Using Exposure Monitoring Results to Make Risk Management Decisions

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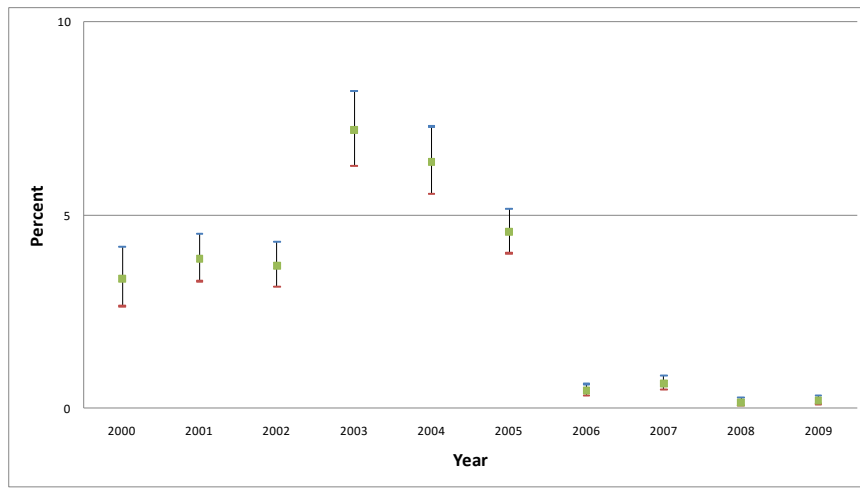
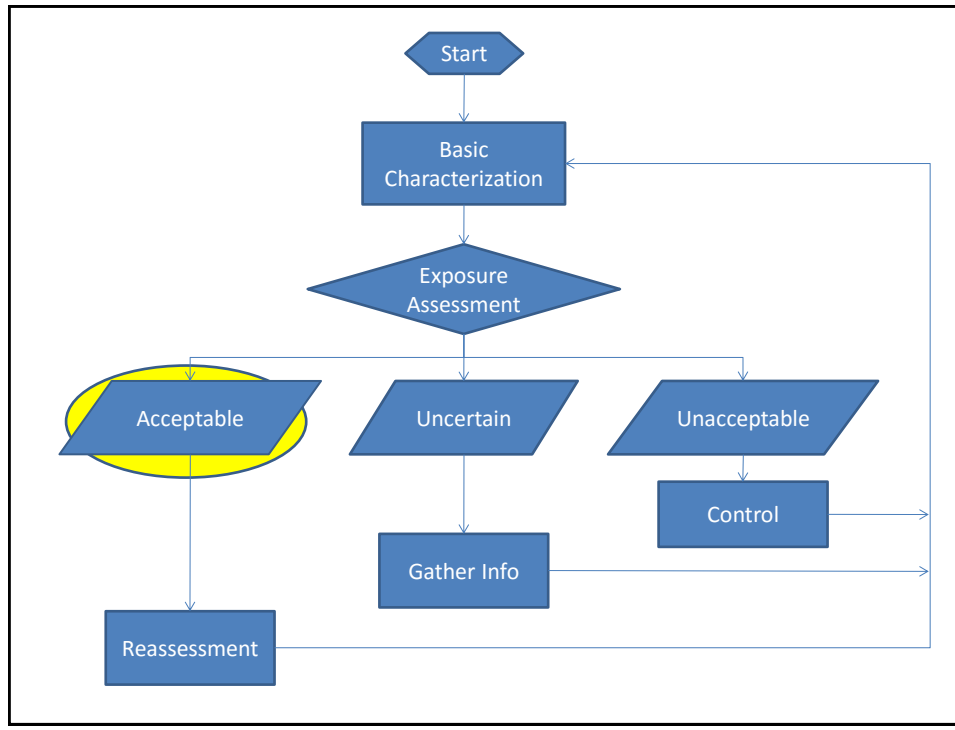
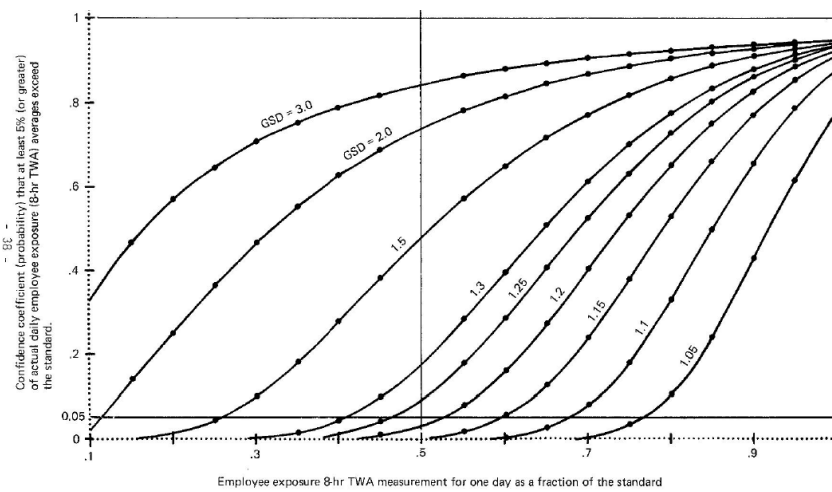
DOE –Wide Beryllium Exposure Trend

Percent Exceeding 0.2 µg/m3 and 95% Upper and Lower Confidence Limits





NIOSH 77-123 Occupational Exposure Sampling Strategy Manual



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Analysis of Variance

By job/by location[a]						
Groups	309		292			
	Between		Within		Total	Total
	$\hat{R}_{95}$	Sigma	$\hat{R}_{95}$	Sigma	Sigma	GSD
5th %ile	1	0	4.2	0.37	0.37	1.44
25th %ile	3.2	0.30	18.3	0.74	0.80	2.22
50th %ile	3.8	0.34	103.3	1.18	1.23	3.43
75th %ile	8.1	0.53	857.6	1.72	1.80	6.07
95th %ile	28.8	0.86	857.6	1.72	1.92	6.85

Symanski E., S. Maberti, and W. Chan: A meta-analytic approach for characterizing the within-worker and between-worker sources of variation in occupational exposure. Ann Occup Hyg. 50(4):343-57 (2006).

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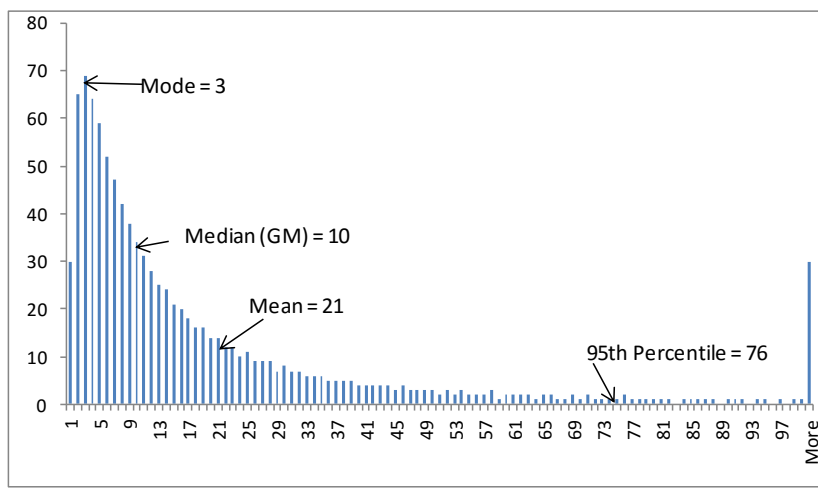
Lognormal Assumption

GM= 10 and GSD = 3.43



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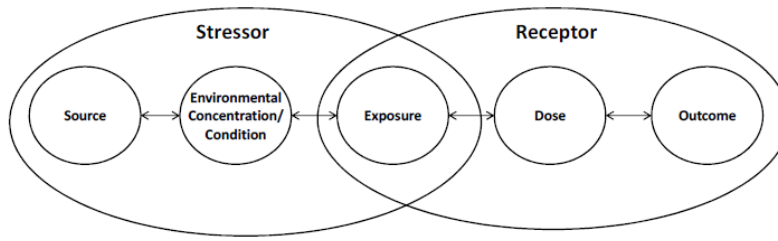
Environmental Health Continuum



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Industrial Hygiene Exposure Monitoring and Control

- Guides day-to-day decisions on the controls needed to perform work safely
- Focused on “recognition, evaluation and control” of the sources of exposure rather than exposure level
- Doesn’t need to be a level linked to individuals’ actual exposure
- Aggregating and summarizing monitoring data can be a secondary use of exposure information gathered to guide risk management decisions

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From: Comparison of formaldehyde exposure levels in two multi-industry occupational exposure databanks using multimodel inference. Lavoué J, Gérin M, Vincent R. J Occup Environ Hyg. 2011 Jan;8(1):38-48.

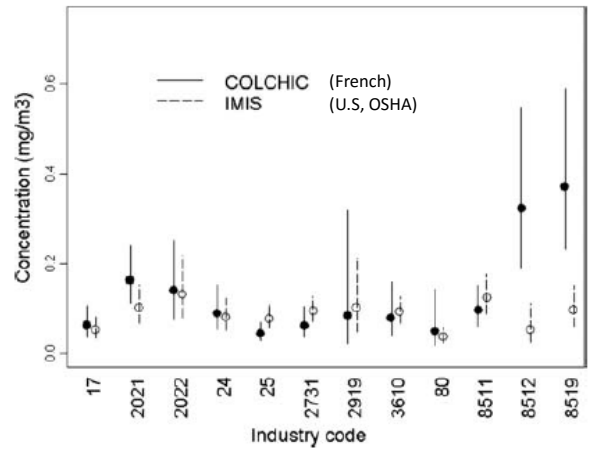

FIGURE 3. Predicted geometric means and associated 95% confidence intervals of formaldehyde long-term exposure levels for IMIS and COLCHIC in industries with >10 data in each source (ISIC codes)

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Proving Conditions are Acceptable Analytical Approach

- Type I Error – Deciding unsafe working conditions are safe
- Type II Error – Deciding safe working conditions are unsafe
- Null Hypothesis – Working conditions are unsafe - H_0
- Alternative Hypothesis – Working conditions are safe - H_a
- Acceptance Criteria – Accept the alternative hypothesis if there is a less than 5% chance of a Type I error

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Specify Acceptance Criteria Occupational Exposure Limits (OELs)

- Regulatory and Authoritative OELs
  - OSHA Expanded Standards
  - ACGIH TLVs
  - NIOSH RELs
- Derived or Provisional OELs
  - Derived from toxicology or epidemiology data
  - EPA IRIS files are authoritative reviews that state no or low observed adverse effects levels
  - Best available technology

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Metrics to Support Decisions

- Accept H_a if 95% confident that fewer than 5% of exposure periods exceed the OEL
  - The 95% upper tolerance limit for the 95^{th} percentile (95-95 UTL)
  - The 95% upper confidence limit (UCL) on the percent exceeding the OEL
- Confidence: in 100 trials with sample size n, the estimate in 95 would be less than the UCL

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Initial Exposure Assessment

- If no prior monitoring results collect preliminary samples for scoping
- Rules of Thumb
  - 6 samples required for valid estimate of confidence interval
  - Regulatory Action Level: If the largest of 6 – 10 preliminary samples > 0.5 x OEL then the 95th %ile is > OEL
  - If the largest is < 0.1 x OEL then 95th %ile is < OEL

Distribution Assumptions

"All Models are Wrong but Some are Useful"

- No Assumptions – Nonparametric Distribution
  - Percentile = rank/(n+1)
  - The largest of 19 = 19/20 = 95th percentile
  - The largest of 59 $0.05^{\wedge(1/59)}$ = 0.95 the 95-95 UTL
- Normal Distribution – Instrument Calibration
  - Results from blanks and spikes will be normally distributed
- Lognormal Distribution – Occupational Exposures
  - Non-zero results skewed by excursions
- Weibull Distribution – Accidental Losses
  - Severe losses are rare events, highly skewed
- Gamma Distribution – Environmental Exposures
  - If zero is expected to be the most common result
  - Use lognormal if a non-zero result is expected.

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Parametric Statistical Methods

- MVUE – Minimum Variance Unbiased Estimator
  - Small sample size (n = 6 to 15)
  - Complete data
- Log Probit Regression (Least Squares)
  - Large sample size (n > 15)
  - Censored data
  - Easy to do in Excel
- MLE – Maximum Likelihood Estimate
  - Large sample size (n > 15)
  - Censored data
  - Can be done in Excel
  - Easy with statistical software

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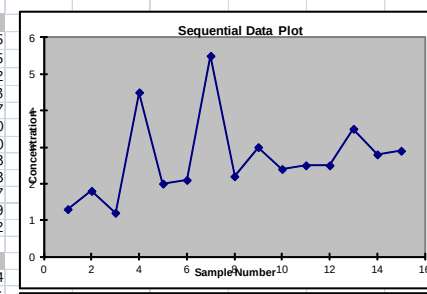
IH Stats Spreadsheet

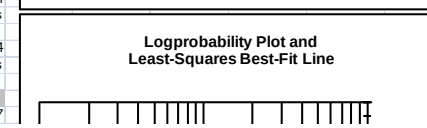
Industrial Hygiene Statistics

For trial and testing only - Please do not distribute

Data Description:

OEL	DESCRIPTIVE STATISTICS	
5	Number of samples (n)	15
	Maximum (max)	5.5
Sample Data	Minimum (min)	1.2
(max n = 50)	Range	4.3
No less-than (<)	Percent above OEL (%>OEL)	6.667
or greater-than (>)	Mean	2.680
1.3	Median	2.500
1.8	Standard deviation (s)	1.138
1.2	Mean of logtransformed data (LN)	0.908
4.5	Std. deviation of logtransformed data (LN)	0.407
2.0	Geometric mean (GM)	2.479
2.1	Geometric standard deviation (GSD)	1.502
5.5		
2.2	**TEST FOR DISTRIBUTION FIT**	
3.0	W-test of logtransformed data (LN)	0.974
2.4	Lognormal (a = 0.05)?	Yes
2.5		
2.5	W-test of data	0.904
3.5	Normal (a = 0.05)?	Yes
2.8		
2.9	**LOGNORMAL PARAMETRIC STATISTICS**	
	Estimated Arithmetic Mean - MVUE	2.677





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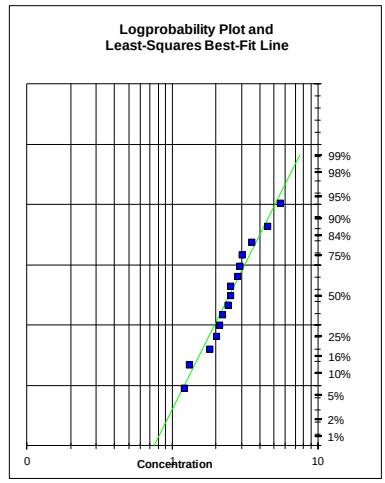
Parametric Statistics

(MVUE – Minimum Variance Unbiased Estimator)



- Arithmetic Mean 2.677
  - LCL,95% 2.257
  - UCL,95% 3.327
- 95th Percentile 4.843
  - UTL95%,95% 7.046
- Percent > OEL 4.241
  - LCL1,95% %>OEL 0.855
  - UCL1,95% %>OEL 15.271
- W-test of fit 0.974

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Log-Probit Regression

Rank	8-Hr TWA	z (probit)	ln(TWA)	Fitted Line
1	< 1.9	-1.53412		0.24023
2	< 1.9	-1.15035		0.409643
3	< 1.9	-0.88715		0.525832
4	2	-0.67449	0.693147	0.619707
5	2.1	-0.48878	0.741937	0.701689
6	2.2	-0.31864	0.788457	0.776794
7	2.4	-0.15731	0.875469	0.848012
8	2.5	-1.4E-16	0.916291	0.917455
9	2.5	0.157311	0.916291	0.986899
10	2.8	0.318639	1.029619	1.058116
11	2.9	0.488776	1.064711	1.133222
12	3	0.67449	1.098612	1.215203
13	3.5	0.887147	1.252763	1.309079
14	4.5	1.150349	1.504077	1.425268
15	5.5	1.534121	1.704748	1.59468

SUMMARY OUTPUT	
Regression Statistics	
Multiple R	0.97384
R Square	0.948364
Adjusted R Square	0.9432
Standard Error	0.073135
Observations	12
ANOVA	
	df
Regression	1
Residual	10
Total	11
	Coefficients
Intercept	0.917455
X Variable 1	0.441442

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Excel Regression Analysis

- In Excel, left click Office button and select “excel options”
- Select “add-ins” and then “analysis toolpak”
- You can also select “solver” for computing maximum likelihood estimates (MLE).
- In an open spreadsheet select the “data” tab, then the “data analysis” icon and scroll down the pick-list to select “regression.”
- In the dialog box, use the log transformed monitoring results as the Y range and the calculated z statistic (probit) as the X range.
- z = normsinv(rank/(n+1))

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Regression Statistics

- Intercept = the mean of the log transformed data
  - Symbolized by *y bar* or the Greek letter μ
  - Geometric Mean (GM) = e^{μ} Excel Command: =exp(μ)
- x variable = the standard deviation of the log transformed data
  - Symbolized by *s* or the Greek letter σ
  - Geometric Standard Deviation (GSD) = e^{σ} = exp(σ)
- Degrees of freedom (*df*) = n – 1
- R^2, goodness of fit metric
  - Interpret the same as the W statistic using AIHA Table IV.5

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Maximum Likelihood Estimates

			Solver Cells			
DATA*	**Log Likelihood of Observation, given estimate of Mean & SD**	**Starter**	**Mean**	0.924899	"=Mean of Log(data)"	
2	-0.120545658	**Starter**	**SD**	0.369817	"= SD of log(data)"	
2.1	-0.04657215					
2.2	0.007749723					
2.4	0.06687652					
2.5	0.075538164					
2.5	0.075538164	Computed arithmetic mean:			2.700078	
2.8	0.035716521	Computed arithmetic standard de			1.753586	
2.9	0.004345105					
3	-0.034513739					
3.5	-0.317184489					
4.5	-1.150562852					
5.5	-2.147595254					
1.9	-1.504955119					
1.9	-1.504955119					
1.9	-1.504955119					
	Total LogLikelihood					
	-8.0660753					

Finkelstein, M.M. and D.K. Verma: Exposure Estimation in the Presence of Nondetectable Values: Another Look.Am. Ind. Hyg. Assoc. J. 62:195–98 (2001).

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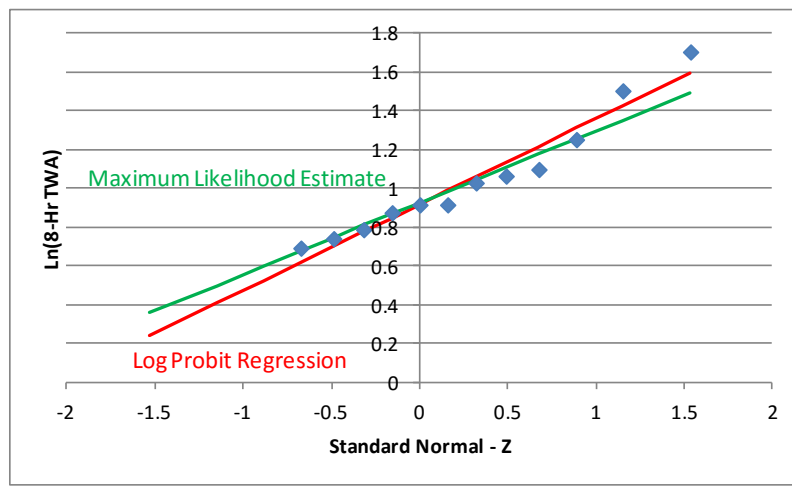
Log Probability Line Fit Plot



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Excel Formulas for Calculating Parametric Statistics

- Percent Exceeding the OEL
  - Z of the OEL = ln(OEL)-μ)/σ
  - % Exceeding OEL =1-normsdist(Z_{OEL}) Display as %
  - Use Z_{OEL} and n to read value from AIHA Figure IV.8
- 95th Percentile = exp(μ+normsinv(0.95)*σ)
- 95-95 UTL = exp(μ+K*σ)
  - Where K is a factor from AIHA Table IV.11
  - For n > 50 see http://www.itl.nist.gov/div898/handbook/prc/section2/prc263.htm

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"Ln 95-95 UTL" Spreadsheet

One-sided Tolerance Limits for Log-Normal or Normal Distributions				
Use: Enter estimated GM, GSD, and the number of samples.				
Geometric Mean (GM) =	2.50			
Geometric Standard Deviation (GSD) =	1.55			
Probability (p) =	95.0%			
Confidence (γ) =	95.0%			
Number of detected results (m)	12			
a =	0.8770			
b =	2.4801			
*Factors for Tolerence Limits (K) =	2.7360			
Upper Tolerance Limit (UTL) =	8.36			
For details see: http://www.itl.nist.gov/div898/handbook/prc/section2/prc263.htm				

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Quasi Nonparametric Upper Tolerance Limits (QNP-UTL)

- "Quasi Nonparametric" Upper Tolerance Limits For Occupational Exposure Evaluations. Davis CB, Wambach PF.J Occup Environ Hyg. 2015;12(5):342-9
- Designed for worst-case data, all or mostly censored and reporting limit (RL) near OEL
- Uses only the largest result (or the RL) and n the number of monitoring results
- A risk rather than exposure metric
- Validates the AIHA rule of thumb that 6 to 10 < 10^{th} is evidence of compliance

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QNP-UTL

- Conservative estimate of the location parameter from order statistics
  - 95% LCL of the percentile of the largest result is $0.05^{1/n}$
  - If n = 8 then the 95% LCL is the 68.77^{th} percentile
  - Z of the 68.77^{th} percentile = 0.48922
- Uses an upper bound for variance in occupational exposure of $\sigma = 2$, GSD = 7.4
  - Analogous to action level use of lower bound of GSD = 1.2
  - Empirical basis in meta-analysis of published exposure basis
  - Theoretical basis – lognormal model produce results similar to Weibull, Gamma and non-parametric methods with this assumption

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QNP-UTL

- RATIO = 95^{th} percentile / 68.77^{th} percentile
  = $\exp(\mu + 1.64485\sigma) / \exp(\mu + 0.48922\sigma)$
  = $\exp((1.64485 - 0.48922) * \sigma)$

- Assuming that $\sigma \leq 2.0$, RATIO is no more than $10.09 \approx 10$; the 95th percentile is no more than about 10 times the 68.77th percentile.

- If the largest of 8 samples or RL is < $1/10^{th}$ the OEL then 95% confident that < 5% exceed the OEL

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QNP-UTL Table

Compare RATIO x largest value with OEL, or compare largest value with TCV% x OEL

N	RATIO	TCV%	N	RATIO	TCV%	N	RATIO	TCV%	N	RATIO	TCV%
8	10.09	9.9%	21	2.9	34.5%	34	1.71	58.5%	47	1.23	81.1%
9	8.52	11.7%	22	2.75	36.4%	35	1.66	60.3%	48	1.21	82.8%
10	7.36	13.6%	23	2.61	38.3%	36	1.61	62.0%	49	1.18	84.5%
11	6.47	15.5%	24	2.49	40.1%	37	1.57	63.8%	50	1.16	86.2%
12	5.76	17.4%	25	2.38	42.0%	38	1.53	65.6%	51	1.14	87.8%
13	5.19	19.3%	26	2.28	43.9%	39	1.49	67.3%	52	1.12	89.5%
14	4.73	21.2%	27	2.19	45.7%	40	1.45	69.1%	53	1.1	91.2%
15	4.34	23.1%	28	2.1	47.6%	41	1.41	70.8%	54	1.08	92.8%
16	4	25.0%	29	2.02	49.4%	42	1.38	72.6%	55	1.06	94.5%
17	3.72	26.9%	30	1.95	51.2%	43	1.35	74.3%	56	1.04	96.1%
18	3.47	28.8%	31	1.89	53.0%	44	1.32	76.0%	57	1.02	97.7%
19	3.26	30.7%	32	1.82	54.9%	45	1.29	77.7%	58	1.01	99.3%
20	3.07	32.6%	33	1.76	56.7%	46	1.26	79.4%	59	0.99	101.0%

For $59 \leq N \leq 92$ the 95%-95% NPUTL is the largest value, etc

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Reporting Limits (RLs)

- The AIHA accreditation program requires labs to establish RLs before analyzing customers samples
- The RL is a statistic – most commonly derived using the EPA MQL method
  - Analysis of blanks -> results not likely to be a blank
  - Analysis of spikes – the low spike about 10x value not likely to be a blank -> accurate within ± 10%
  - Factor of 2 or more to accommodate day-to-day variation from instrument drift and media interference

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Excel Spreadsheets

- IHSTATS: Implements methods discussed in the AIHA "Strategy" book. Complete data methods
- LPR and MLE: Implements censored data methods recommended by "Strategy" book
- Ln 95-95 UTL: Computes the 95% Upper Tolerance Limit of the 95th percentile from estimated GM, GSD and the number of detected results (m)
- QNP-UTL: Calculates Ratio, TCV and UCL of percent exceeding from n, the number of results and largest measured value.

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Free Statistical Software

- The R Project for Statistical Computing
  - http://www.r-project.org/
  - Dominates academic statistics
  - Huge library of contributed packages
- EPA ProUCL Software
  - https://www.epa.gov/land-research/proucl-software
  - Supports the EPA DQO process
  - Best methods for censored and complete environmental monitoring data

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Respirable Silica Monitoring Results While Working With Concrete

Task Name	n	Largest 8-Hr TWA (µg/m3)	Detected	QNP 95% UCL of % Exceeding OEL	Additional Samples Needed	% Exceeding with PF 10 Respirator
Drilling - Handheld Portable Drill	11	5	Yes	6.5%	3	0.4%
Core Drilling	6	4.3	No	12.5%	6	1.1%
Pouring / Mixing Grout	7	6.7	Yes	14.7%	10	1.4%
Bush Hammering	8	8.4	Yes	15.1%	13	1.4%
Core drill/chipping hammer	8	5.8	Yes	16.1%	14	0.9%
Rotary Hammer Drill	15	14	Yes	11.5%	18	0.9%
All Work Tasks Combined	55	14	Yes	3.7%	NA	0.1%

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Discussion

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