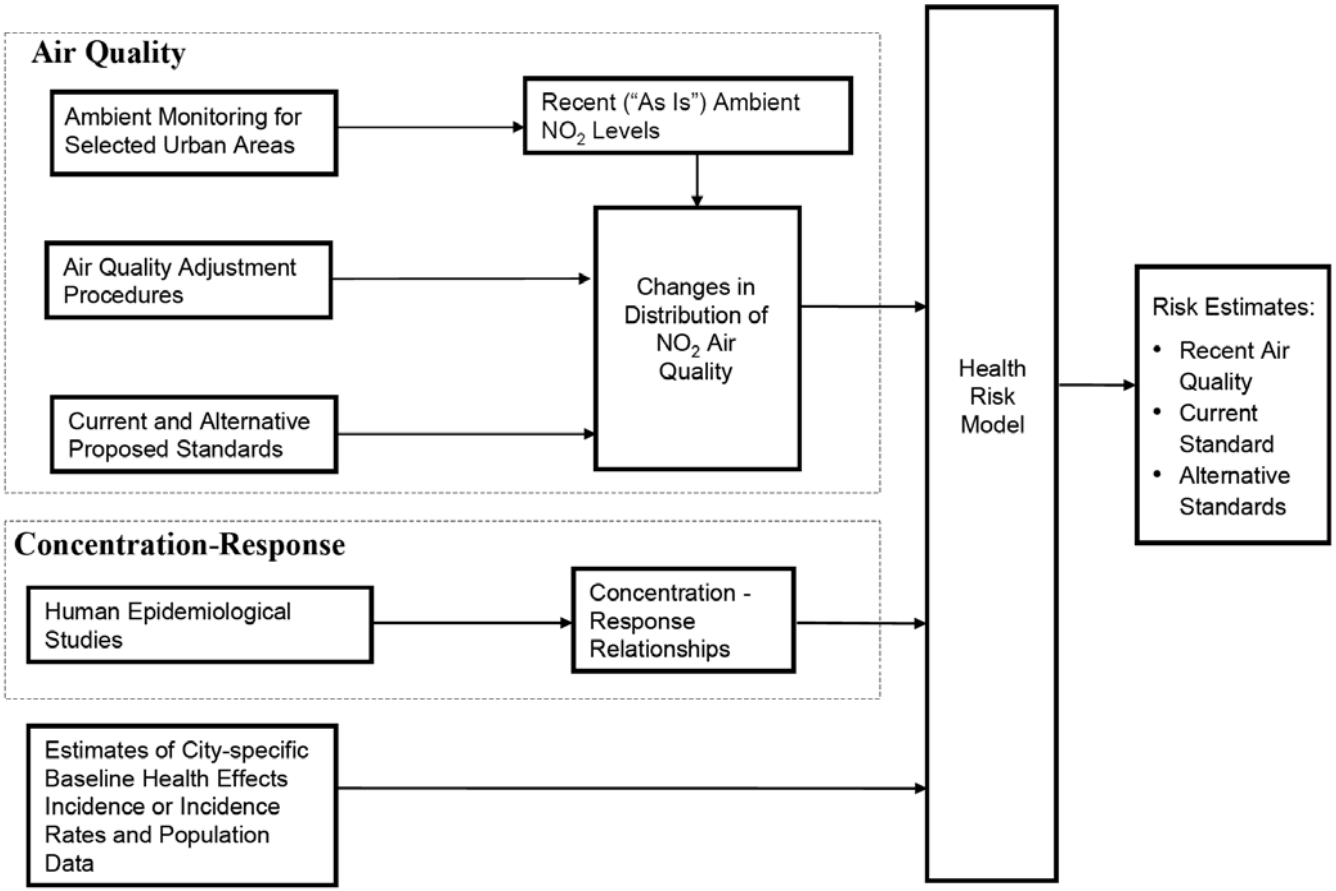


Figure 9-1. Major components of nitrogen dioxide health risk assessment for emergency department visits.

Inputs to Risk Assessment

- Air quality information
  - "As is" (recent air quality) from monitor used in Tolbert et al. (2007) study for 2005-2007
  - Calculated 3-day moving average of 1-h maximum NO2 concentration as input to risk assessment
  - Proportional air quality adjustment to simulate just meeting annual standard and alternative 1-h standards
- Concentration-response functions
  - Included both single- and multi-pollutant models from the Tolbert et al. (2007) study
  - C-R functions based on 3-day moving average of 1-h daily maximum NO_2 concentration
- Baseline health effects incidence data
  - Obtained from authors – 41 of 42 hospitals with emergency depts provided data
  - Most recent year (2004) included 36 of 42 hospitals, so baseline incidence is somewhat underestimated - ~122,000 ED visits annually

Quantitative Risk Assessment: Results

Table 9-3. Estimated Incidence of Respiratory ED Visits Associated with "As Is" NO_2 Concentrations and NO_2 Concentrations that Just Meet Alternative Standards in Atlanta, GA, Based on Adjusting 2007 NO_2 Concentrations.*

Other Pollutants in Model	Incidence of Respiratory Emergency Department Visits Associated with "As is" NO_2 Concentrations and NO_2 Concentrations that Just Meet the Current and Alternative Standards**									
	"as is"	current annual standard	Atternative 98th percentile 1-hr daily maximum standards (ppm)				Alternative 99th percentile 1-hr daily maximum standards (ppm)			
			0.05***	0.1	0.15	0.2	0.05	0.1	0.15	0.2
none	3400 (1800 - 4900)	9800 (5300 - 14200)	2400 (1300 - 3500)	4700 (2500 - 6900)	7000 (3800 - 10200)	9300 (5000 - 13400)	2200 (1200 - 3300)	4400 (2400 - 6400)	6500 (3500 - 9500)	8600 (4700 - 12500)
CO	2900 (1000 - 4800)	8400 (2900 - 13700)	2000 (700 - 3400)	4000 (1300 - 6700)	6000 (2000 - 9900)	7900 (2700 - 12900)	1900 (600 - 3200)	3800 (1300 - 6200)	5600 (1900 - 9200)	7400 (2500 - 12100)
O_3	1700 (-100 - 3500)	5100 (-200 - 10100)	1200 (-100 - 2500)	2400 (-100 - 4900)	3600 (-200 - 7200)	4800 (-200 - 9500)	1100 (-100 - 2300)	2200 (-100 - 4500)	3300 (-200 - 6700)	4400 (-200 - 8900)
PM_{10}	1200 (-700 - 3000)	3600 (-2100 - 8900)	800 (-500 - 2200)	1700 (-1000 - 4300)	2500 (-1500 - 6400)	3400 (-1900 - 8400)	800 (-400 - 2000)	1600 (-900 - 4000)	2400 (-1400 - 5900)	3100 (-1800 - 7800)
PM_{10}, O_3	700 (-1300 - 2600)	2100 (-4000 - 7800)	500 (-900 - 1900)	1000 (-1800 - 3700)	1500 (-2800 - 5500)	1900 (-3700 - 7300)	500 (-900 - 1700)	900 (-1700 - 3500)	1400 (-2600 - 5100)	1800 (-3400 - 6800)

*Estimated incidences of respiratory emergency department visits are based on the concentration-response functions estimated in Tolbert et al. (2007) [results corresponding to Figure 2 in Tolbert et al. (2007) were obtained via personal communication with P. Tolbert]. All models use a 3-day moving average of the daily 1-hr. maximum NO_2 concentration and apply to all ages.

**Incidence was quantified down to 0 ppb. Incidences are rounded to the nearest 100.

***Alternative 1-hr daily maximum standards are characterized by a concentration of m ppm and an nth percentile, requiring that the average of the 3 annual nth percentile 1-hr daily maxima over a 3-year period be at or below m ppm.

Note: Numbers in parentheses are 95% confidence intervals based on statistical uncertainty surrounding the NO_2 coefficient.

Uncertainty and Variability

- Causality – while uncertainty exists, ISA concludes a likely causal relationship with NO_2 itself or NO_2 acting as an indicator for itself and other components of ambient air associated with combustion processes
- Uncertainty about estimated C-R relationships
  - Confidence intervals reflect statistical uncertainty, but not uncertainties about whether correct model form or possible role of co-pollutants
  - Risk estimates presented for both single and multi-pollutant models
- Adequacy of ambient NO_2 monitors as surrogate for population exposure to ambient NO_2
- Adjustment of air quality distribution to simulate just meeting standards
- Baseline incidence
  - Possible year-to-year variability
  - Underestimate of incidence since have 36 of 42 emergency departments included
- Uncertainty about extent to which risk estimates for Atlanta are representative of other urban locations in U.S.

Key Observations

- Respiratory-related ED visits estimated to result from exposures to NO_2 for a single urban area (Atlanta) upon just meeting current standard and several alternative 1-hr standards
  - Provides useful perspective on likely overall magnitude and pattern of NO_2-related ED visits for urban areas in the U.S.
- Largest risk estiamtes associated with single-pollutant C-R functions
- Risk estimates redcued for various co-pollutant models (with CO, O_3, and PM_{10}), often by factor of two or greater and wider confidence intervals
- Only 1-h standards resulting in reduction in estimated risks (from as is case) were the 98th and 99th percentile 1-h standards set at 0.05 ppm
- Changing level of potential 1-h standards has bigger impact on risks than form of standard (98th vs. 99th percentile)
- Overall pattern of risks similar across three year period examined