

# CO NAAQS Review: Draft Policy Assessment

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**US Environmental Protection Agency**  
Office of Air Quality Planning and Standards

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# Overview

- Policy Assessment (PA)
  - Purpose and description
  - Considerations for primary standards
  - Consideration of a secondary standard
  - Overview of CASAC Charge



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# Policy Assessment

## – Purpose and Description

- Staff analysis of key science-policy issues to facilitate Administrator's judgment on CO NAAQS
  - Interprets and integrates information from ISA and REA
    - Includes consideration of ISA evidence and air quality analyses beyond the focus of quantitative REA
  - Facilitates CASAC advice on adequacy of the current standards and any appropriate alternative standards
  - Precedes rulemaking phase



# Policy Assessment for Primary Standards

- Adequacy of Current Standards
  - Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and draft REA, support or call into question the adequacy of the protection afforded by the current CO standards?
- Alternative Standards
  - To what extent does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and draft REA, support consideration of alternatives to the current CO standards to provide increased protection from ambient CO exposures?



# Policy Assessment for Primary Standards – Evidence-based Considerations

- Evidence available since last review continues to indicate:
  - Ischemia-related effects is most sensitive endpoint
  - Hypoxia due to COHb formation is best characterized mechanism of CO effects
  - Cardiovascular and other diseases with reduced oxygen availability are potential susceptibilities
    - Coronary artery disease (CAD) continues to be best characterized susceptibility
  - Clinical studies and estimates of COHb levels associated with ambient CO exposure play key role in conclusions on ambient CO levels associated with health effects
- Since last review, epidemiological database supporting ischemic outcomes is expanded, and coherent with clinical evidence
- Previously identified uncertainties are somewhat reduced, some remain:
  - Clinical significance of ischemia-related changes observed at lowest doses in controlled human exposure studies
  - CO/COHb levels at which other potentially susceptible populations may be affected and nature of those effects
  - Expanded body of epidemiological evidence includes own set of uncertainties



# Policy Assessment for Primary Standards

## - Risk-based Considerations

- Current/potential alternative lower standards provide differing maximum COHb levels in simulated at-risk populations
  - Just meeting current 8-hour (controlling) standard
    - Less than 4% of either study population with estimated maximum COHb  $\geq 2\%$
    - More than 80% of both study populations estimated to have maximum COHb below 1.5%
  - Just meeting alternative 8-hour standard of ~3 ppm
    - More than 99% of both study populations with maximum COHb below 1.5%
- Some uncertainties previously identified have been reduced, some still remain
- Public health implications of exposure/dose estimates affected by
  - Interpretation of clinical significance of response at lowest COHb levels tested in controlled human exposure studies (i.e., weight given to different benchmarks)
  - Judgments regarding potential significance of estimated COHb levels for other potentially susceptible populations



# Policy Assessment for Primary Standards

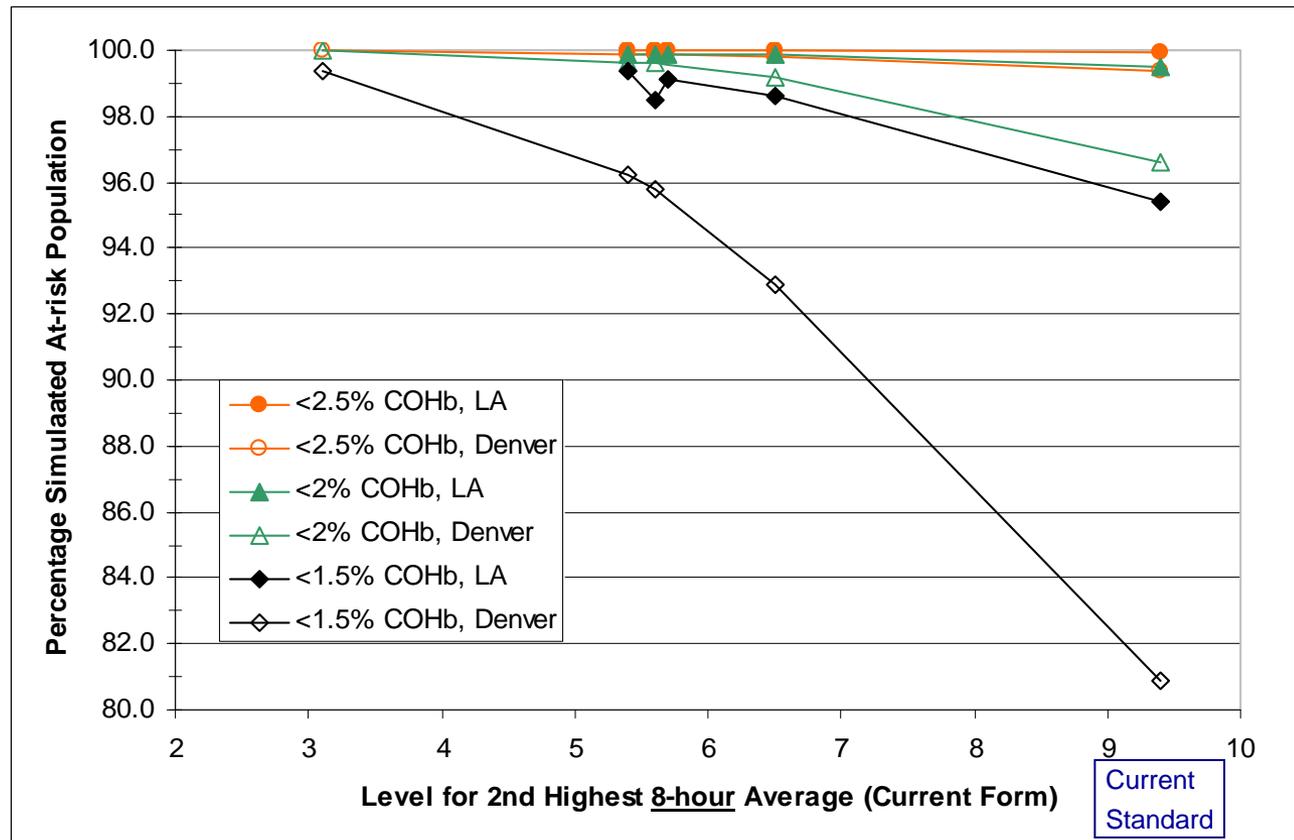
## - Integration of Evidence and Exposure/Risk

### Public health policy considerations for 8-hour standard

- Nature and severity of the effects considered
- Appropriate COHb benchmark on which to focus
- Adequate margin of safety for at-risk population

### ... for 1-hour standard

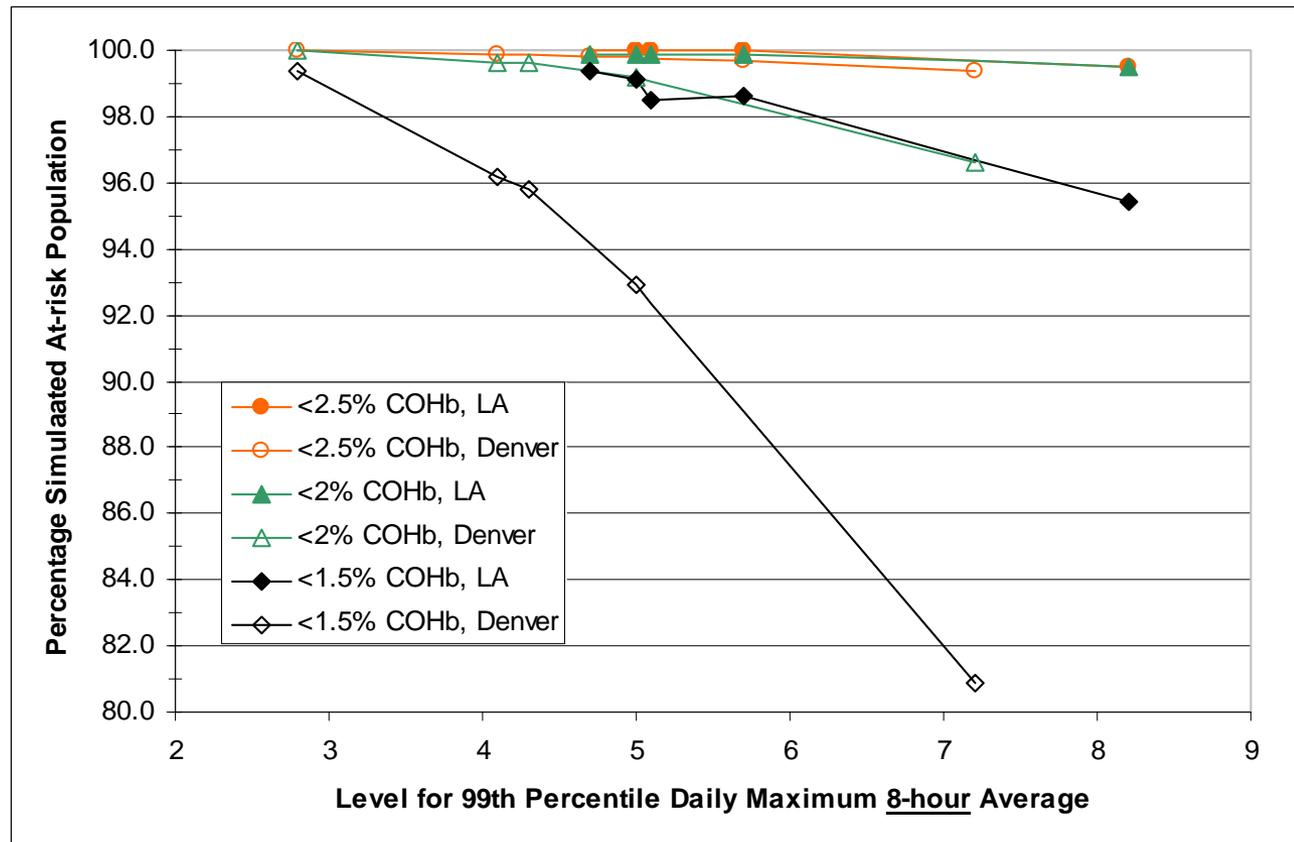
- As above, and
- Peak levels and frequency of occurrence



# Policy Assessment for Primary Standards

## - Integration of Evidence and Exposure/Risk

- Public health policy considerations for 8-hour standard
  - Nature and severity of the effects considered
  - Appropriate COHb benchmark on which to focus
  - Adequate margin of safety for at-risk population
- ... for 1-hour standard
  - As above, and
  - Peak levels and frequency of occurrence



# Policy Assessment for Primary Standards

- Adequacy of Current Standards
  - May or may not be judged adequate, depending on judgments regarding
    - Nature and severity of the effects at lowest COHb levels tested
    - Weight placed on the different benchmarks
    - Weight placed on epidemiological studies
    - Adequate margin of safety for at-risk population
- Alternative Standards
  - For 8-hour standard, may be appropriate to consider levels from 9 – 3 ppm
    - Lower end of range depends on same judgments as above
    - In conjunction with consideration of revising the level, it may be appropriate to consider a concentration-based form, such as
      - 99th percentile (or fourth highest) daily maximum, averaged across 3 years
  - For 1-hour standard, appropriate to consider range of policy options including retaining, revising or revoking, depending on judgments on role for this standard relative to 8-hour standard



# Policy Assessment for Secondary Standard

- Does the currently available scientific information provide support for considering the establishment of a secondary standard for CO?
  - Evidence-based considerations
    - No evidence of non-climate welfare-related effects at CO concentrations related to current standards
    - Insufficient evidence for consideration of a CO standard based on climate
      - Direct climate-forcing effects of ambient CO are weak and highly variable spatially
      - Most climate forcing associated with CO is indirect and relates to ambient levels of greenhouse gases, methane and ozone
      - Insufficient information to interpret how ambient CO levels would affect local, regional and national climate changes due to the spatial variability and localized chemical interdependencies involving CO, methane and ozone



# Policy Assessment

## - Overview of Charge for CASAC Review

- Background, including air quality information
- Organization, key policy-relevant questions and level of detail
- Primary standards
  - Adequacy of protection provided by current standards
    - Characterization and integration of
      - Health effects evidence, including differences from last review
      - Quantitative exposure/dose estimates (REA), including significance from public health perspective
      - Important uncertainties, particular those significant to drawing conclusions regarding adequacy
    - Considerations informing initial conclusions
    - Panel views on adequacy of current standards
  - Potential alternative standards
    - Considerations informing characterization of options
    - Rationale provided to justify range of policy options presented
    - Panel views on range of alternatives appropriate to consider
- Consideration of secondary standard
  - Characterization of current evidence, including climate-related effects

