

Risk & Technology Review (RTR-II) Assessment Plan

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Background



The Federal
Clean Air Act

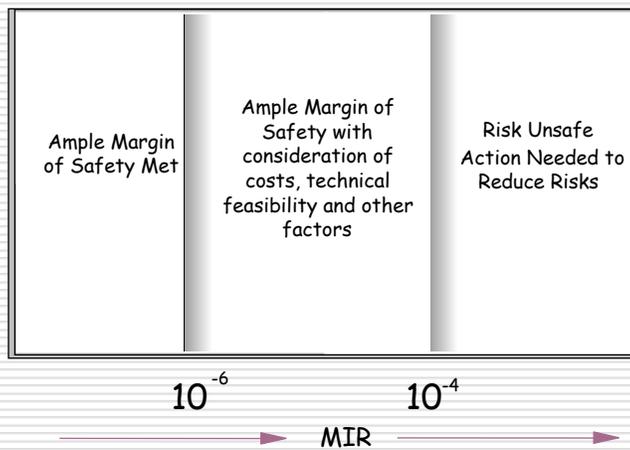
- Since 1990, EPA has promulgated 96 technology-based standards for stationary industrial sources of hazardous air pollutants (HAP)
- CAA requires review of residual risk and technology for these standards
- The first 8 reviews show the MACT standards generally did a good job, but may not provide adequate control in some cases
- Reviews have been time-consuming and resource-intensive
- EPA is trying a new approach – grouping analyses together to facilitate consistency and timeliness
 - Use available data from National Emissions Inventory
 - Provide for technical review of each source category's data to improve quality of underlying risk assessment

How We Make Residual Risk Decisions – the Benzene NESHAP Decision Process



- Goals
 - Goal 1: Limit MIR to no higher than about 100 in a million (MIR = Maximum Individual Risk = person exposed to max concentrations near a facility for 70 years)
 - Goal 2: Protect the greatest number of persons possible to approximately 1 in a million lifetime cancer risk or lower
- Step 1: determine “acceptable risk” considering all health info, including uncertainty (max MIR ordinarily about 100 in a million)
 - Max MIR may be more or less, depending on **incidence**, persons within various risk ranges, and uncertainties
 - Incidence should not be limited to, e.g., 1 case/year, but rather weighed along with other risk info
- Step 2: set standard to provide “ample margin of safety”, considering health info and other relevant factors (costs, feasibility)

Relevant Cancer Risk Ranges



What Process are We Proposing for RTR –II?



- First Group Of Standards - Extract MACT category information from latest emissions inventory (2002 NEI) for the 34 MACT standards with compliance dates of 2002 and earlier (corresponds to 51 source categories)
- Model each MACT category to obtain inhalation risks, including cancer risk and incidence, population cancer risk, non-cancer effects (chronic and acute), key HAP drivers
- Provide for public review of inventory (via ANPRM) and technical review of inventory with risk results to get comments, and, as appropriate, obtain better source data

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What Process are We Proposing for RTR–II ? (cont'd)



- Remodel the categories based on the revised inventory data
 - Identify “no action” for low-risk source categories
 - Identify categories with potentially significant non-inhalation risks; move to RTR-III
 - Evaluate effectiveness and cost of additional risk reduction options for the remaining source categories
- Make acceptability and ample margin of safety determinations for each source category
- Propose, address public comments, and take final action on each source category

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MACT Standards Included In RTR-II



1. Chromium Electroplating
2. Polymers & Resins II
3. Secondary Lead Smelters
4. Petroleum Refinery I
5. Aerospace
6. Marine Vessels
7. Wood Furniture
8. Shipbuilding
9. Printing & Publishing
10. Off-site Waste Treatment
11. Polymers & Resins I
12. Polymers & Resins IV
13. Primary Aluminum
14. Pulp & Paper MACT I and III
15. Pharmaceuticals
16. Flexible Polyurethane Foam
17. Ferroalloys
18. Polyether Polyols
19. Mineral Wool
20. Primary Lead Smelting
21. Phosphoric Acid
22. Phosphate Fertilizers
23. Wool Fiberglass
24. Portland Cement
25. Oil & Natural Gas
26. Natural Gas Transmission
27. Steel Pickling
28. Acetal Resins
29. Acrylic/Modacrylic fibers
30. Hydrogen Fluoride
31. Polycarbonates
32. Publicly Owned Treatment Works
33. Secondary Aluminum
34. Pulp & Paper Mact II

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Charge question #1

- Is the scope of the assessment appropriate for the stated purpose?
- Is the overall approach clearly and adequately explained for review?

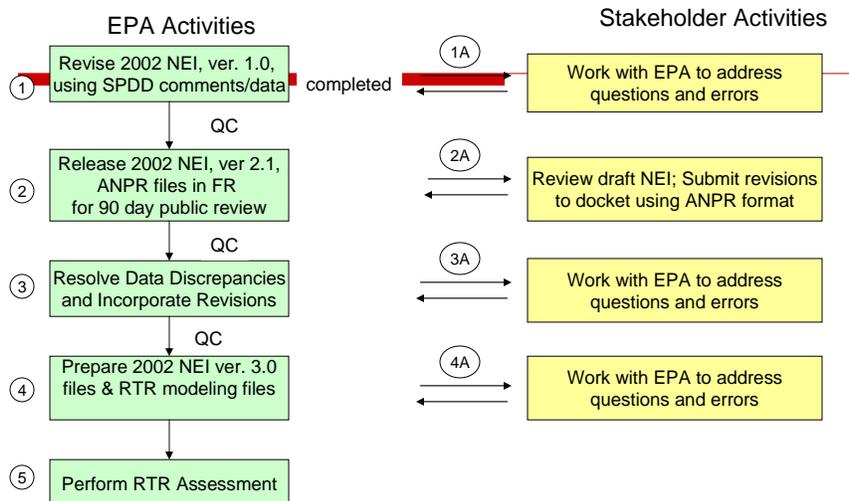
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Residual Risk and Technology Review Assessment

- Emissions inventory
- Multipathway screening
- Dispersion modeling
- Exposure assessment
- Dose-response assessment
- Risk characterization

RTR inventory development process



Development of initial RTR inventory

- EPA has completed detailed review of 2002 National Emissions Inventory (NEI)
- Revisions
 - MACT Codes - facilities and processes within facilities associated with category
 - Emission
 - Stack parameters
 - Geographic coordinates
- New data for
 - Petroleum refineries
 - Polymers and Resins II
 - Polymers and Resins IV
 - Secondary lead smelting
 - Shipbuilding

Review and comment on initial inventory

- EPA will post initial RTR inventory on CHIEF web site, announce with ANPR
 - 90-day comment period
 - Comments accepted only electronically, via ANPR NEI database
 - Documentation must accompany proposed revisions
- EPA will share preliminary assessment results with technical experts (State agencies, industry trade groups) to facilitate their direct reviews

Development of final RTR inventory

- EPA will evaluate and incorporate proposed revisions
 - Review proposed revisions and documentation
 - Resolve data discrepancies between proposed revisions and original data source
 - Incorporate revisions
 - Post revised final inventory files on CHIEF website

Charge question #2a

- Short of creating a federal mandate for reporting emissions to the EPA, do the methods by which the NEI was developed, reviewed, and compiled result in a technically-credible database that can support regulatory assessment and action?
- If not, can you suggest ways to improve it?

Charge question #2b

- Do the plans for conducting an engineering review and incorporating currently-available refined emissions and source data into the inventory add value to the assessment?
- Does the plan for soliciting public comment through an advanced notice of rulemaking add scientific credibility to the inventory?
- Is the plan for reconciling comments on the inventory adequate?
- If not, can you suggest other approaches for reconciling such comments?

Multipathway and ecological screening

- Goals
 - Identify source categories with potential ecological or multipathway health risks
 - Set them on separate, refined analytical path
 - Expedite inhalation-only assessments in RTR II
- Process
 - 2-part screening process
 - Part 1 – Simple
 - Part 2 – Intermediate refinement
 - Full refined assessment performed in RTR III

Method – Part 1

- Preliminary inventory
- ISCST3 dispersion modeling
- HHRAP multipathway exposure and risk estimates
- Human health only
- Already completed

Method – Part 1

- Model facility
- "Worst-case" subsistence farmer/fisher population
- 13 PB-HAPS*
- OAQPS recommended dose-response values for oral exposure
- Output – back-calculated emission rates
 - 1e-6 lifetime cancer risk
 - HQ = 1
 - *Dioxins/furans ranked separately, using inventory from 1995 dioxin reassessment

Results – Part 1

- Compared emission rates to ANPRM data for 34 categories
- PB-HAPs of greatest concern are
 - POM
 - Mercury compounds
 - Dioxins/furans
- From several source categories
 - Ferroalloys
 - Pulp and paper
 - Petroleum refineries
 - Primary and secondary aluminum
 - Portland cement
- Will flag these as emission inventory is reviewed

Method – Part 2

- Final inventory
- Health and ecological
- TRIM dispersion, exposure, ecological and health risks
 - State-of-the-art fate-transport model
 - Built-in conservative screening scenarios for:
 - Human and Ecological receptors

Results – Part 2

- Output – facility-specific threshold emission rate for each Eco-HAP and PB-HAP (except for dioxins/furans)
- Compared to facility emissions in NPRM inventory
- Source categories that exceed thresholds evaluated for ecological and multipathway risks in RTR III
- Dioxins and furans treated as in Part 1, but with updated inventory from new dioxin reassessment

Uncertainties in the multipathway risk screening

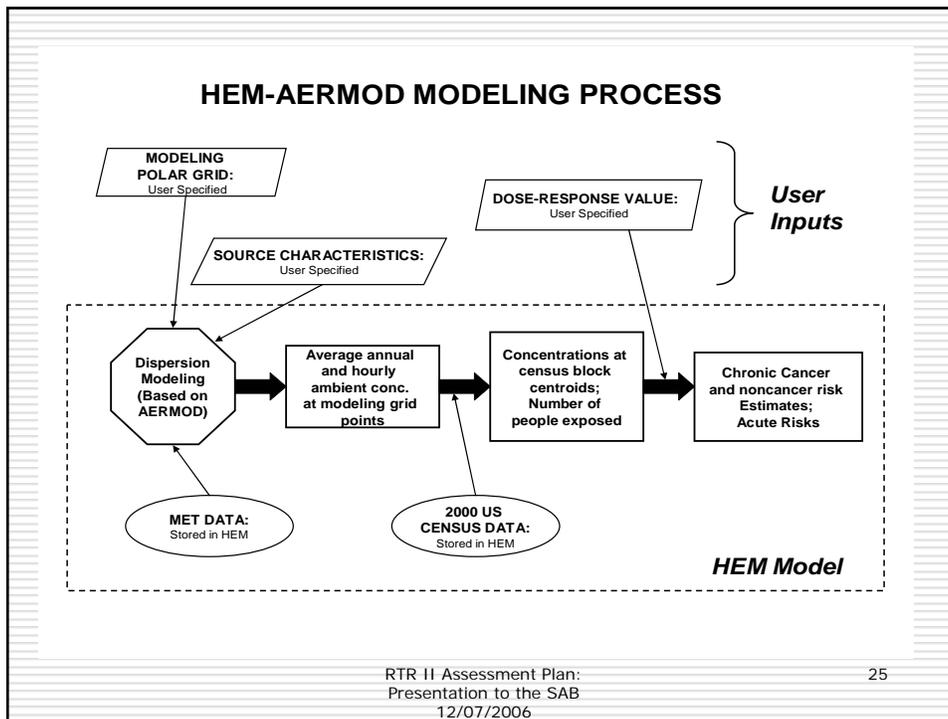
- Usual uncertainties apply
 - Emissions inventory
 - Dispersion modeling
 - Dose-response assessment
- Specific uncertainties
 - Hg assumed 50-50 elemental-divalent when unspecified
 - High-end meteorological station
 - High-end receptor population
 - Background exposures not included
 - Ecological risks not included until Part 2

Charge question #3

- Are the methods planned for selecting source categories with potentially significant ecological risks or multi-pathway human health risks for a separate, more refined ecological and multipathway assessment sufficiently health-protective?
- Are there ways that you might suggest for improving such screening techniques that can make them less conservative and still scientifically defensible?

Dispersion Modeling: Human Exposure Model (HEM) -AERMOD

- What is HEM-AERMOD?
 - a modeling system that incorporates:
 - dispersion model (AERMOD)
 - population data (2000 Census)
 - health data (OAQPS recommendations)
 - to estimate:
 - inhalation risks
 - chronic (long term) cancer risks
 - chronic non-cancer risks (TOSHI)
 - population exposures and incidence
 - estimate maximum acute (short term) exposure
 - facility specific risks
 - pollutant specific risks



RTR Modeling Approach Using HEM-AERMOD

- Built off of HEM3 (ISCST3) model
- Used AERMOD (04300) – latest version of EPA's preferred model for site-specific applications
- Run for each facility
- Model domain/receptors selected for each facility
- Meteorological data selected for each facility
- Acute emissions multiplier of 10, chosen for screening
- Model Options:
 - Regulatory default option
 - Terrain effects included
 - All sources run in rural mode
 - No building downwash
 - No plume deposition or depletion

RTR - Modeling Domain and Receptors for HEM-AERMOD

- User defines model domain
 - radius of overall domain
 - transition from discrete modeling to interpolation
 - specification of polar receptor network
- Modeling of blocks
 - nearby blocks are modeled separately
 - beyond the transition point, concentrations are interpolated based on the polar receptor network
 - block locations (geographic centers) based on 2000 Census
 - On property receptors removed

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RTR - Modeling Domain and Receptors for HEM-AERMOD (cont)

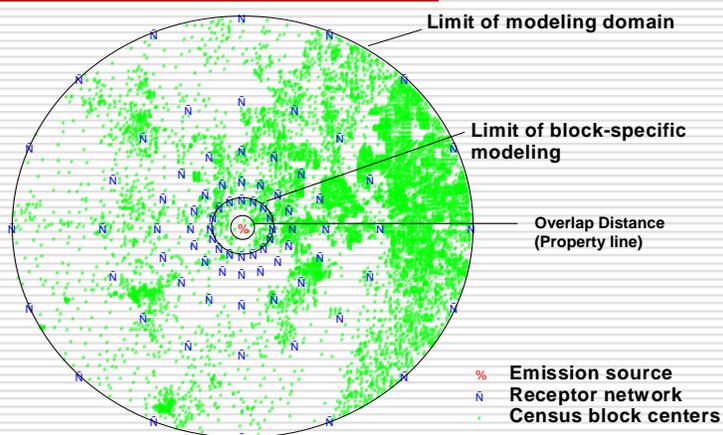
Parameter	Value
Modeling domain size – maximum distance to be modeled ^a	50km
Cutoff distance for modeling of individual blocks ^b	2000-3000 meters
Overlap distance – where receptors will be considered to be on plant property ^b	30m
Polar receptor network:	
Distance to the innermost ring ^a	100m
Number of concentric rings	13
Number of radial directions	16

a: Measured from the center of the facility. b: Measured from each stack at the facility, and from the edges of each area or volume source.

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RTR - Modeling Domain and Receptors for HEM-AERMOD (cont)



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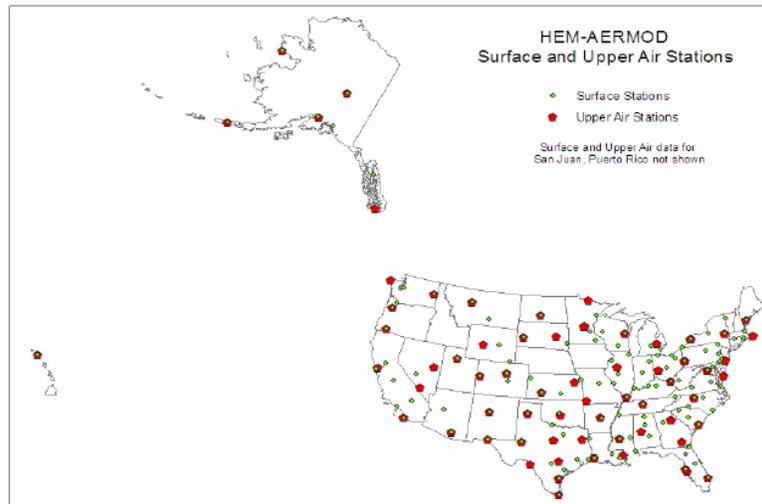
RTR- Model Inputs for HEM-AERMOD

- Terrain Elevations
 - Census block – actual elevation
 - Polar grid - highest census block elevation within sector
 - Hill Elevations - Derived from elevation of surrounding census blocks
- Meteorological Data
 - Processed 122 NWS stations using “average” surface features using AERMET
 - Nearest NWS station selected for each facility
 - 1 year (1991) of data

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HEM-AERMOD Meteorological Stations



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RTR - Outputs from HEM-AERMOD

- Category-specific results for each facility
 - Chronic
 - Maximum Individual Risk (MIR) - highest risk at a census block centroid (cancer & noncancer)
 - Cancer incidence
 - Cancer risk distributions
 - Acute
 - Maximum off-site impact – highest of census block and polar grid receptors
 - Pollutant-specific and source-specific contributions to maximum risk levels
- Individual facility results combined to get source category-specific results for:
 - Total Population exposures, risks by risk bins
 - Total Cancer incidence

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Charge question #4

- Does the coupling of the AERMOD dispersion model with the census block human exposure modeling (HEM) approach to estimating individual and population exposures represent a credible approach for this goal?
- Are there other more credible approaches available for the estimation of inhalation risks from the types of source categories being examined?
- Is the level of accuracy of this approach acceptable for the purposes of residual risk decision-making?
- Are there any specific source categories, sources, or pollutants for which this approach might be considered inadequate?

Chronic inhalation exposure

- Chronic inhalation exposure related (but not identical) to ambient concentrations
- Also influenced by
 - Daily activity
 - Long-term mobility
- Preliminary assessment– streamlined, simplified screen
 - Assume ambient conc. = exposure
- Final assessment – more complex, refined
 - Include long-term mobility

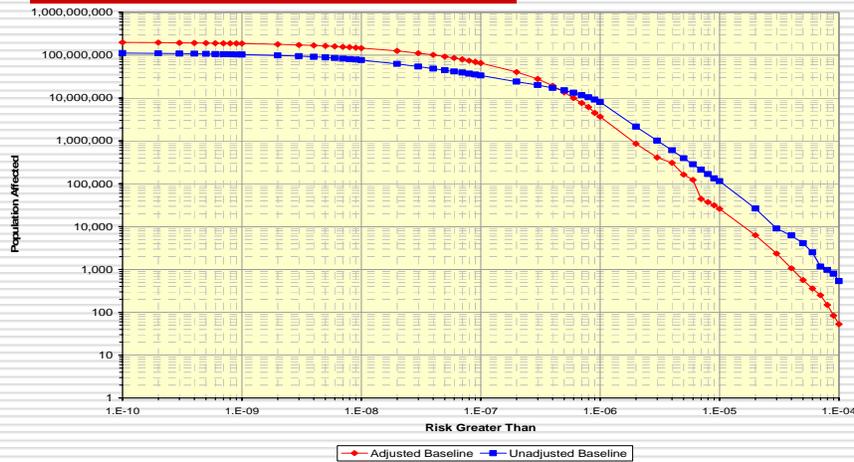
Long-term mobility adjustment

- Input data from 3 sources
 - 70-y exposure distribution
 - Residence time data (Census Bureau)
 - Likelihood of emigrating (EPA regression of Census data)
- Probabilistic calculations
 - Random receptors assigned location and duration
 - At end of duration, assigned either emigration or a new home in the modeled area
 - Exposure aggregated multiple residences, ending at emigration or 70 y
 - Replacement of receptors
 - Population growth not included

Residence Time (Johnson & Capel, 1992)

More than (years)	Less than (years)	Probability
0	2	0.05
2	3	0.05
3	4	0.15
4	9	0.25
9	16	0.25
16	26	0.15
26	33	0.05
33	41	0.03
41	47	0.01
47	51	0.005
51	55	0.003
55	59	0.001
59	85	0.001

Example output



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Daily activity not proposed to be included because...

- NATA experience suggests that estimated long-term exposures change 25% or less, in both directions
- Block centroid concentrations will underestimate actual ambient levels for some residents, overestimate for others
- These two effects tend to offset

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Acute inhalation exposure

- Estimated at location of highest modeled offsite 1-h concentration
- I.e., we will assume it is possible for a person to have a 1-h exposure anywhere outside the facility boundary

Uncertainties in chronic inhalation exposure

- Daily activity not included – moderate high bias
- Block centroid represents all residents – moderate low bias for some, high for others
- Long-term mobility
 - Not included in preliminary estimates – high bias for individual risk, low bias for population size, no bias for incidence
 - Included in final estimates, based on national data that may not represent local conditions
 - Renders 70-y span of risk estimates moot. Real duration of assessment should be facility life, which is often unknown or unpredictable
- Background sources not included by design

Uncertainties in acute inhalation exposure

- Hourly emission rates not in inventory; 10 x default estimate for all
- Assumes simultaneous occurrence of maximum emission rate, worst-case meteorology, and a human receptor
- If screen identifies potential acute exposures of concern, these assumptions will be replaced with source category-specific data

Charge question #5

- The plan describes a screening methodology for identifying potentially-significant acute exposures from routine emissions.
 - Is this method appropriately protective?
 - Can you suggest ways to refine the proposed acute exposure assessment process to enable it to support decision-making?

Charge question #6

- Beyond the use of AERMOD-HEM, is the methodology planned for characterizing exposure commensurate with the needs of residual risk assessments?
- Specifically, do the underlying theory and data used to account for the effect of population migration on exposure make our lifetime population risk assessment more or less defensible than assuming that the exposed population lives in the same location for a lifetime of 70 years?
- Is omitting the attenuation of exposure concentrations associated with building penetration justifiable when estimating lifetime risks for these chemicals and these types of sources?
- Is omitting the impact of short-term human activity patterns on exposures acceptable for these purposes?

Dose-response assessment

- Desirable qualities for DR information in the national-scale assessment:
 - Sound science (i.e., independent external peer review)
 - Reflecting current knowledge
- In that order

Dose-response metrics for chronic exposure

- Carcinogens
 - Unit risk estimate (URE) -- Risk per ug/m³ inhalation exposure for lifetime
 - Carcinogenic potency slope (CPS) – Risk per mg/kg/d ingestion exposure for lifetime
- Non-carcinogens
 - Reference concentration (RfC) -- A continuous inhalation exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime
 - Reference dose (RfD) – An estimate of a daily oral exposure for a chronic duration to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.
 - Uncertainty spanning an order of magnitude
 - Includes sensitive subgroups

Chronic dose-response in the RTR

- Sources having those qualities:
 - EPA IRIS
 - Does not cover all substances
 - Currently lags behind advances
 - ATSDR
 - Non-cancer assessments only
 - California EPA
 - UREs and RELs for "hot spots" program
 - Reviewed by peers and public
- Sources used in priority order above

Dose-response metrics for acute exposure

- No effect levels
 - ATSDR minimum risk level (1-14 day)
 - CA OEHHA reference exposure level (1-hour)
- Effect levels
 - NAC Acute exposure guideline levels (10 min – 8 hour)
 - AIHA emergency response planning guidelines (1-hour)

Acute dose-response in the RTR

- No priority order used
 - Metrics have different definitions
 - Developed for different purposes
 - By different agencies
 - At different times
- RTR will compare 1-hour exposure estimates with all metrics

Adjustments to dose-response values

- Unspeciated HAP category reported (e.g., cyanide compounds)
 - Apply a category-specific speciation profile to emissions, if possible (e.g., for metals, POM)
 - Otherwise, use the dose-response value for the most toxic compound (e.g., glycol ethers, cyanide compounds)
- Use the same URE for formaldehyde as in NATA99 (i.e., CIIT Centers for Health Research, 1999)
- Set the URE for Ni compounds at 65% of the IRIS value (assuming that Ni emissions are 65% insoluble and crystalline)
- Apply a URE for 2-nitropropane developed by the Health Council of the Netherlands
- Simplify POM dispersion modeling by separating emissions into 8 non-overlapping groups, each with an appropriate URE, as in NATA99

Uncertainties in dose-response assessment

- Extrapolation from...
 - High to low doses
 - Animals to humans
 - Short- to long-term exposures
- Model uncertainty for carcinogens
- Un-assessed HAPs

Charge question #7

- Is the plan for using available dose-response information (e.g., sources of information, prioritization scheme) appropriate for the purposes of this assessment?
- If not, can you suggest ways to improve it?

Risk characterization

- Based on EPA's principles of clarity, transparency, and consistency
 - 1995 Policy for Risk Characterization
 - 2002 Information Quality Guidelines
- Uncertainties discussed in each section
- Risks for plants with no inventory will be extrapolated from existing data

Risk metrics for each source category

- Acute
 - Most exposed individual
- Chronic
 - Maximum individual risk
 - Distribution of risk to all individuals
 - Distribution of risk to susceptible subgroups
 - Incidence (cancer)

Quantifying risk

- Lifetime cancer risk = LAE x URE
 - Incidence = Risk x Population in each census block, summed across blocks
 - Supplemental guidelines for early life exposure will be applied to mutagens
- Noncancer hazard quotient = AE / RfC
 - Clearly caveated – not a probability, and not proportional to actual risk

Mixtures, as per EPA Guidelines

- Use dose-response for entire mixture if available
- Otherwise:
 - Carcinogens – additivity of effects (sum risks across compounds)
 - Noncarcinogens – additivity of dose
 - Combine by MOA if possible
 - Otherwise sum HQs by target organ

Outputs for each source category

- Emissions summary
- Summary of chronic risk for category
- Summary of acute risk for category
- Summary of risk for each facility
- Table of generic sources of uncertainty and variability
- Discussion of uncertainty and variability specific to each particular source category

Source	Influence on risk estimate				Quantifiable?
	Over	Under	Mixed	Unknown	
Emissions inventory					
Inconsistent basis for estimates				X	No
Location errors				X	No
Inclusion of all major & area sources	X				No
Release parameter errors				X	No
Dispersion model					
Model used				X	Yes
No building downwash			S		Yes
No plume depletion	S				Yes
Choice of meteorological data			S		No
No atmospheric chemistry	S				Yes
Exposure assessment					
No daily activity			S		Yes
Local migration using national data			S		No
No background risks		L			Yes
Dose-response assessment					
Interspecies extrapolation	M				No
Intraspecies extrapolation	X				No
Linear low-dose extrapolation	X				No
Lack of assessments for some HAPs		X			No
Risk characterization					
No dietary exposure		S			Yes
No individual risk			S		No
Summing across HAPs				X	No

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Charge question #8

- What are the strengths and the weaknesses of the overall conceptual approach to risk characterization planned for this assessment?
- Does the characterization plan adequately cover sensitive subpopulations and early-life exposures?
- Does the risk characterization plan appropriately aggregate cancer risks?
- Does the risk characterization plan appropriately aggregate noncancer risks?

Charge question #8 (cont'd)

- ❑ What are the strengths and weaknesses of the planned approach for characterizing important uncertainties, variabilities, and limitations?
- ❑ Given the underlying science and the intended purposes of the assessment, can you suggest ways that the characterization of uncertainty and variability could be improved, made more transparent, or integrated more effectively into the risk characterization?

Charge question #9

- ❑ Has any important scientific information been omitted from this assessment plan that could impact a subsequent regulatory decision?
- ❑ In your opinion, will the overall approach for the 51 source categories provide results that will be sufficient to support regulatory decision-making in the context of EPA's residual risk program?