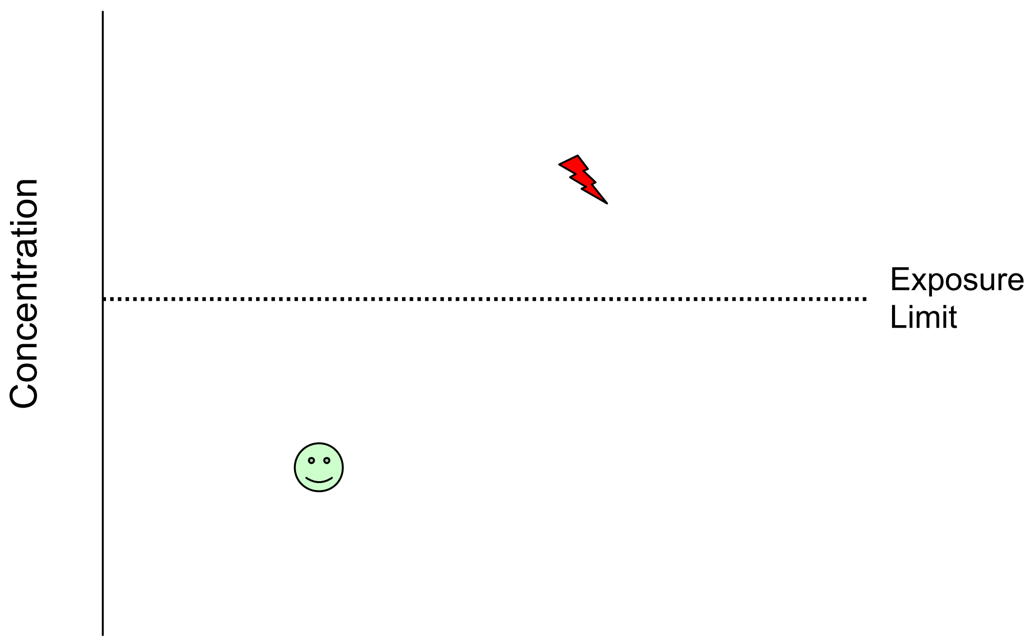
Compliance Decision Making

Current Practice in Occupational Field

- "intraoccular trauma test", i.e., is any single measurement greater than the exposure limit?



Current Practices in Environmental Field

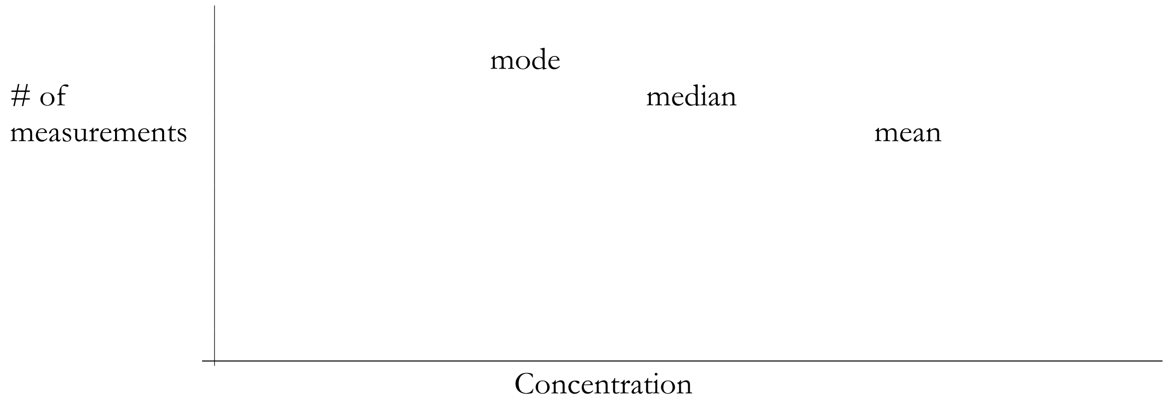
- water pollution: Canadian jurisdictions often use "running geometric mean" of sequential measurements as basis for testing compliance of fecal coliform levels

> "The geometric mean of at least 5 samples, taken during a period not to exceed 30 days, should not exceed 2000 *E. coli*/L**.** Resampling should be performed when any sample exceeds 4000 *E. coli*/L."
> **Guidelines for Canadian Recreational Water Quality**
> Prepared by the Federal-Provincial Working Group on Recreational Water Quality of the Federal-Provincial Advisory Committee on Environmental and Occupational Health. 1992

- air pollution: US EPA uses upper confidence limit

Using the Occupational Field to Highlight Issues

- problems with single measurement comparisons from the workers' viewpoint: "*you should have been here the other day*"



GSD =	1.5	2.0	2.5	3.0	3.5	4.0
Probability that measured concentration < the mean	58%	64%	68%	71%	73%	76%

- problems with single measurement comparisons from the employers' viewpoint: "*best way to ensure compliance would be to take no samples*."

Number of Measurements	Probability of 1 measurement being > the exposure limit (EL)*
0	0%
1	2%
2	5%
5	10%
10	19%
20	36%
50	75%
90	99%

* assuming mean concentration is 1/4 the EL and GSD = 2.0

ASSURING COMPLIANCE FOR ACUTE HAZARDS

- suggestion by Rappaport (1991) and British Occupational Hygiene Society (1993)

- damage occurs in short time, must assess **peaks** by using short sampling time
  - every peak important, therefore need to either
    - monitor continuously with source or personal alarm monitors, or
    - institute 'fail-safe' controls that will prevent hazardous peaks

ASSURING COMPLIANCE FOR CHRONIC HAZARDS

- some simplified suggestions are presented here (based on the approach suggested by the AIHA Exposure Assessment Strategies Committee)

- damage occurs after long-term exposure, therefore take enough samples over time to obtain reasonable estimate of **arithmetic mean** exposure

- **group** employees, and take **random** samples:
  - consider work process, procedures, job descriptions, process schedules, climactic conditions
  - group (stratify) people or area sample locations, to the extent possible, according to potential exposures, so that you feel comfortable that the employees in the group would have essentially the same exposure distributions, so that monitoring exposures of any employee(s) would provide data useful for predicting exposures of the remaining employees
  - sample randomly from each group
  - "similar exposure group", SEG; previously "homogeneous exposure group, HEG

- note that Rappaport criticizes the SEG approach
  - relies on "professional judgment" rather than data for grouping workers
  - suggests that measurement data be used to group workers into "uniformly exposed groups" with a quantitative criterion for grouping

$$ {}_{BW}R_{95} = \frac{\text{97.5\%ile of distribution of worker means}}{\text{2.5\%ile of distribution of worker means}} = \frac{\overline{X}_g\, S_g^{1.96}}{\overline{X}_g\, S_g^{-1.96}} = S_g^{3.92} \leq 2 $$

  - this is equivalent to a ${}_{BW}S_g \leq 1.2$

- if SEG is not "uniformly exposed", some workers' mean exposures may exceed EL, even though SEG mean exposure is < EL
- certain agencies have agreed with Rappaport's criticism (e.g., the British Occupational Hygiene Society); they recommend a ${}_{BW}R_{95} \leq 4$ or a ${}_{BW}S_g \leq 1.4$

- take 8-hr samples (or other appropriate long duration) selected randomly from period required for adequate averaging

- calculate upper and lower confidence limits around the **arithmetic mean**
  - arithmetic mean most closely related to body burden
  - if upper 95% confidence limit (UCL) < standard or action level: compliance
  - if lower 95% confidence limit (LCL) > standard or action level: non-compliance
  - for situations in between, may require more sampling to decide compliance

    or

    could simply decide to implement controls

  - to calculate one-sided 95% confidence limits around the mean
    - determine whether distribution is best approximated by normal or lognormal distribution
    - calculate parameters of distribution (mean, standard deviation, or geometric counterparts)
    - calculate standard error

    - calculation of **arithmetic** one-sided **95% confidence limits** around **arithmetic mean** if exposures are **normally distributed** (t-distribution estimates, use t-table in most stats texts)

$$UCL_{0.95} = \bar{x} + t_{df,0.95}\,(s/n^{1/2})$$
$$LCL_{0.95} = \bar{x} - t_{df,0.95}\,(s/n^{1/2})$$

    - calculation of **geometric** one-sided **95% confidence limits** around **arithmetic mean** if exposures are **log-normally distributed** (Lands exact estimates, use H-tables in Perkins text)

$$UCL_{0.95} = \exp\,[\bar{x}_L + 0.5s_L^{\,2} + H_{0.95}\,(s_L\,/(n - 1)^{1/2})]$$
$$LCL_{0.95} = \exp\,[\bar{x}_L + 0.5s_L^{\,2} + H_{0.05}\,(s_L/(n - 1)^{1/2})]$$

- this method and similar ones are also recommended by US EPA for determining **compliance of environmental exposures**

> EPA recommends using the average concentration to represent "a reasonable estimate of the concentration likely to be contacted over time. Because of the uncertainty associated with estimating the true average concentration at a site, the **95 percent upper confidence limit (UCL) of the arithmetic mean** should be used for this variable."
>
> US EPA TECHNICAL SUPPORT CENTER FOR MONITORING AND SITE CHARACTERIZATION, http://www.epa.gov/nerlesd1/tsc/software.htm Last updated November 6, 2007. Accessed, Nov. 19, 2007

- note that 1977 Leidel, Busch, and Lynch manual suggests similar approach but uses **coefficient of variation of measurement method** (rather than standard error of mean) to estimate confidence limits around a **single measurement**: $UCL = x_i + 1.65\ CV_{(measurement\ method)}$

HOW OFTEN TO SAMPLE

- most common approach for compliance sampling is to relate sampling frequency to the average exposure level
- e.g., the CEN (1992) suggests the following minimum schedule for periodic monitoring:
  - > 1/2 to 1 times the OEL — every 16 weeks
  - > 1/4 to 1/2 times the OEL — every 32 weeks
  - ≤ 1/4 times the OEL — every 64 weeks

- note offset from 52 weeks

- > OEL: control exposure, then resample
- change in process or other conditions, resample
- exposures <<<< OEL, no need to resample, unless there is a change in conditions

HOW MANY SAMPLES TO ENSURE COMPLIANCE?

- Leidel, Busch, and Lynch (1977) suggested required number of samples to ensure some from highest exposure group with given level of confidence ("worst case" method where "worst" not easily identified):

TABLE A-1. SAMPLE SIZE FOR TOP 10% (τ=0.1) AND CONFIDENCE 0.90 (α=0.1) (USE n=N if N ≦ 7)

Size of group (N)	8	9	10	11-12	13-14	15-17	18-20	21-24	25-29	30-37	38-49	50	∞
Required No. of measured employees (n)	7	8	9	10	11	12	13	14	15	16	17	18	22

TABLE A-2. SAMPLE SIZE FOR TOP 10% (τ=0.1) AND CONFIDENCE 0.95 (α=0.05) (USE n=N if N ≦ 11)

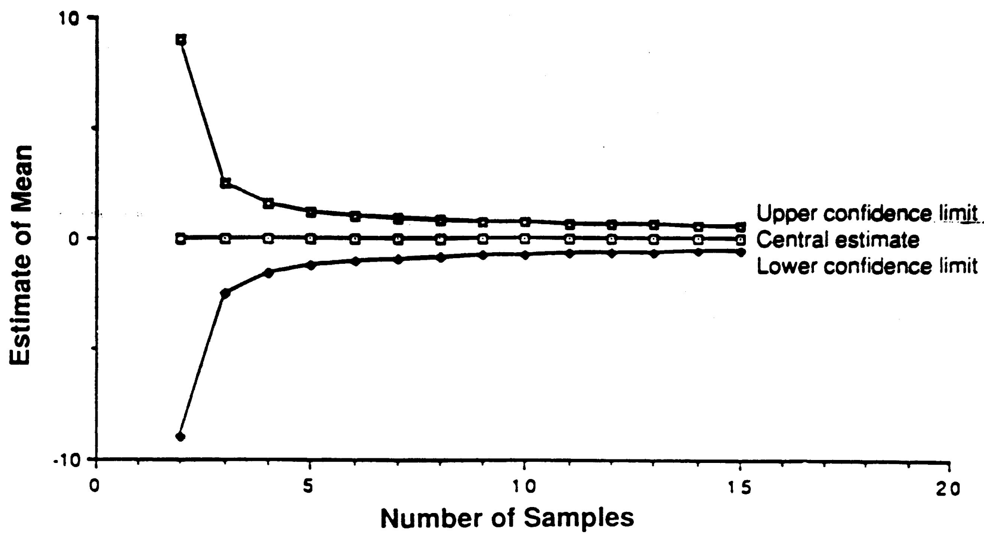
Size of group (N)	12	13-14	15-16	17-18	19-21	22-24	25-27	28-31	32-35	36-41	42-50	∞
Required No. of measured employees (n)	11	12	13	14	15	16	17	18	19	20	21	29

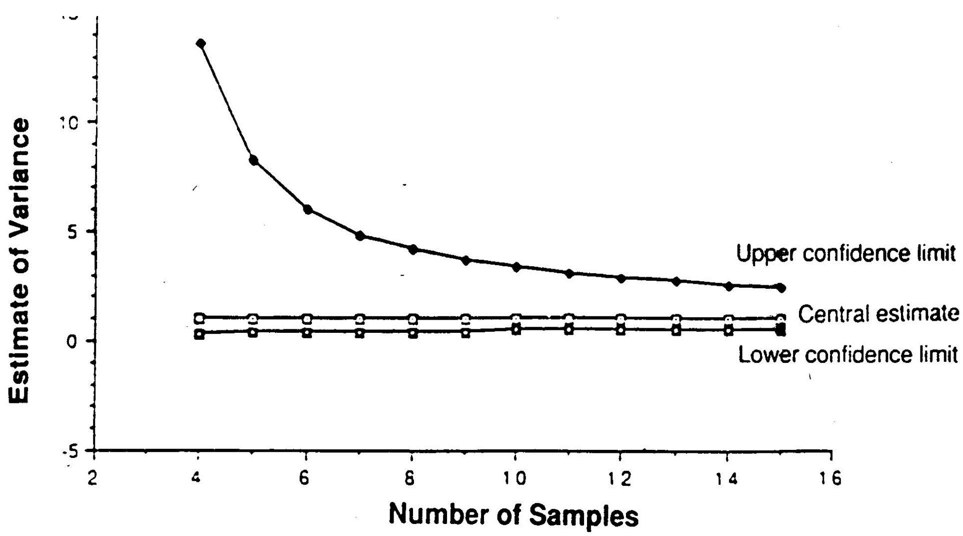
- Rappaport and Selvin (1987) provide number of samples required to ensure mean exposure is less than a given exposure limit

Number of samples required to have 95% confidence (i.e., α = 0.05) that the true mean exposure (from a log-normal distribution of 8-hr TWAs) is less than a given exposure limit (power = 90%)

mean/exposure limit	s_g = 1.5	2.0	2.5	3.0	3.5
0.10	2	6	13	21	30
0.25	3	10	19	30	43
0.50	7	21	41	67	96
0.75	25	82	164	266	384

- Hawkins, Norwood, and Rock (1991) suggest diminishing returns with increased sample sizes, i.e. little improvement in confidence limits around means and variances (standard deviation squared) with additional sampling (figures below developed using t-table and assumption of a normal distribution)





- Mulhausen and Damiano (1998) suggest that "fewer than 6 measurements leaves a great deal of uncertainty about the exposure profile", but "a reasonable approximation of an exposure distribution often is possible with about 10 samples; however, for rigorous goodness-of-fit testing . . . 30 measurements or more might be needed"