


A Review of Current TCE Short-Term Indoor Air Standards

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PURPOSE OF THIS TALK

To provide a review of various short-term trichloroethylene (TCE) action levels for indoor air, until such time that EPA Headquarters finalizes their assessment on this topic

EPA Updates TCE Inhalation RfC in 2011

- USEPA Releases TCE Toxicity Profile, September 2011
  - Recommends **2 µg/m³** inhalation RfC
  - Previous inhalation RfC = **10 µg/m³**

  - 5-fold ↑ noncancer inhalation toxicity
  - 5-fold ↑ noncancer risk

- New inhalation RfC (2 µg/m³) based on 2003 Johnson et al study

EPA/635/R-09/011F
www.epa.gov/iris

EPA

TOXICOLOGICAL REVIEW

OF

TRICHLOROETHYLENE

(CAS No. 79-01-6)

In Support of Summary Information on the Integrated Risk Information System (IRIS)

September 2011

U.S. Environmental Protection Agency
Washington, DC

Findings of 2003 Johnson et al Study

- Fetal heart malformations observed during 21-day gestational period of Sprague-Dawley rat **based on oral exposure**.
- Critical effect occurred ***in utero***, which translates to human cardiac development concerns in **pregnant women exposed to TCE.**

Controversy Surrounding 2003 Johnson et al Study

- To date, fetal heart malformation results NOT replicated in other studies, including:

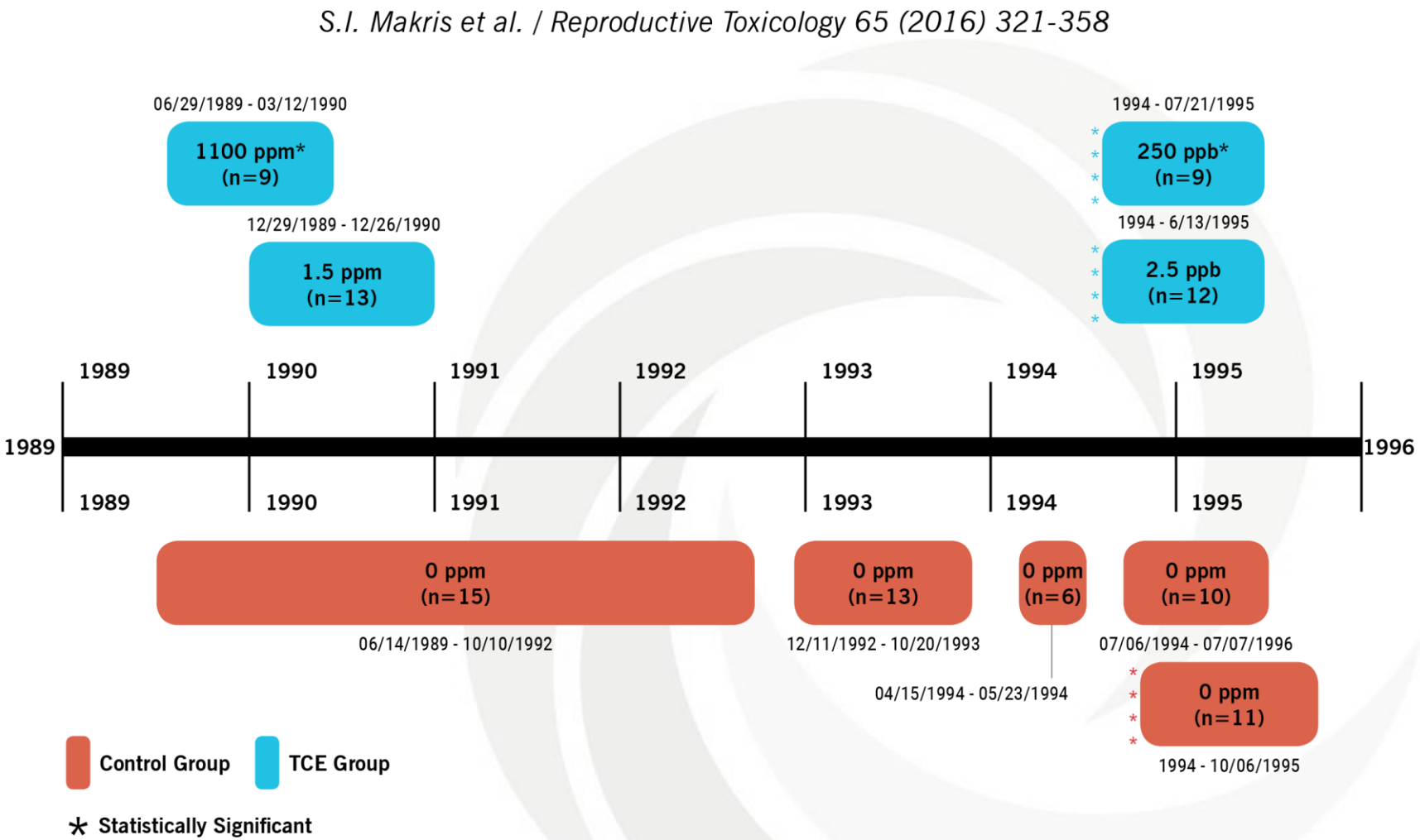
- FIVE TCE rodent/rabbit inhalation studies
  - Carney et al., 2006
  - Dorfmueller et al., 1979
  - Hardin et al., 1981
  - Healy et al., 1982
  - Schwetz et al., 1975

- TCE administered via oral dosing with Johnson collaboration (Fisher et al., 2001)

2003 Johnson et al Study Issues

- Study results varied widely and were not uniformly distributed
  - Infers low confidence in the study itself (Alliance for Risk Assessment, 2013)
- Unconventional study design may be **impossible to replicate**
  - Cobbled different studies over 6-year period in which treated & control animal groups were not evaluated at the same time; temporal gap between 2 lower dose & 2 higher dose groups (Makris et al., 2016)
  - 5 separate control group datasets (*small sample size with increased statistical variability*) were combined and treated as one dataset vs one large control group (*preferred approach*)

2003 Johnson et al Study Timeline

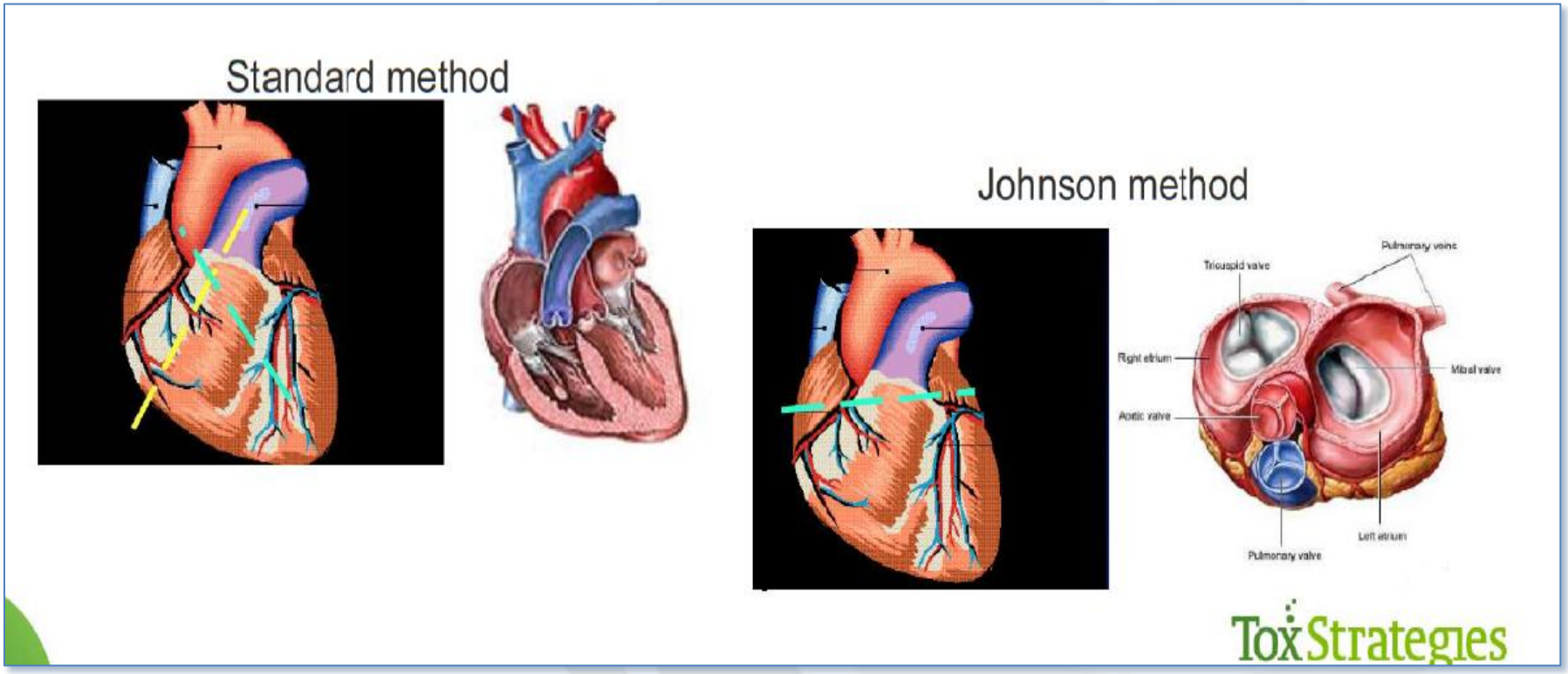


Controversy Surrounding 2003 Johnson et al Study

- Study animals may have been genetically predisposed to cardiac development by TCE & metabolites
  - Possibility of genetic drift in rat strain/source in last 10-20 years (Makris et al., 2016)
  - Dawson et al, 1993 only other oral study w/ observed cardiac defects, which was also conducted at University of Arizona
- Why does this matter?
  - In humans, cardiovascular malformations are common birth defects with
    - Environmental exposure
    - Genetic predisposition (Makris et al., 2016)

Controversy Surrounding 2003 Johnson et al Study

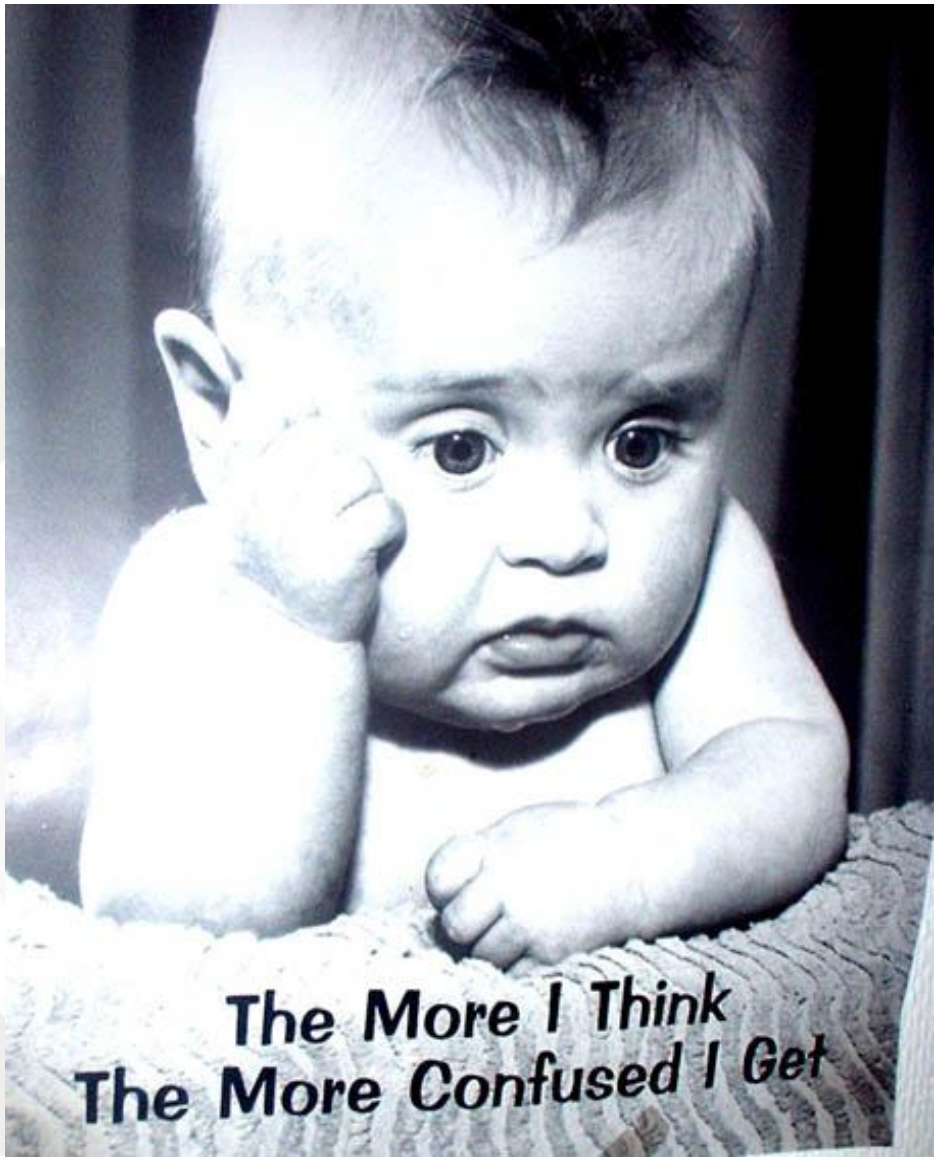
- Used unconventional method for examining fetal heart
  - Potential damage to fragile heart valves during examination



Slide Credit: Laurie Haws, ToxStrategies

Ponder this…

How do we navigate risk management of short-term (developmental) endpoints?



ATSDR Risk Management of TCE in Indoor Air

- In **2013**, ATSDR recommended **21 µg/m³** protective of short-term and intermediate exposure at TWO sites
- In **2014**, ATSDR drafts TCE toxicological profile, which identifies **2 µg/m³** as intermediate (52-week) and chronic MRL
- ATSDR has not developed an acute MRL, which would be protective of an exposure lasting from 1 – 14 days

2013 ATSDR Study #1

- Millsboro, DE TCE Site
  - Between Oct 2004-Oct 2005, drinking water contaminated with TCE
  - Prior to treatment, residents were exposed to TCE volatiles through household use of water
  - ATSDR used the **Human Equivalent Concentration (HEC_{99})** of **21 ug/m^3** derived from Johnson study to compare against **24-hr average indoor air conc.**

2013 ATSDR Study #2

- Pohatcong Valley Superfund Site
  - 1972-1981, drinking water contaminated with TCE
  - Prior to treatment, residents were exposed to TCE volatiles through household use of water
  - ATSDR used the **Human Equivalent Concentration (HEC_{99}) of 21 ug/m^3** derived from Johnson study to compare against **TWA indoor air conc**.
  - **21 ug/m^3 is a reasonable, allowable TWA indoor air concentration for residents over a period of approximately 10 years.**

How Do We Evaluate Risk From Inhalation Exposure?

- Johnson study gestation period = 21 days

- Human cardiac development extrapolation = 24-26 days; Averaging Time for risk-based calculation = 24 days (Alliance for Risk Assessment, 2013)

vs.

24-hour Averaging Time (EPA RAGS, Part A)

Terminology Review

- **Risk-Based Remediation Goal (RBRG) vs Removal Action Level (RAL)**
  - Hazard Quotient (HQ) is key difference
  - $HQ = \frac{concentration}{screening\ level}$

  - **RBRG**
    - **Protective of long-term health**
    - Allowable HQ = 1.0
  - **RAL**
    - **Protective of short-term health (assuming immediate action will be taken)**
    - Allowable HQ = 3.0 (per EPA 2008 guidance)

Terminology Review, continued

Other Terms for Removal Action Level or RAL

"Short-term Concentration"

-EPA Region 10

"Accelerated Response Action Level"

-EPA Region 9

"Urgent Response Action Level"

-EPA Region 9

Calculation of Risk-Based Concentration (RBC) Protective of Indoor Worker (USEPA RAGS, Part F)

$$RBC\ (ug/m^3) = \frac{HQ}{\left[\frac{ET}{24} \times EF \times ED\right] / [AT_{nc} \times RfC \times CF]}$$

- HQ = hazard quotient
- ET = exposure time (hours/day)
- EF = exposure frequency (days/year)
- ED = exposure duration (years)
- AT_{nc} = averaging time, noncancer (days) = ED x 365 days/year
- RfC = inhalation reference concentration (mg/m^3)
- CF = conversion factor (1,000 ug/mg)

Typical Indoor Worker Assumptions, Chronic Exposure Scenario

$$RBC\ (8.8\ ug/m^3) = \frac{HQ}{\left[\frac{ET}{24} \times EF \times ED\right] / [AT_{nc} \times RfC \times CF]}$$

- HQ = hazard quotient (1.0)
- ET = exposure time (8 hours/day)
- EF = exposure frequency (250 days/year)
- ED = exposure duration (25 years)
- AT_{nc} = averaging time, noncancer (9,125 days) = ED x 365 days/year
- RfC = inhalation reference concentration (TCE = 0.002 mg/m^3)
- CF = conversion factor (1,000 ug/mg)

Range of Indoor Worker Assumptions
Short-Term TCE Exposure Scenario

$$RBC\ (ug/m^3) = \frac{HQ}{\left[\frac{ET}{24} \times EF \times ED\right] / [AT_{nc} \times RfC \times CF]}$$

- HQ = hazard quotient (1 or 3)
- ET = exposure time (8-10 hours/day)
- EF = exposure frequency (1 - 24 days/year)
- ED = exposure duration (1 year)
- AT_{nc} = averaging time, noncancer (1 - 24 days) ≠ ED x 365 days/year
- RfC = inhalation reference concentration (TCE = 0.002 mg/m^3)
- CF = conversion factor (1,000 ug/mg)

Worst-Case Indoor Worker Assumptions
Short-Term TCE Exposure Scenario

$$RBC\ (4.8\ ug/m^3) = \frac{HQ}{\left[\frac{ET}{24} \times EF \times ED\right] / [AT_{nc} \times RfC \times CF]}$$

- HQ = hazard quotient (1)
- ET = exposure time (10 hours/day)
- EF = exposure frequency (1 days/year)
- ED = exposure duration (1 year)
- AT_{nc} = averaging time, noncancer (1 day) ≠ ED x 365 days/year
- RfC = inhalation reference concentration (TCE = 0.002 mg/m^3)
- CF = conversion factor (1,000 ug/mg)

Response-Oriented Indoor Worker Assumptions
Short-Term (One Week) TCE Exposure Scenario

$$RBC\ (25.2\ ug/m^3) = \frac{HQ}{\left[\frac{ET}{24} \times EF \times ED\right] / [AT_{nc} \times RfC \times CF]}$$

- HQ = hazard quotient (3)
- ET = exposure time (8 hours/day)
- EF = exposure frequency, one week (5 days/year)
- ED = exposure duration (1 year)
- AT_{nc} = averaging time, noncancer (7 days) ≠ ED x 365 days/year
- RfC = inhalation reference concentration (TCE = 0.002 mg/m^3)
- CF = conversion factor (1,000 ug/mg)

EPA Risk Management of TCE in Indoor Air

- Difference between **RBRG** protective of acute & chronic indoor air exposure & **RAL** for indoor air resulting in immediate action:

  - HQ = 1.0, RBRG development (USEPA, 1991)
  - HQ = 3.0, RAL development (USEPA, 2008)

The intention of a 3-fold increase in HQ is to allow a cushion between long-term health protectiveness and short-term immediate action.

EPA Risk Management of TCE in Indoor Air

USEPA Regions 7, 9 and 10 have mixed messages on what is appropriate HC

Inappropriate to use RBRGs to determine whether immediate action is necessary

EPA's Risk-Based TCE Indoor Air Levels for Workers

Source	Screening Levels and RALs	Basis for Concentration*
EPA Region 7 Action Level (EPA, 2016)	**8-hour TCE = 6 ug/m^3; 10-hour TCE = 4.8 ug/m^3**	Based on commercial/industrial exposure over 24 hours, inhalation RfC (2 ug/m^3), HQ = 1.0**
EPA Indoor Worker Regional Screening Level (RSL) (EPA, 2016)	**TCE = 8.8 ug/m^3**	Based on long-term worker exposure (8-hour workday, 250 days per year for 25 years), inhalation RfC (2 ug/m^3), HQ = 1.0
EPA Region 9 RAL (EPA, 2012a)	**TCE = 15 ug/m^3**	Based on acute (short-term) 10-hr workday, inhalation RfC (2 ug/m^3), HQ = 3.0
EPA Region 10 Short-Term Concentration (EPA, 2012b)	**TCE = 8.4 ug/m^3**	Based on 21-day exposure period, inhalation RfC (2 ug/m^3), HQ = 1.0**
EPA Region 9 Accelerated Response Action Level (EPA, 2014)	**8-hour TCE = 8 ug/m^3; 10-hour TCE = 7 ug/m^3**	Based on short-term commercial/industrial exposure, inhalation RfC (2 ug/m^3), HQ = 1.0**
EPA Region 9 Urgent Response Action Level (EPA, 2014)	**8-hour TCE = 24 ug/m^3; 10-hour TCE = 21 ug/m^3**	Based on short-term commercial/industrial exposure, inhalation RfC (2 ug/m^3), HQ = 3.0

* Both the HEC_{99} and RfC used to determine screening levels and RALs were calculated using the Johnson et al., 2003 study. However, as described above, these inhalation-based values are extrapolated from an oral exposure study. Furthermore, the Johnson study results varied widely, indicating a high degree of uncertainty. Finally, no other study has been able to replicate the toxicological, critical effects observed in the Johnson study.

** HQ of 1.0 is not consistent with EPA (2008) HQ of 3.0 for short-term exposure.

State Adoption of TCE Indoor Air Levels

State	Residential (ug/m³)		Industrial (ug/m³)	
	Long-Term RBRG	Short Term Action Level	Long-Term RBRG	Short Term Action Level
CA	1	--	3	--
CO	0.48	2	3	8.8
CT	2	5	--	8.8
IN	2	20	--	20
MA	2	6	8.8	24
MI	2	--	8.8	--
MN	2	--	6	--
NY	2	--	2	--
OH	2	6	8.8	26

Thank you

Questions?

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