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#### **Getting Started (Summary)**

A statistical tool like HYGINIST is useful if the <u>effectiveness</u> of working condition control measures is assessed using discontinuous exposure measurements.

HYGINIST includes 6 transactions:

- 1. data entry and mutation,
- 2. examining distribution shape,
- 3. estimating the descriptive statistics,
- 4. extrapolation to unsampled periods and compliance test against a limit value,
- 5. comparing the exposure data with other sets of descriptive statistics,
- 6. establishing the minimum sample size for an unbiased estimate of long-term compliance control.

This Help further explains:

- How to apply the HYGINIST statistical methods in working conditions control
- The many aspects of the Lognormal distribution
- Installing and running the program
- Program operations
- Register for regular use.

If HYGINIST is <u>started</u>, then the following Splash screen appears. After installation it will include the next Login box.

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If the Login form is filled out correctly then the HYGINIST start page appears after a few seconds, in which all form and constants are loaded. Now you can start with the exposure data management and analysis.

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Regards Theo Scheffers

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# Accuracy

The difference between the measurement and the truth (Hawkins 1991), the extent in which calculations or estimations, the true value approximate

# **B.2.4.3 The linear estimator**

The most simple, method to estimate the arithmetic mean of the Lognormal distribution uses Formula  $\underline{B-3}$  with xi=ci. This estimator of the mean is consistent, which means unbiased for infinite sample size.

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### **B.2.1 Mean and standard deviation**

All estimators of  $EXP(\mu)$  and  $EXP(\sigma)$  use the following formulas for mean and standard deviation:

$$\overline{x} = \frac{\sum_{i=1}^{W} x_i}{M} B-3$$

$$s = \sqrt{\frac{\sum_{i=1}^{w} (x_i - \overline{x})^{e}}{M-1}}_{B-4}$$

both with:

 $x_1 = \log(c_1)$  b-5

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# **B.2.4 Location (2). The arithmetic mean**

The arithmetic mean  $\beta$  (first moment):

- has the units of measurement of concentration (or intensity),
- can take every real value over zero (by definition).

In the Lognormal distribution  $\beta$  is a function of EXP( $\mu$ ) and EXP( $\sigma$ ):

 $\beta = EXP\left(\mu + \frac{\sigma^2}{2}\right)_{B-15}$ 

The arithmetic mean  $\beta$  of a series:

- grab sample measurements within a reference period is a measure for the TWAreference period,
- more days TWA8 hour measurements is a measure for the mean dose of accumulating agents (Seixas 1988) like asbestos, silica, cadmium et cetera.

•

There are four sample estimators:

- The maximum likelihood (see **B.2.4.5**)
- The unbiased (see **B.2.4.1**)
- the minimal mean square error (see **B.2.4.2**)
- The linear (see B.2.4.3)

Confidence limits around the arithmetic mean estimator are calculated in B.2.4.4

## **B.2.4.5 The maximum likelihood estimator**

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#### **B.2.4.1 The unbiased estimator**

The 'uniformly minimum variance unbiased' estimator (UMVU; Shimizu 1988b p 29, Finney 1941) of the arithmetic mean AM of the Lognormal distribution can be derived, in the same way as was done for GM<sub>u</sub>, in a Taylor series expansion (see Shimizu 1988b p30 & 31 formula 2.3. & 2.6.):

$$AM = GM * \phi \left(\frac{s^{t}}{2}\right)$$

with

 $\Phi(t) = 1 + \frac{(M-1)^* t}{M} + \frac{(M-1)^{3*} t^2}{M^{2*} (M+1)^* 2!} + \frac{(M-1)^{5*} t^3}{M^{3*} (M+1)^* (M+3)^* 3!} + \dots _{B-16}$ 

Although well known in industrial hygiene (Oldham 1953, Galbas 1975, Bar-Shalom 1975 part II page 47; 1976 page 472, Leidel 1977, Owen 1980) its use is inhibited because of the believed possible deterrent to its users (Dewell 1993) and/or misinterpretation (Selvin 1989).

The superior characteristics of formula 5.16 over other estimators (e.g. the maximum likelihood and direct estimators) are described by Kuo-Hsing Chang (1990) and Attfield (1992, 1993). formula B-16 converges much more quickly to a constant value than formula B-11. For s<sub>2</sub>>.1 the relative increase in the 7<sub>e</sub> or 8<sub>e</sub> term is, for all values of MD2, less than 1E-8. In BASIC, formula B-16 is programmable in a small subroutine.

#### **B.2.4.2** The minimal mean square error estimate

The estimator with the smallest mean square error among the estimators (Zhou 1998) is:

$$AM = GM * \phi \left(\frac{(M-3)*s^{t}}{2*M}\right)$$

with

 $\Phi(t) = 1 + \frac{(M-1)^{*}t}{M} + \frac{(M-1)^{*}t^{2}}{M^{*}(M+1)^{*}2!} + \frac{(M-1)^{*}t^{3}}{M^{*}(M+1)^{*}(M+3)^{*}3!} + \dots$ B-28

This estimator can only be applied for sample sizes of at least four.

### **B.2.4.4 Confidence limits**

Exact confidence limits exist (Land 1971, Bar-Shalom 1975). They can be established (Armstrong 1992, see Example 33) using the tables (Land 1975) or can be calculated as such (Land 1988 6.1). HYGINIST calculates the <u>exact limits</u> but also the <u>approximate</u> <u>method</u> that was used in HYGINIST version 2.2 and earlier.

#### See example 51

<u>Figure 23</u> Rankit plot of 2000 AM values. <u>Figure 24</u> Rankit plot of 2000 AM values. Monte Carlo Lognormal. Sample size 50 Monte Carlo Lognormal. Sample size 50 Contents - Index

### **5.2.1 Uniform most powerful**

The 'uniform most powerful' (=UMP) test for the arithmetic mean of a Lognormal distribution is developed by Land (1971, 1988 p89 & 103), introduced in the industrial hygiene by Galbas (1975) and Bar-Shalom (1975, 1976), and supported by Leidel (1977 page 55) and Coenen (1978). The UMP is:

- most highly preferred because it is unbiased with minimum variance,
- difficult in its use, because it can only be solved analytically, for sample size odd.

HYGINIST for Windows contains the algorithm to calculate the UMP estimator of:

- the probability that the mean exceeds the limit
- the Upper confidence limit of the mean
- if:
- Sample size is 3<M<1001
- confidence 90%<D<99.75%

Example 32 The UMP test for the arithmetic mean of a Lognormal distribution

## Example 32 The UMP test for the arithmetic mean of a Lognormal distribution

#### \*.HYG file Description

HAW117 With 14 random TWA<sub>8 hour</sub> PAS total dust above LL=1.4 mg/m<sub>3</sub> the chronic health hazard was tested. The plotting positions y=10log(GM/H)=-0.66 and s=10log(GSD)=0.08 (see screen 24a) falls inside compliance area of Nomogram 4.3 in Leidel (1977 page 58). Since GSD is in part explained by CVt (see Example 57), the situation is in real compliance.

LEIDEL56 With 8 TWA<sub>20</sub> min Ethyl alcohol PAS data the TWA<sub>8 hour</sub> is classified against H=1000 PPM (Leidel 1977 page 56). Entering y=0.002 and s=0.14 in the nomograms, results that the situation is classified as possible overexposure (like Leidel concluded 1977 p.57). Because the location parameter GM is independent of CVt, overexposure is real even without good knowledge of the corrected GSD (see Example 57).

BAR\_SI25 In an industrial plant 6 grab sample measurements of carbon monoxide were performed for a particular employee at the hours 9, 10, 11, 12, 14, and 16. (Bar-Shalom 1975 page I-25). If the resulting y= -0.02 and s=0.22 are entered in the nomograms, then the situation is classified as possible overexposure against a TWA8hour=50 PPM.

OWEN716 The 15 grab sample airborne Chlorine concentrations are used to classify for a TWA<sub>8 hour</sub> standard of 1 PPM. After introducing a two-sided accuracy range of 0.25-9 PPM the rankit estimators are GMg=.88 PPM, GSDg=6.81 and df=10. Extrapolation towards the plotting positions y=-0.00 and s=0.67 for df+1=11 in Leidel (1977 figure 4.3.). indicates possible over exposure (Owen 1980 p716)

### **Table 1 Example data from different sources**

\*.HYG file agent Sample Limit dimension Source size M value H ALBRE220 TWA8 hr Aspartame 4 ? µG/M3 Albrecht (1989) p220 ACN8 9 TWA8 hr Acrylonitril 116 4 PPM Swaen (1992) BAR SI25 Grab Sample Carbon monoxide 6 50 PPM Bar-Shalom (1975) pI-25 BILAN304 TWA8 hr Methylene bisphenyl 5 0.005 PPM Bilan (1989) p304 sprayer indoor isocvanate (MDI) BOLEY62 TWA8 hr Total dust 12 10 MG/M3 Boleij (1987) p62, paper plant BOLEY85 TWA8 hr ZnCl2 total Dust 7 mg/m3 Boleij (1987) p85 CHIP123 Lead 10 50 µG/M3 Booher (1988) p123 COHEN132 max. Susquehanna River flood levels 20 - 106\*ft3/sec Cohen (1988) p132 CONOV195 two-digit telephone numbers 50 - - Conover (1980) p365 DEWELL24 TWA8 hr Respirable dust 8 5 MG/M3 Dewell (1989) p24 DEWELL42 TWA10 min Formaldehyde 10 2C PPM Dewell (1989) p42 DEWELL44 Welding fumes 11 5 MG/M3 Dewell (1989) p44 GUPTA271 Mice survival time 10 - days Gupta (1952) p271 & Schneider (1986) p69 & 88 HALD151 Diameters of rivet heads 500 - mm Hald (1952) p151 HAW104 TWA8 hr Chlorine 10 0.5 PPM Hawkins (1991) 104 HAW117 TWA8 hr Total dust 15 10 MG/M3 Hawkins (1991) 117 LEIDEL56 TWA20 min Ethyl alcohol 8 1000 PPM Leidel (1977) p56-60 LEIDEL61 Grab sampled Ozone 35 0.1 PPM Leidel (1977) p61-62 LEIDEL63 TWA10 min Hydrogen Sulphide 5 20C PPM Leidel (1977) p63-64 LEIDEL67 TWA8 hr Dioxane 10 100 PPM Leidel (1977) p67-69 LEIDL103 Grab sampled HF 12 3C PPM Leidel (1977) p103-4 LD103 10 HF minus background 0.1 ppm 12 3C PPM Leidel (1977) p103-4 LEIDL104 TWA8 hr Methylmethacrylate 24 100 PPM Leidel (1977) p104 MOF134NS TWA10-30 min Methoxyfluorane 16 - PPM Potts (1988) p134 Nonscavenged MOF134S TWA10-30 min Methoxyfluorane 6 - PPM Potts (1988) p134 Scavenged OWEN716 Grab sampled Chlorine 15 1 PPM Owen (1980) p 716 POSTB11I TWA8 hr Styrene 14 100 PPM Post (1989) A11 Inlayers 08 thru 14 POST1008 TWA8 hr Styrene 9 100 PPM Inlayer/press 10/4 and 08/15 POST08P4 TWA8 hr Styrene 5 100 PPM Inlayer 08 press 4 POST10P5 TWA8 hr Styrene 4 100 PPM Inlayer 10 press 5 RANDOM20 Monte Carlo 2000 - - Lognormal distribution  $EXP(\mu)=1, EXP(\sigma)=2.71828$ SARH212 90Sr in milk 10 - nCu/M3 Sarhan (1962) p212 SCHNE224 Items under stress 50 1 time units Schneider (1986) p224 SCHNE70 Failure distance of locomotives 96 ? 103 miles Schneider (1986) p70 SOLV198 TWA8 hr Hydrocarbons 45 575? MG/M3 Scheffers (1985) p19 X07-10 Chemical X 30 - PPB Gustafson (1991) ch7

### F.1 Computer program and quantitative evaluation

### **F.1.1 English references**

F.1.2 Non English references

### **F.1.1 English references**

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### **5.2.2 Approximation**

Screen 24b displays the:

- probability that the arithmetic mean  $\beta$  is above limit H for dfD25 and GSDD1.64,
- confidence limits including the arithmetic mean  $\beta$  with confidence U%.

The approximate test of  $\beta$  against limit H is based on the following statistic (Jahr 1987, Armstrong 1992):

$$t_{df} = \frac{\text{LOG}\left(\frac{\text{H}}{\text{AM}}\right) * \sqrt{\text{df}}}{\text{LOG(GSD)}}$$

Formula 5-12

Deviate t<sub>df</sub> is, under the null hypothesis, supposed to follow the Student distribution. Estimator A $\beta$ >H of the right side chance  $\alpha\beta$ >H is calculated using t<sub>df</sub>, df and the Student distribution. The corresponding upper confidence limit  $\zeta\beta$ ,U is derived from by logarithmic transformation:

 $C_{\beta,U\%} = AM * GSD \frac{t_{\alpha,df}}{\sqrt{df}}$  Formula 5-13

Example 33 Comparing different estimators of the confidence interval of the arithmetic mean

## Example 33 Comparing different estimators of the confidence interval of the arithmetic mean

Based on the maximum likelihood estimator AMML=exp(+ $s^2/2$ )=1058 PPM, Armstrong (1992 table II) calculated the two-sided 95% confidence limits for the 8 TWA<sub>20</sub> min's Ethyl alcohol (LEIDEL56.HYG) using the exact (Land 1971) and four approximate methods. The bottom line is calculated with <u>5.13</u>.

Method two-sided 95%-tile in ppm Exact 824 1437 simple Student 800 1294 Lognormal Student 808 1386 Cox 841 13322 modified Cox 802 1397 <u>5.13</u> 788 1402

Because the sample has a normal shape and GSD is small and completely explained by CVt (see <u>Example 57</u>), it is difficult to draw any solid conclusion. The approximate method 5.12 seems to have a high sensitivity of finding possible overexposure but a low specificity of rejecting compliance.

Using one-sided values of confidence 2.5% and 97.5% The exact Land method provides in HYGINIST a confidence range of 831.4 thru 1470 ppm

### Maximum likelihood

One of the methods that provides estimators of the parameters of a parent population from samples. ML estimators fulfil certain criteria for consistency, efficiency and sufficiency. In fact ML estimators are consistent, tend to Normality for large sample size, have minimum variance in the limit at least, and provide sufficient statistics where such exist (Kendall 1947 volume II par. 17.22)

# Example 57 CVt Influence on GSD in example data

\*.HYG Description

#### <u>file</u>

LEIDEL63 5 short period exposures to hydrogen sulphide provides an uncorrected relative standard deviation w/AM=0.11. Adjusting GSD=1.12 is not possible because w/AM < CVt=0.12 (Leidel 1977 page 79 table D-1).

HAW117 After removing two results (because the local exhaust system had misfunctioned during sampling) and entering a lower detection limit at LL=1.4 mg/m3 (outlier correction), the remaining 14 TWA8 hour total dust (Hawkins 1991 p117) provides GSDg=1.19 (Figure 11) and w/AM=0.18. Adjusting GSDg for random measurement errors using df=13 and total dust CVt=0.15, provides a GSDadj=1.1

BOLEY62 Boleij (1987 page 63) corrected GSD for CVt, in a series TWA8 hour total dust from a papermill. That is why the GSD=2.68, calculated on the complete sample, differs from the GSD=2.5 presented by the author. Using the raw data, 9 out of 12 ex ceed a lower detection limit of 1.8 mg/m3 (see Figure 12) providing GMg=4.7 mg/m3, GSDg=3.35 and w/AM=1.33, which overshadows any reasonable total dust CVt. So adjusting GSD in this sample is not necessary.

For LEIDEL67.HYG and HAW117.HYG the untransformed Shapiro probability A(W) gives the highest conformity of shape (see <u>Example 15</u>), a second indication that random error determined the variance.

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### **Example 15 Other transformations**

Conformity with other distributions than the Lognormal is found in the following examples from Table 1:

\*.<u>HYG file</u> Description BILAN304 Bilan (1989 p304) indoor sprayer with MDI exposure: A(W)<sub>log</sub>=43.7%, A(W)<sub>lglg</sub>=83%, DEWELL24 Dewell (1989 p24) dust in foundry: A(W)<sub>log</sub>=34.3%, A(W)<sub>lglg</sub>=82%, LEIDEL56 Leidel (1977 p56) 8 TWA<sub>20</sub> min Ethyl Alcohol (Figure 10): A(W)<sub>log</sub>=41.8%, A(W)<sub>unt</sub>= 94.9%, A(W)<sub>x<sup>2</sup></sub>=99.2% Contents - Index

#### **Example 51 Arithmetic mean**

In Figure 23 and Figure 24 the cumulative distributions of 2000 AMs are displayed on Logprobability scale. AMs are calculated from a series of M=50 or M=2 Monte Carlo Lognormal deviates ( $\mu$ =0,  $\sigma$ =1). Lognormal fit of the AM distribution improves with increasing sample size. The Lognormal approximation of the AM distribution can be described by the following descriptive statistics

- EXP(μAM) is nearly EXP(μ+σ<sup>2</sup>/2)=1.6
- EXP(σAM) is nearly EXP(σ)+SQR(1/df) =2.72 (df=1) & 1.15 (df=49).

The rankits estimators displayed in Figure 22 and Figure 23 are comparable:

- GMgdf=1=1.7 and GSDgdf=1=2.73
- GMgdf=49=1.7 and GSDgdf=49=1.19

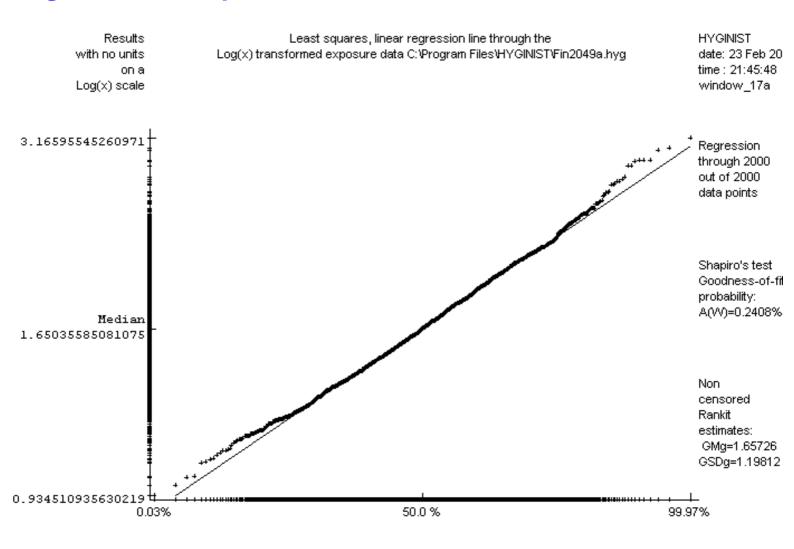
The 50th and 1950th values of the sample data of Figure 22 are 1.19 and 2.29, respectively. The 95% two-sided confidence interval of AM is:

•  $e_{0.5-2.149/\%(49)=1.21}$  and  $e_{0.5+2.827/\%(49)=2.47}$ , based on Land (1975 page 413; s=1, df=49), .

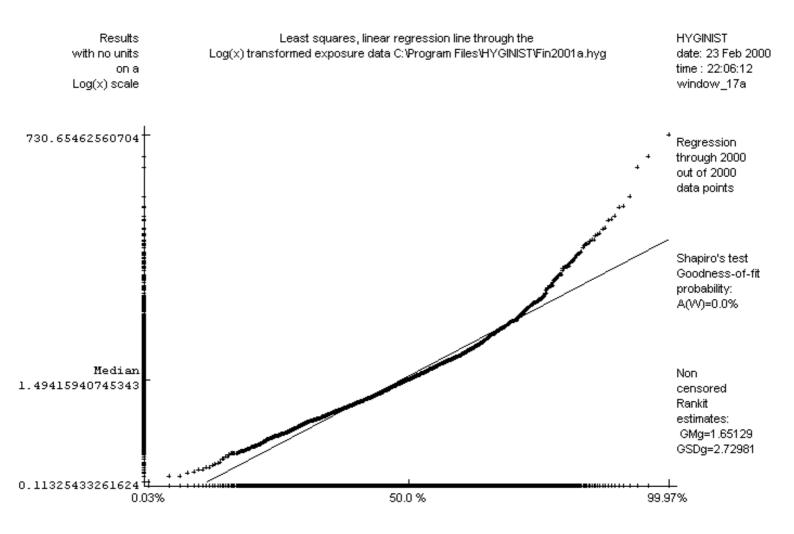
• 1.22 and 2.17, based on the approximate method of Jahr (1987).

<u>Figure 23</u> Rankit plot of 2000 AM values. <u>Figure 24</u> Rankit plot of 2000 AM values. Monte Carlo Lognormal. Sample size 50 Monte Carlo Lognormal. Sample size 50

### Figure 23 Rankit plot of 2000 AM values. Monte Carlo Lognormal. Sample size 50



### Figure 24 Rankit plot of 2000 AM values. Monte Carlo Lognormal. Sample size 50



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## **B.2.5 Variance (2). The relative, arithmetic standard deviation**

The variance (the second moment) of the Lognormal distribution is (Finney 1941 formula 4, Mehran 1973, Shimizu 1988b p9 formula 4.3 and Attfield 1992):

$$\omega^2 = \text{EXP}(2\mu + \sigma^2) * [\text{EXP}(\sigma^2) - l]_{\text{B-17}}$$

The unbiased estimator with minimum variance is (Finney 1941 formula 15, Shimizu 1988b p31 formula 2.7):

$$w = GM * \left[ \phi \left( \frac{s^2}{2} \right) - \phi \left( \frac{M - 2}{M - l} * s^2 \right) \right]^{1/2}$$
B-18

with  $\phi(t)$  as <u>formula B-16</u>. The relative, arithmetic standard deviation (Shimizu 1988 page 10) is:

$$\frac{\omega}{\beta} = \sqrt{\exp\left(\sigma^2\right) - l}$$
B-19

formula B-19 is independent of the location and is also called the sample coefficient of variation (Shimizu 1988b formula 4.10). Its estimator w/AM is the ratio of formula B-18 and formula B-16. w and w/AM are used in the comparison with the:

- measurement coefficient of variation CVt,
- the grouping interval -C.

If CVt and -C/AM are of the same order of magnitude as w/AM, then the Lognormal shape of the exposure variability will be camouflaged.

The most simple method to estimate the standard error of the Lognormal distribution uses the formula B-4 with xi=ci.

### **Asymptotic unbiased**

Asymptotic unbiased or consistent estimator: An estimator which expectation equals the parameter by infinite sample size

### **Autocorrelation**

the phenomenon that observations in a series are dependent upon the preceding

### **Averaging time**

a period of time for which the measuring procedure yields a single result (prEN 482)

### **Bias**

systematic error (Hawkins 1991 156). Consistent deviation of the results from the true value (ISO 6879)

### **Censored distribution**

A distribution with a known fraction of observations outside the detection range (Hald 1949)

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### **B.3.1 Censored sample estimators for EXP(m)**

In the case of a censored sample the program estimates  $\mu$  from the linear regression through the uncensored data M' in the rankits plot. GMg is the regression line median, corresponding to the 50%-tile on the x-axis (R<sub>j</sub>=0):

$$GM^{g} = EXP\left(\frac{\sum_{i=1}^{j=u} \left[x_{i} - LOG(GSD^{g})^{*}R_{i}\right]}{M^{*}}\right)$$

In formula formula B-21 *II* and *uI* are the lowest and highest uncensored data rank and *M'* is the number of results between the accuracy limits. Formula B.21 is identical with the linear, alternative estimators of Gupta (1952 5.2. formulas 31 through 35) and Sarhan (1962 p208 formulas 10C.2.1 and 10C.2.2). See Example 14, 21 and 44 on the rankit estimators for mean and variance of strontium in milk.

#### Example 52 Comparing untransformed linear estimators

For uncensored samples the rankit estimator is as effective as the classical estimators (see <u>B.2</u>). They are more effective than classical solution where results below the detection lower limit LL receive the value .5\*LL (Hornung 1990, Hawkins 1991 p 104). <u>Example 53</u> suggest that the rankits estimators should be preferred in industrial hygiene.

## Example 14 Comparing xcg and scg with estimators from literature

#### \*.HYG file Description

HALD151 The rankit estimators of the untransformed diameters of rivet heads (=13,4304 mm

and s=0,1098 mm Figure 24) are in close agreement with the ML estimators (=13,429 mm and s=0,111 mm) of Hald (1952). Both estimations are based on the  $M^{=}310$  rivet heads above the lower detection limit of 13.40 mm.

The number of degrees of freedom is df=310+190/2-1=404.

The standard deviation  $s_{cg}=0.11$  mm overshadows the grouping interval -C=0.05 mm. Because of the small relative standard deviation  $s_{cg}/x_{cg}=.00812$ , the Lognormal model may be effective as well, with GMg=13.4 mm and GSDg=1.00815.

SARH212 Students measuring Strontium-90 concentrations in milk.

Introducing both a lower limit of LL=8 pCu/l and an upper limit of

10 pCu/l results in M`=5 uncensored data out of M=10 (see Figure 25).

The untransformed rankit estimators of  $\mu$  and  $\sigma$  are x<sub>cg</sub>=9.33 pCu/l and s<sub>cg</sub>=1.87 pCu/l which are equal to the values calculated by Sarhan (1962 page 212).

HAW104 10 TWA's chlorine (.HYG). 3 Below LL=.05 PPM. The untransformed Normal probability

plot (Figure 8) shows an almost perfect regression through the uncensored data. The Normal descriptive statistics are  $x_{cg}$ =.1948 PPM and  $s_{cg}$ =.1992 PPM.

## **Example 21 Comparing GMg and GSDg with estimators from literature**

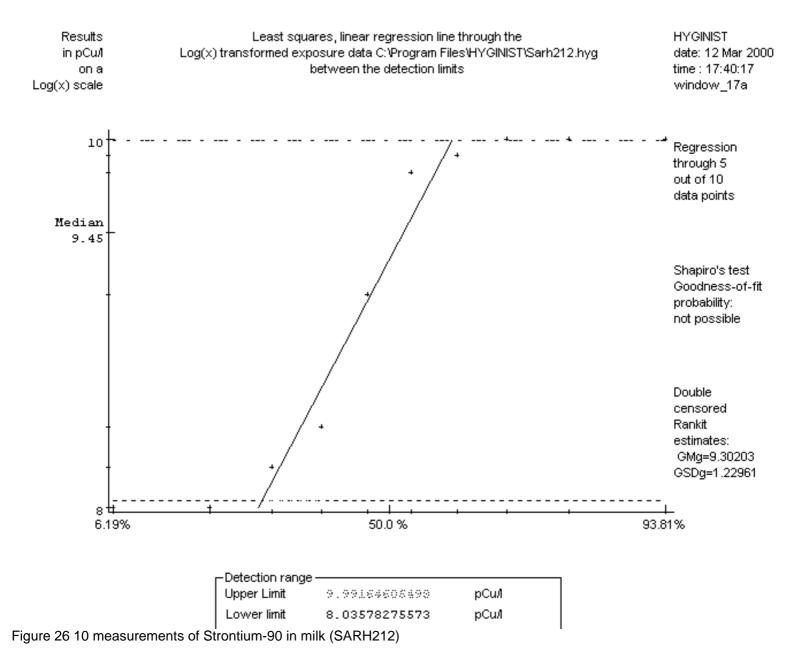
#### \*.HYG file Description

SCHNE224 GMg=9.1 and GSDg=2.12 (see Figure 5) of items under stress are in close agreement with the biased corrected, restricted ML estimators GM=10.942=8.7 TU and GSD=10.3123=2.05 (Schneider 1988 p 224).

LEIDL104 Leidel (1977 p105) estimates GM=34 PPM and GSD= 1.9 from the Lognormal probability plot on 24 TWA8 hour Methyl Methacrylate concentrations in the job category "Mix man". Introducing a virtual lower limit of LL=8 PPM in Screen 17d (see Figure 21), results in GMg=34.5 PPM and GSDg=1.91 PPM based on the complete M`=24 data.

#### **Example 52 Comparing untransformed linear estimators**

Students measuring Strontium-90 concentrations in milk with  $\mu$ =9.22 picoCuries per litre. The 2 lower and the 3 upper extremes (outliers) were excluded from the 10 observations (SARH212.HYG). From the untransformed, double censored sample the rankit regression estimators are mean =9.3251 and standard deviation s=1.8679. These values are equal to the alternative estimators =9.33 and s =1.87 and comparable with the exact estimators x=9.29 and s=1.69 (Sarhan 1962).



# **B.2 Parametric descriptive statistics (complete sample)**

The Lognormal probability density function is completely described by its descriptive statistics  $\mu$  and  $\sigma_2$  (Shimizu 1988 page 2):

$$g(C) = \frac{l}{\sigma^* C^* \sqrt{2\pi}} EXP\left(-\frac{1}{2} * \frac{\left[LOG(C) - \mu\right]^2}{\sigma^2}\right) \text{ for } C > 0$$

$$g(C) = 0 \quad \text{for } C \le 0 \qquad \qquad B-2$$

<u>Table 17</u> displays the symbols used for the population parameters and sample estimators, and refers to the formulas and pages where the algorithms are displayed.

Descriptive statistics are measures for:

- location (modus, median, geometric and arithmetic mean, fractions, extreme values)
   (B.2.2 & B.2.4),
- variance (arithmetic and geometric standard deviation, range) (B.2.3 & B2.5), and
- shape (degrees of freedom, GSD, the higher moments of the normal distribution like kurtosis and skewness).

Descriptive statistics are normally divided in two groups:

• parametric descriptive statistics, which can describe completely a continuous probability density function: the (Log)normal mean and standard deviation s, the Weibull variance and shape, the Chi-square shape df (Shapiro 1991 page 6 & 8),

• distribution free descriptive statistics, which are independent of the shape and thus characterize the probability density function only in part: the extremes, median, modus, fractions and the number of results above or below the industrial hygiene limit value.

The relation between the four measures of location of the Lognormal distribution is: <u>Modus</u> < <u>Median</u> = Geometric mean  $Exp(\mu)$  < Arithmetic mean  $\beta$ .

See <u>example 50</u>

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## Table 17 Notations used for the Lognormal descriptive statistics

Name Descriptive statistic formula & page Population parameter Sample estimates uncensored censored Measures for location Mean of log(C)  $\mu$  formula B-3 -

Geometric Mean EXP( $\mu$ ) GM, GMu, GMg formula B-9 & formula B-21 & formula B-11 formula B-11

Arithmetic Mean  $\beta$ =EXP( $\mu$ + $\sigma$ <sup>2</sup>/2) AM formula B-16 formula B-16

Median EXP(µ) ME - -

Modus EXP( $\mu$ - $\sigma^2$ ) - - -

Measures for scale Variance of log(C)  $\sigma^2 s^2$  formula B-4 -

Geom. Standard Dev.  $EXP(\sigma)$  GSD, GSDg formula B-13 formula B-20

Arithmetic Standard-  $\omega$ =EXP( $\mu$ + $\sigma^2/2$ )\* w formula B-18 formula B-18 Deviation (ASD) sqr{EXP( $\sigma^2$ )-1}

Relative ASD  $\omega/\beta$ =sqr{EXP( $\sigma^2$ )-1} w/AM formula B-19 formula B-19

### Modus

The value in a distribution with the highest frequency.

### **Median**

The most central result or, in case that sample size is even, the arithmetic mean of the untransformed two most central data

### **B.2.2 Location (1). The geometric mean**

The geometric mean  $EXP(\mu)$ :

- is a measure of source strength (Seixas 1988, Rock 1982),
- has a unit dimension of intensity or concentration,
- can take every real value over zero,
- is identical to the median.

If an estimator of  $EXP(\mu)$  exceeds a corresponding hygienic limit value H, then at least one result of the sample exceeds limit H.

There are four sample estimators:

- the maximum likelihood (see <u>B.2.2.3</u>)
- The unbiased (see **B.2.2.1**)
- The median
- The rankit estimator

For the confidence limits around GM see B.2.2.2

#### Notes:

- GM in B.6 is biased but consistent: for limited sample size it overestimates  $EXP(\mu)$  on the average. See <u>B.2.2.1</u>.
- If the sample include undetectables then GM is estimated using rankit regression B.3.1.
- GM is necessary for the calculation of:
- tests on the limit value (chapter 5), and
- inference statistics (chapter 6).
- sample size calculations (<u>chapter 7</u>)

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### **B.2.2.3 The maximum likelihood estimator**

The most commonly used estimator for  $EXP(\mu)$  for a sample without undetectables is the antilog of the sum of the logarithms of the results c<sub>i</sub>, divided by the sample size M:

 $GM = EXP(\overline{x})_{B-6}$ 

with  $\overline{x}$  defined as in formula <u>B.3</u>.

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#### **B.2.2.1 The unbiased estimator**

The bias of the Geometric Mean estimator GM (see  $\underline{B.6}$ ) is exactly known (Laurent 1963 formula 1):

 $E(GM) = EXP\left(\mu + \frac{\sigma^2}{2M}\right)_{B-7}$ 

The average overestimation EXP( $\sigma_2/2M$ ) decreases with increasing sample size M. For  $\sigma_2$  about unity, a common value for the variance, and M<=10 the bias is >=5%. An unbiased estimator of EXP( $\mu$ ) with minimum variance was developed by Laurent (1963, see Shimizu 1988 page 29). Laurent's algorithm (1963, formula 7), however, is a Bessel function of the first kind and order (M-3)/2, and is difficult to calculate with values for the descriptive statistics which are relevant in industrial hygiene.

The following algorithm is more effective in industrial hygiene. The bias function EXP( $-\sigma_2/2M$ ) is first expanded in a Taylor series (Abramowitz 1970 formula 4.2.1.):

$$EXP\left(\frac{-\sigma^{2}}{2M}\right) = \sum_{k=0}^{\infty} \frac{\left(-\frac{\sigma^{2}}{2M}\right)^{k}}{k!}$$
$$= 1 - \left(\frac{\sigma^{2}}{2M}\right) + \left(\frac{\sigma^{4}}{(2M)^{2} + 2!}\right) - \left(\frac{\sigma^{6}}{(2M)^{3} + 3!}\right) + \dots B-8$$

In the Taylor series the unbiased and efficient estimator of the numerator  $\sigma_{2k}$  is (Laurent 1963 formula 4):

$$\mathsf{E}(\sigma^{2k}) = \frac{\Gamma\left(\frac{\psi\cdot 1}{2}\right)}{\Gamma\left(k + \frac{\psi\cdot 1}{2}\right)} * s^{2k} * \left(\frac{\mathsf{M}}{2}\right)^{k} \mathsf{B-9}$$

The ratio of the two Gamma functions G[(M-1)/2] and G[k+(M-1)/2] can be expanded and easily programmed in a series using formula 6.1.22 of Abramowitz (1970):

$$\frac{\Gamma_{u}}{\Gamma_{k,u}} \frac{1}{(k-1+\frac{u-1}{2})^{*}(k-2+\frac{u-1}{2})^{*}...^{*}(\frac{u-1}{2})} \qquad (k \ge 0)$$
B-10

Substitution of formula B-10 in formula B-9 and than in the numerator of formula B-8 results in an unbiased estimator for  $EXP(\mu)$  with minimum variance:

$$GM^{u} = GM \star \phi \left( - \frac{s^{2}}{4} \right)$$
with
$$\Phi(t) = \sum_{k=0}^{\infty} \left( \frac{\Gamma u}{\Gamma_{k,u}} \star \frac{t^{k}}{k!} \right)$$
B-11

The accuracy of BASIC is such (see D.3) that formula B-11 is calculable for GSD/M<sup>2</sup><6. Because M<sup>2</sup>>=4 (by definition) and GSD's are mostly smaller than 24 (see <u>B.2.3</u>), formula B-11 is effective in industrial hygiene practice. Depending on the values of s and M,  $\underline{O}(t)$  needs up to thirty terms before a constant value is reached.

# **B.2.3 Variance (1). The geometric standard deviation**

The geometric standard deviation  $EXP(\sigma)$  is a parameter:

- of scale and shape (see Figure 21 in Shimizu 1988a p10, Shapiro 1991 p6),
- without a dimension,
- larger than unity (by definition).

If all sample data are equal, then the <u>estimator of  $EXP(\sigma)$ </u> equals unity and is useless.

According to Leidel (1977 page 73) group GSDs commonly occur in the range 1.5 to 2.5. In Dutch series Buringh (1989, 1991) found GSD values between 1.4 and 3.5. For the estimation of the sample size Corn (1985 p 176) uses a EXP( $\sigma$ ) between 2.2 and 2.5. Kromhout (1993) reports a median GSD=2.41 in 45 studies yielding almost 20000 measurements. GSDs seem to have been increasing the last few decades, especially in chemical industry (Kromhout 1993). A change in organizing work (from fixed post operations to team structure) is a possible explanation.

Some windows in this manual will show the value GSD=EXP(1)=2.71828 as an example.

#### **B.2.3.1 The unbiased estimator**

The unbiased estimator of  $EXP(\sigma)$  with minimum variance is the antilog of the standard deviation of the logarithms of the results:

 $GSD = EXP(s)_{B-13}$ 

with s as defined in formula  $\underline{B.4}$ . For confidence limits of the GSD see  $\underline{B.2.3.2}$ 

#### **B.2.3.2 Confidence limits**

The variance ratio  $s_2/\sigma_2$  follows, under the null hypothesis (s= $\sigma$ ), the Chi-square distribution (Abramowitz 1970 26.4). The limits, including EXP( $\sigma$ ) with confidence U%, are calculated using (Land 1988 page 98 4.1.2.):

$$GSD_{U\%} = GSD^{\pm} \frac{X_{U\%, df}}{\sqrt{M}}$$

where  $\chi_{U\%,df}$  is the square root of the Chi-square distribution with df degrees of freedom.

#### **B.2.2.2 Confidence limits**

LOG(GM)/ $\mu$  follows, under the null hypothesis, the Student distribution (Snedecor 1980, 4.9). The upper and lower limits, including EXP( $\mu$ ) with confidence U%, are calculated using (Land 1988 page 93 3.1 and 3.2):

```
GM_{W} = GM * GSD^{-\frac{(180)}{\sqrt{M}}} B-12
```

where tu%,df is the deviate of the Student distribution with df degrees of freedom and U% is the desired percentage of the confidence limit, mostly 5% and/or 95%. The two-sided confidence interval is the fraction between two confidence limits.

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### **5 EXTRAPOLATION AND COMPLIANCE TESTING**

The tabs <Upper Limit UTL> and <Mean UCL> calculate the <u>effectiveness</u> of workplace control measures on exposure by:

- extrapolating the exposure data to general results,
- testing exposure distribution against an industrial hygiene limit value.

Based on the exposure assessment goal and the required sample properties, <u>Table 7</u> helps to choose the statistical method that is appropriate for extrapolation and compliance testing.

Table 7 Choosing the most appropriate method to generalize and test series sample exposure data.

Industrial Hygiene extrapolation and compliance testing deals with estimating:

- The true <u>fraction of the distribution</u> beneath a certain value
- The true value of a descriptive statistic, mostly the arithmetic mean

#### Remarks.

Calculations presented are performed exclusively with:

- the estimators of  $EXP(\mu)$  and  $EXP(\sigma)$  and the number of degrees of freedom df,
- the industrial hygiene limit value H and the desired percentage U%,
- the Noncentral Student or special cases of this distribution (Owen 1968).

The theory of the Lognormal methods used in this chapter is described extensively by Land (1988 page. 87-106).

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### **Effectivity, Effectiveness**

The combined minimum of systematic (bias, accuracy) and random errors (efficiency, variance, precision). Increases if the systematic error of the first and second kind and the random error decrease

### Table 7 Choosing the most <u>appropriate</u> method to generalise andtest series sample exposure data.

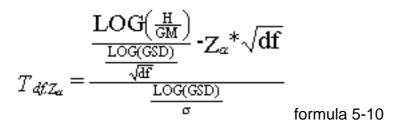
_	<u> </u>			
	Required Uncen-	l sample proj	perties	-
	sored sample	Lognormal-		Statistical method.
Exposure assessment goal	size	conformity	GSD <sup>2</sup>	Chapter (screen)
Long term TVVA <sub>reference period</sub> con- trol <sup>3</sup> :Which fraction of the TVVA <sub>ref per</sub> exceeds the limit value H <sub>ref per</sub> ?	≥20	≥ very good	≤3.5	Standard Normal (Leidel) →par. 5.1.2, (Screen 24)
	≥2	≥ accept- able	>1	Unbiased Student (Wilks) →par <sub></sub> 5.1.3, (Screen 25)
What is the confidence δ that H <sub>ref per</sub> is exceeded ≤α% of the times?	→≥2	≥ accept- able	>1	Noncentral Student (Tug- gle) par. <mark>5.1.4</mark> , (Screen →26)
Dose assessment. What is the: grab sample based chance of exceeding H <sub>ret per</sub> ?	df<25	≥ accept- able	≤3	Dose, UMP (Bar-Shalom) →par. <mark>5.2.1</mark> (Screen 24)
TWA <sub>ref per</sub> based chance that dose β <sub>ref per</sub> exceeds H <sub>ref per</sub> ?	≥ 2	≥ accept- able	>1	Dose, approximate (Jahr) →par. 5.2.2 Screen 27
Ceiling control: What is the confi- dence δ that H <sub>ceiling</sub> is exceeded ≤α% of the times?	≥5	Rejected	-	→Nonparametric par. <u>5.3</u> -
	≥2	≥ acceptable	>1	Noncentral Student par. →5.3.3 Screen 26

Statistical analysis can prove poor quality in a data series but cannot improve it (The "rubbish in, rubbish out" principle). The user should have basic knowledge on exposure assessment, including assessment strategy and compliance control and should act accordingly to perform extrapolation and compliance testing successfully.

### 5.1.4 Noncentral Student, tolerance limits (Tuggle)

To improve the NIOSH decision scheme (Leidel 1977 figure 1.1 page 11) when GSD>2, the one-sided tolerance limit (OTL) method was introduced by Tuggle (1981, 1982). The Belgium Standard Institute (BIN 1987) officially published an assessment strategy based on Tuggle's method. Screen 27 displays the confidence  $\delta$  that < $\alpha$ % of the exposures is over limit H.

The confidence  $\delta(C\alpha_{<100-U\%>H})$  with a fixed non-compliance probability  $\alpha_{<100-U\%}$  is estimated with the following test statistic (based on Tuggle 1982 formula B-2 page 345):



Tdf,z $\alpha$  is, under the null hypothesis, a deviate of the Noncentral Student distribution. The estimator D{C $\alpha$ <100-U%>H} is calculated using Tdf,z $\alpha$  the number of degrees of freedom df and the noncentrality parameter Z $\alpha$ , the deviate corresponding with the standard normal probability  $\alpha$ =100-U%.

```
Input U, Tdf,Z\alpha and/or df output D(C\alpha<100-U%>H)

\alphaW50% - Not accepted U%=100-\alpha value in screen 21

50-\alphaW10-14% - central Student formula 5.6

UD99.9999% - Not accepted U%=100-\alpha value in screen 21

0<Tdf,Z\alpha<10-16 - 50 %

Tdf,Z\alphaD10-16 W200 algorithms of Owen (1956 formula 3.9 & 1968 page 464)

Tdf,Z\alphaD10-16 >200 Normal approximate Algorithm 26.7.10 (Abramowitz 1970)
```

According to Leidel (1977 page 118) an employer should try to attain  $\delta D95\%$  confidence that workers exposure is with  $\alpha W5\%$  over the limit.

The upper or one-sided tolerance limit (UTL)  $\zeta \alpha_{<100-U\%,\delta}DU\%$  is estimated using:

 $C_{\alpha < 100 U\%} = GM * GSD^{T_{d/\alpha\beta}}$ formula 5-11

The program calculates the one-sided upper tolerance limits (UTL) if the desired percentage U% is more than 50%. The UTL is the concentration under which U% of the population data lies with U% confidence.

The one-sided upper tolerance limit (UTL) is calculated as follows:

• first a linear interpolation from D=0% to D=100% with GM/GSD as the initiating value and GSD as the multiplication constant

• If the situation is reached that D(n+1)>100-U%>D(n), then an inverse linear approximation (General Falsi or False position; Abramowitz 1970 chapter 3.9.3) is performed. The accuracy of UTL is such that ABS[D(UTL)-U%)<0.01%.

If the desired confidence U% and the GSD are extreme high and the sample size is extreme low, then the interpolation may take some time.

A non-iterative algorithm to calculate the inverse Noncentral Student based  $C\alpha_{<100-U\%,\delta}Du\%$  does not exist. The approximations of Patel (1982 chapter 7.11 page 204 Cornish-Fisher expansion), Johnson and Kotz (1970 30.5 page 194) and Owen (1968 page 468 a comparison of different algorithms) are, for common industrial hygiene values of M (small <10) and GSD (large >2), inaccurate. One-sided tolerance factors  $T_{df,\alpha,\delta}$  for specific values of Z $\alpha$  and Z $\delta$  can be found in the tables of Resnikoff (1957), Ciba-Geigy (1980), Odeh (1980), Bezemer (1981), Tuggle (1982), Hawkins (1991 Table IV.1 page 136) and the charts in BIN (1987). There are small differences between the tolerance factors used by Tuggle and Hawkins (both from NBS 1966) and the tables of Odeh (1980). The latest is considered more accurate.

Example 31 Noncentral student tolerance limits

#### 5.1.3 Unbiased estimate of compliance (Wilks)

To improve the small sample bias of the NIOSH test statistic (see table 9) the unbiased method of Wilks was introduced in industrial hygiene (Scheffers 1987). The method has been developed in the quality control of large scale product lines with homogeneous conditions (e.g. chemical refineries, battery production; Proschan 1953 page 556), which is comparable with long-term non-compliance control in similar exposure groups. Screen 26 displays the unbiased estimation of the non-compliance probability and the corresponding tolerance limit.

The algorithm developed Wilks (1941) was proven mathematically correct by Proschan (1953). The unbiased non-compliance probability test against limit H is based on the following test statistic:

$$t_{df} = \frac{\text{LOG}\left(\frac{\text{H}}{\text{GM}}\right)}{\text{LOG}(\text{GSD})^* \sqrt{1 + \frac{1}{\text{df} + 1}}}$$
Formula 5-5

tdf follows, under the null hypothesis, the central student distribution. The right sided non-compliance probability At is the Student density distribution integrated from tdf to infinity:

$$A_{t_{af}} = \frac{\Gamma\left(\frac{df+1}{2}\right)}{\sqrt{df^*\pi} * \Gamma\left(\frac{df}{2}\right)} * \int_{t_{df}}^{\infty} (1 + \frac{x^2}{2})^{\frac{df+1}{2}} dx$$

with

 $t_{df} > 0$ 

Formula 5-6

The Student distribution is a special case of the Noncentral Student (Owen 1968) with noncentrality parameter  $Z\delta$ =0. non-compliance probability AC>H in 5.3 is calculated from tdf and df using:

ABS(tdf) df output AC>H %=100 \* At

<1E-16 - 50 %

>=1E-16 <=30000 Power series of Owen (1968 page 465). Relative accuracy -A%/A%=1E-4

>=1E-16 >30000 Normal approximate Algorithm 26.7.8 (Abramowitz 1970)

The corresponding tolerance limit  $QU >= 100 \cdot \alpha\%$  is derived from formula 5.5 by logarithmic transformation:

5.1.3 Unbiased estimate of compliance (Wilks)

$$\mathcal{C}_{U \gg 100 \alpha \%} = GM * GSD^{*\alpha, q} \sqrt{\frac{1+\frac{1}{df+1}}{df+1}}$$
 Formula 5-7

The unbiased Student tolerance factor  $t\alpha$ , df is calculated from  $\alpha$  and df using:

Input  $\alpha$  % and df output t\alpha,df

ABS(a-50)<0.00001 % ≥1 0

$$\tan\left(\frac{(50-A)*\pi}{100}\right)$$
 Formula 5-8

$$X * \sqrt{\left(\frac{2}{1 - X^2}\right)}$$
 with  $X = 1 - \frac{A}{50}$   
Formula 5-9

 $0.0001 \le \alpha \le 99.9999\% 2$ 

 $0.0001 \le \alpha \le 99.9999\% \ge 3$  and  $\ge 1000$  Newton-Raphson iteration (Abramowitz 1970 3.9.5.) on the power series of Owen (1968 page 465), with the asymptotic expansion 26.7.5. (Abramowitz 1970) as initiator. -t/t<1E-6

0.0001<= α <=99.9999% >1000 Asymptotic expansion 26.7.5. (Abramowitz 1970)

<0.0001% or >99.9999% Any value not accepted U% value in screen 21

The unbiased estimate is effective in large <u>similar exposure groups</u>. With small but efficient sampling plans the <u>effectiveness</u> of control measures in a SEG can be assessed using control charts, examining goodness-of-fit and non-compliance probability calculations, just as is done in quality control for over decades (see e.g. Morrison 1958). ÇU≥##% overestimates CU≥##% on the average. For an unbiased estimate ÇUD##%, see Owen (1968 page 461).

Example 28 Wilks tolerance limits and compliance probability

Figure 15 Vinylchloride Control chart in a SEG PVC operators TWA8 hours over 1987-1993

Figure 16 Lognormal probability distribution of 37 VCM TWA8hours

Example 29 Unbiased estimate of the long-term TWA control effectiveness

Example 30 Different number of degrees of freedom

#### Similar exposure group

• A group of workers performing the same tasks on the average and with a long term exposure variability that outshines any systematic between worker exposure variability (ad hoc).

## Example 28 Wilks tolerance limits and compliance probability

\*.HYG name File description Size Units df H AC>H% ÇU<=5% ÇU>=95%

BOLEY62 TWA8 hour PAS 12 mg/m3 9 10 28.3 0.46 48.2 papermill total dust

COHEN132 maximum flood levels 20 106ft3/sec 18 - - 0.23 0.68

DEWELL24 TWA8 hour respirable 8 mg/m3 6 5 0.08 1.02 2.37 dust in foundry

DEWELL44 TWA8 hour PAS 11 mg/m3 9 5 89.8 3.82 32.4 welding [MIG] fume

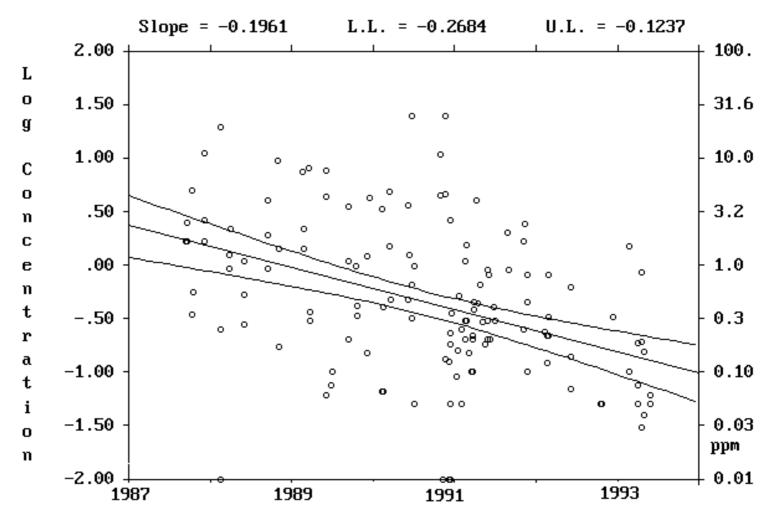
GUPTA271 mice survival after 10 Days 7 - - 36.2 86.6 inoculation with tuberculosis

HAW117 TWA8 hour PAS 15 mg/m3 13 10 7\*10-5 1.59 3.02 total dust

SCHNE224 Survival of items 50 TU 30 1 99.7 2.5 33.4 under stress

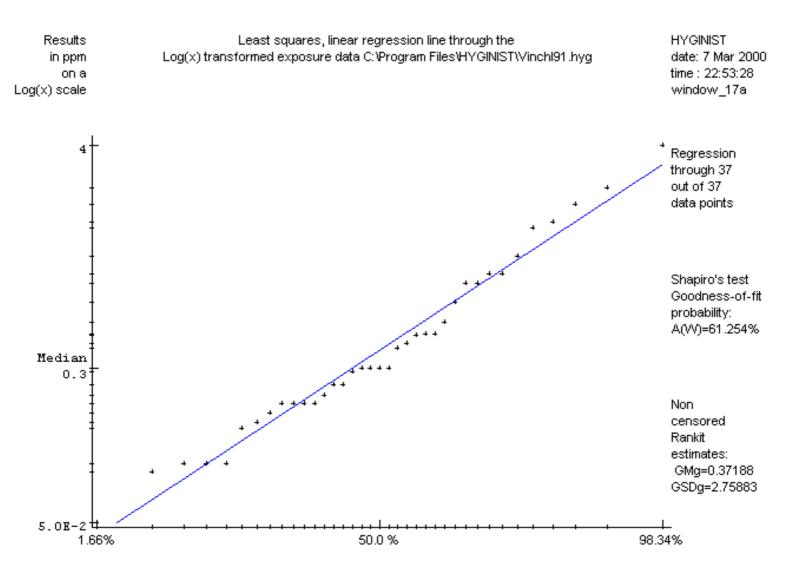
For SCHNE224 a lower quality limit is introduces of H=1 TU, which should be exceeded by 99% of the items.

## Figure 15 Vinylchloride Control chart in a SEG PVC operators TWA8 hours over 1987-1993



Calender years

## Figure 16 Lognormal probability distribution of 37 VCM TWA8hours



#### **Example 29 Unbiased estimate of the long-term TWA control effectiveness**

#### \*.HYG file Description

LEIDEL67 The 10 TWA8 hour Dioxane, see Figure 1 and screen 25), sampled on different days in a period of 6 months on one employee are tested against the H8 hour=100 PPM. Because GSD=1.63 and LOG(H/GM)=0.24 are both small, the bias of the standard normal method is also small (see table 9). The unbiased estimate AC>H=32.4% corresponds with the Pn=.0309 calculated by Leidel (1977 page 69).

LEIDL104 With 24 TWA's in the job category "Mix man" in a facility using Methyl methacrylate the unbiased estimate of the non-compliance probability is  $A_{C>H}$ = 5.7068 %, indicating (in deviation with the NIOSH method see Example 27) that control measures are necessary.

VINCHL91 In a PVC production plant, the SEG polymerisation shift workers are monitored on

Vinylchloride using a routine plan using a stratified PAS TWA8 hour sampling plan (every four weeks, one day, three consecutive measurements, around the clock). The results since 1987 are displayed in the exposure control chart Figure 15. A limit H<sub>8 hour</sub>=7 PPM is derived from the European Community exposure limit H<sub>EC,1</sub> year=3 PPM (EC 1978 L197/16). The Lognormal fit of the 37 TWA8 hour data in 1991 is complete (Figure 16 and Aw=0.974=63 %). With df=36, GM=0.37, GSD=2.73 unbiased estimate is AC>H=0.3 % and the upper tolerance limit cu>=95%=2.1 PPM, indicating that the control measures are effective. See Example 34 for the test against H<sub>1</sub> year=3 PPM.

- In a sample with GSD=2.71828 the ratio upper tolerance limit/geometric mean is for: df=1 -> C95%/EXP( $\mu$ )>=2182.

So compliance is reached if the geometric mean exposure EXP( $\mu$ ) is below 0.05% of the limit value H. The lower accuracy limit of measurement methods for contaminants in workplace air will in most cases not include H/2000. Increasing df to infinite decreases C95%/EXP( $\mu$ )

asymptotically to the standard Normal ratio of 5.18 (see further chapter 7).

# Example 30 Different number of degrees of freedom

\*.HYG file Description

SCHNE224 The survival of items under stress is Lognormal distributed (Schneider 1986 page

224; see Figure 5). If the (accelerated) lifetime is above 1 time units (TU), then an item conforms the quality limit. 15 items out of a sample of 50 failed before 6 TU. In a conservative approach, using df=M'-1=14, AC>1 TU=99.4% and  $\zeta$ 5%=2.3 TU, indicates only a borderline difference from the values calculated in Example 29.

The tables 1.#.# of Odeh (1980 page 18 through 69 using  $\gamma$ , 1-P and N for confidence  $\gamma$ , non-compliance probability  $\alpha$ , and sample size M respectively) provide tolerance factors for:  $\delta$ = .995, .99, .975, .95, .9, .75, .5, .25, .1, .05, .01, .005 1- $\alpha$ = .75, .90, .95, .975, .99, .999 M= 2(1)100(2)180(5)300(10)400(25)650(50)1000, 1500, 2000, 3000,5000,10000,  $\infty$ 

#### **Example 31 Noncentral student tolerance limits**

#### \*.HYG file Description

LEIDL104 The 24 TWA<sub>8 hours</sub> indicate that the confidence of being in compliance for job category "Mix man" in a facility using Methyl methacrylate is  $\delta$ =51%. Thus consecutive sampling plans with M=24, will have a chance of 51% of finding non-compliance probability  $\alpha$ W5%.

SOLV198 From 45 TWA8 hours Hydrocarbons during solvent based paint rolling and spraying the two-sided 95% tolerance limits with  $\delta$ =95% confidence (9.4 and 1076 mg/m3) were calculated using the tolerance factor k7=2.408 from Ciba-Geigy (1980). The one-sided tolerance factor for calculating the 2.5% and 97.5% limits with  $\delta$ =95% is Tdf, $\alpha$ , $\delta$ =2.463 and provides 8.9-1141 mg/m3.

- Tuggle (1981 p 491) evaluated 3 measurements of 0.60, 0.58 and .63 with a PEL of 1.0. The sample 10log=-0.22 (GM=0.6) and s=0.02 (in real s=0.018 thus GSD=1.02). With the use of the tolerance factor Tdf, $\alpha$ =5, $\delta$ =95=7.655 the UTL=-0.22+7.655\*.22=-0.08 is less than 10log(PEL)=0. Only because of the unrealistic small sample GSD this small sample size problem is in compliance.

SCHNE70 The 97.5% UCL of U=90% of the 96 locomotives, With 37 failures before 135,000 Miles is estimated from the data presented by Schneider (1986 example 6.3 page 202) as 547,016 Miles. This mileage value corresponds, however, with  $Dc_{\alpha<10\%}>547,016=90.5\%$  for the Noncentral Student with df=65. The tolerance limit calculated with table 1.4.1. of Odeh (1980) is  $C_{\alpha<10\%,\delta D97.5\%,df=65=174,249*2.11718_{1.657}=603,883$  Miles.

HAW117 From 14 random TWA8 hour PAS total dust above LL=1.4 mg/m3 the one-sided upper tolerance limit including 90% of the concentrations with 95% confidence and df=13 is H=3.1712 mg/m3. This is comparable with the values calculated by Hawkins (1991) page 140 table IV.2 bottom line (UTLc=3.06 and 3.29). See also Example 57.

- In a sample with GSDD2.71828 the ratio upper tolerance limit/geometric mean is for:
- df=1 ° C $\delta$ D95%, $\alpha$ <5%,df=1/EXP( $\mu$ )D2.5384\*1011
- df=2 ° CδD95%,α<5%,df=2/EXP(μ)D2113.28

Due to the limitations in the industrial hygiene sampling/analytical methods, a concentration of H/2000 is difficult to assess for most contaminants in workplace air. Increasing df decreases  $C\delta D_{95\%,\alpha<5\%}/EXP(\mu)$  asymptotically to 5.18.

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#### **5.1.2 Standard Normal (Leidel)**

This generally accepted, long-term non-compliance probability method obtains its status from the recommendation of the USA's "National Institute of Occupational Safety and Health" (Leidel 1977). As is displayed in screen 25, its application is tied to such rigorous criteria on sample size, Lognormal fit and variance, that most industrial hygiene data sets cannot be evaluated using this method.

To estimate  $\alpha_{C>H}$ , Leidel (1977 page 69) replaced log(C)- $\mu$  and  $\sigma$  in formula 5-1 with the estimators LOG(H/GM) and LOG(GSD) respectively. The non-compliance probability test is based on the following statistic:

$$Z = \frac{\text{LOG}\left(\frac{\text{H}}{\text{GM}}\right)}{\text{LOG}(\text{GSD})}_{\text{formula 5-2}}$$

Z is, under the null hypothesis, a deviate of the standard Normal distribution with probability AC>H:

$$A_{Z} = \frac{1}{\sqrt{2^{*} \pi}} \int_{Z}^{\infty} e^{-x^{2}/2} dx$$
 formula 5-3

The standard Normal distribution is a special case of the Noncentral Student (Owen 1968) with df=infinite and noncentrality parameter  $Z\delta=0$ . non-compliance probability Ac>H in 5.3 is calculated from Z using:

input value Z output Ac>H=100 \* Az

```
ABS(Z)<1E-14 50 %
ABS(Z)<+5 the power series 26.2.11 of Abramowitz (1970). Accuracy -A<1E-12%
5<ABS(Z)<=37 the approximate fraction expansion AS 66 of Hill (1973). Accuracy -A<1E-
11%
<-8 100 %
-8<=Z<37 1E-300 <=Az<+99.99999999999999
>37 0 %
```

The tolerance limit  $C_{UD100-\alpha\%}$  is derived from formula 5.2, by exponential transformation:

 $\mathbf{C}_{U \ge 100 \cdot \alpha\%} = GM * GSD^{Z_{\alpha}}$  formula 5-4

The standard Normal tolerance factor Z $\alpha$  is calculated from  $\alpha$  using: Value of  $\alpha$  output Z $\alpha$ ABS( $\alpha$ -50)<1E-4 % 0 D1E-4% and <=99.9999% Polynomials AS 111 of Beasley (1977), followed by the inverse interpolation of Abramowitz1970 p954 Example 5). Accuracy -Z<5\*1E-16 <1E-4 % or >99.9999% Not accepted U% values in screen 21

Example 26 NIOSH tolerance limits and compliance probability

Example 27 Calculating standard normal tolerance limits from literature sources

# Example 26 NIOSH tolerance limits and compliance probability

\*.HYG name File description Size units df H AC>H % ÇUW5% ÇUD95%

LEIDEL67 TWA8 hour Dioxane 10 PPM 9 100 31.0 35.1 175.4 LEIDL104 TWA8 hour Methyl methacrylate 24 PPM 23 100 4.7 12.1 98.0 RANDOM20 standard Lognormal deviates 2000 - 1999 - - 0.19 5.11 SCHNE70 Locomotive controls 96 103 miles 37 - - 50.7 598.4

See Example 28 for more details.

#### **Example 27 Calculating standard normal** tolerance limits from literature sources

\*.HYG file description

LEIDL104 With 24 TWA8 hour Methyl methacrylate in the job category "Mix man", the NIOSH non-compliance probability is  $A_{C>H}=4.7$  % (see screen 25 and Example 26).

Engineering controls are not necessary (Leidel 1977 p104). This conclusion contrasts with the unbiased method (see Example 29).

LEIDEL67 Leidel (1977 4.4 p65) utilised 10 TWA<sub>8 hour</sub> Dioxane (see Figure 1) to illustrate the NIOSH method of using the probability of non-compliance to decide if engineering controls should be installed. The non-compliance probability  $A_{C>H}=31\%$  equals  $P_n=.0309$  calculated by Leidel (1977 page 69). Since non-compliance is so obvious, there is no reason to criticise the use of the standard normal method because of its small sample size (see <u>table 7</u>).

RANDOM20 The 5th and 95th percentile values in the series 2000 Monte Carlo standard Lognormal deviates are 0.1933 and 5.053, and agree with the calculated values .1927 of 5.110 (see <u>Example 26</u>)

SCHNE70 The Lognormal fit (see Figure 6) and the number of failed locomotives are such that standard Normal extrapolation is allowed (see <u>table 4</u>). Schneider (1986 example 6.3) calculates the 10th percentile as  $10_{1.826+3}=66,988$  Miles using the bias corrected estimators of  $\mu$  and  $\sigma$ . The standard Normal lower tolerance limit is almost equal:  $C_UW_{10\%}=66,634$  Miles.

# Table 4 Lognormal goodness-of-fit decision scheme

What's the shape of logarithmic Is the Goodness- Transfor- Uncen Lognormal transformed scatterplot sample of-fit mation sored <u>conformity</u> within the accuracy range, censored <u>A(W)% fit</u> Sample along the regression line ? ? size

straight line no ≥95 best ≥20 perfect ditto yes - best ≥20 very good

slightly curvilinear no ≤95 best ≥20 good

linear tendency, slightly oscillating no  $\ge$ 95 best  $\ge$ 3 good ditto no 5-95  $\ge$ 2nd best  $\ge$ 3  $\ge$ acceptable ditto yes -  $\ge$ 2nd best  $\ge$ 3  $\ge$ acceptable

unknown (descriptive statistics only), but reliable assessment strategy - - -  $\ge$ 2 Acceptable

Curvilinear no <95 <2nd best  $\geq$ 3

Oscillating no <5 - ≥3 Lognormality

oscillating or curvilinear yes - <2nd best ≥3 Rejected

This categorical classification increases from rejected (nonconformity), acceptable, good, very good, to perfect (complete conformity).

Low A(W) values of the omnibus W-test of Shapiro (1965) indicate low conformity with the Lognormal shape.

The Lognormal goodness-of-fit rank order, among the transformations (< less than, <= at most, => at least).

The number of exposure data  $M\$  within the accuracy range

See § 5.1.1 for the differences between the three statistical methods

If the measurement method random error (CVt\*AM) or the grouping interval (@C) are larger than the arithmetic standard deviation w (see § 4.1.1), then GSD should be adjusted (see §B.6). If GSD>1.4, then random error is in most cases irrelevant.

#### **B.6 GSD and CVt**

Part of the sample variance may be explained by the non-systematic measurement error CVt. Based on the relation between EXP( $\sigma$ ) and the arithmetic mean  $\beta$  and variance  $\omega^2$  (Leidel 1977, table M-1):

$$\sigma = \sqrt{\text{LOG}\left(1 + \frac{\omega^2}{\beta^2}\right)}$$

with the population descriptiv e statistics :

 $\sigma = \text{standard deviation of } \log (C_i)$ 

 $\omega = arithmetic$  standard deviation of  $C_i$ 

 $\beta$  = arithmetic mean of  $C_i$ 

A relative adjustment factor R can be derived using w2=wt2-se2 with:

• wt<sup>2</sup> the total arithmetic variance of the sample data (see formula B-16),

• se2 the variance caused by measurement error and, according to Leidel (1977 p50 NOTE), se2= $(CVt^*H)^2$ .

$$GSD_{adj} = R_{adj}^{GSD} * GSD$$
with
$$R_{adj}^{GSD} = \frac{EXP \sqrt{LOG \left(1 + \frac{w_t^2 - (CV_t^*H)^2}{AM^2}\right)}}{EXP \sqrt{LOG \left(1 + \frac{w_t^2}{AM^2}\right)}}$$

AM and wt<sup>2</sup> are the unbiased estimators of the arithmetic mean  $\beta$  and the arithmetic standard deviation  $\omega$  (see formulas 5.16 and 5.18). If wt<CVt\*H, then the square root of a negative number is extracted in the denominator and formula 5.27 becomes incalculable. In Example 56 values of GSD<sub>adj</sub> and wadj/AMadj are calculated for relevant values of GSD, M, and CVt. For M>10 or GSD>2.71828 the influence of random measurement errors CVt<.35 is irrelevant. The same applies for MD2, GSDD1.4 and CVt<.

Example 56 Adjusting GSDs and w/AM for different values of M and CVt

Example 57 CVt influence on GSD in example data

### Example 56 Adjusting GSDs and w/AM for different values of M and CVt

Sample size Sample descriptive Statistics CVt=.05 CVt=.25 M GSD w/AM GSDadj Wadj/AMadj GSDadj Wadj/AMadj 2 1.1 0.0952 1.0845 0.081 - -2 1.4 0.3303 1.3951 0.327 1.2562 0.223 2 2 0.6425 1.9970 0.641 1.9219 0.603 2 2.71828 0.8611 2.7157 0.860 2.6513 0.836 2 3.5 1.0024 3.4974 1.002 3.4334 0.984

5 1.1 0.0953 1.0846 0.081 - -5 1.4 0.3314 1.3952 0.331 1.2600 0.224 5 2 0.6822 1.9972 0.680 1.9287 0.636 5 2.71828 0.9679 2.7161 0.967 2.6633 0.936 5 3.5 1.1915 3.4980 1.191 3.4513 1.166

10 1.1 0.0954 1.0846 0.081 - -10 1.4 0.3395 1.3952 0.336 1.2623 0.228 10 2 0.6390 1.9974 0.717 1.9342 0.669 10 2.71828 1.0736 2.7164 1.072 2.6724 1.038 10 3.5 1.3907 3.4985 1.390 3.4637 1.363

50 1.1 0.0954 1.0846 0.081 - -50 1.4 0.3446 1.3953 0.341 1.2654 0.231 50 2 0.7680 1.9976 0.766 1.9407 0.714 50 2.71828 1.2387 2.7169 1.239 2.6831 1.202 50 3.5 1.7604 3.4991 1.759 3.4774 1.732 The adjustment of GSD and w/AM>CVt, increases if w/AM is about equal to CVt. Contents - Index

#### **5.1 Long-term TWA control**

To assess long-term compliance with hygiene limit H, 3 statistical extrapolation methods are presented and ranked in the increasing probability that H is considered as being an element of the exposure distribution. Use <u>table 7</u> to choose the appropriate method.

Table 8 combines the names found in literature for measures of long-term TWA extrapolation parameters, and the names (in bold) and symbols used in the screens 25 through 27.

Table 8 Names, parameters and estimators for assessing long-term TWA control

Upper and lower limits  $\zeta \delta (100-U)/2 <= \#\#\%$  and  $\zeta \delta (100+U)/2 >= \#\#\%$  of the two-sided tolerance interval U% are calculated by introducing successively  $\delta (100-U\%)/2$  and  $\delta (100+U\%)/2$ .

## Table 8 Names, parameters and estimators for assessing long-term TWA control

Name Population sample chapter parameter estimate
Long-term non-compliance probability (NIOSH 1977 p65) αC>H AC>H <u>5.1.2</u> & Percentage of the TWAs above the limit H <u>5.1.3</u>
One-sided or right-sided fraction
Fraction TWAs in compliance with the limit value H
Chance αC>H that one TWAreference period exceeds H
Acute health hazard (Hawkins 1991 page 56)

Upper tolerance limit One-sided or right-sided tolerance limit CUD##% CUD##%Concentration above U% of the population 5.1.2 & Lower tolerance limit 5.1.3 One-sided or left-sided tolerance limit CUW##% CUW##%Concentration below 100- $\alpha\%$  of the population

Confidence  $\delta$  of desired  $\alpha \ \delta(C\alpha < 100 - U > H) D(C\alpha < 100 - U > H) \frac{5.1.4}{5.1.4}$ Confidence  $\delta$  that  $<\alpha\%$  of the concentration are over H non-compliance probability  $\alpha$  with confidence  $\delta \ \alpha(C\delta DU\% > H) A(CUD##\% > H) \frac{5.1.4}{5.1.4}$ Fraction TWAs with confidence  $\delta$  in compliance with H Chance  $\alpha$  with confidence  $\delta$  that one TWAref per exceeds H

Upper tolerance limit with confidence  $\delta C\alpha < 100-U,UD\#\% C\alpha < 100-U,UD\#\% \frac{5.1.4}{5.1.4}$ One-sided tolerance limit (OTL, Tuggle 1982) Concentration above 100- $\alpha$ % of the population with confidence  $\delta$ 

#### **5.2 Dose assessment**

The Tab "UCL" helps to assess the:

- TWAref per or the chance of exceeding Href per, from a series grab samples,

- the Lognormal arithmetic mean  $\beta_{\text{long term}}$  and the chance that it exceeds H<sub>ref per</sub>, from a series TWA<sub>ref per</sub>,

- the chance that the mean of a series TWAref per exceeds Href per, on the average.

This is useful for:

• the "Classification of exposure for an 8-hour TWA standard, based on grab or partial period, consecutive sample measurements" (Leidel 1977 page 55) and

• the cumulative or average daily dose (Seixas 1988) or the chronic health hazard (Hawkins 1991).

Table 10 displays the symbols and some of the names found in literature for the extrapolation parameters of the Lognormal arithmetic mean and the names (in bold) used in screen 24.

Table 10 Names, parameters and estimators of dose assessment

Upper and lower confidence limits  $\zeta\beta$ , (100-U)/2=<% and  $\zeta\beta$ , (100+U)/2##% of the arithmetic mean are calculated by introducing successively (100-U%)/2 and (100+U%)/2 in screen 21.

# Table 10 Names, parameters and estimators of dose assessment

Name Population Sample Parameter Estimate

Probability  $\alpha$  that mean  $\beta$  exceeds limit H  $\alpha\beta$ >H A $\beta$ >H non-compliance probability  $\alpha$  of the arithmetic mean  $\beta$ .

Upper Confidence limit of  $\beta$  C $\beta$ ,U>=##% Ç $\beta$ ,U>=##% One-sided or right sided confidence limit of the mean Upper concentration with confidence 100- $\alpha$ % over population mean  $\beta$ 

Lower Confidence limit of  $\beta$  C $\beta$ ,U<=##% Ç $\beta$ ,U<=##% One-sided or left sided confidence limit of the mean Lower concentration with confidence  $\alpha$ % over population mean  $\beta$ 

### 7.1 Stop sampling

Tab 34a displays the situation when  $A_{t,df=1}<\alpha$ , so in which compliance is reached for every sample size M>1.

In this special case the Wilks test statistic is:

 $A_Z \leq 100$ -  $U\% \leq A_{t_{dij \geq l}}$  formula 7-4

Because the Student distribution is only defined for integer values of df, the confidence of compliance with the limit value is higher than expected on the average even for df=1. In statistical terms it is not possible to conclude "Stop measurement program, the confidence is sufficient!". This is the domain of the experienced industrial hygienist, but this situation could justify such a decision.

From screen 34a it can be concluded that if:

- the ratio GM/H<.25,
- the variance GSDW1.20 and

- the desired noncompliance probability  $\alpha {=} 5\%$ 

then the exposure will be considered as in compliance on the average for every sample size. The upper line in table 1 of Scheffers (1987) provides, for different values of GSD, the ratio GM/H for which sampling is less useful.

# Example 50 The most effective measures to quantify exposure

Which descriptive statistics are used depends on the agent, the goal of the strategy, the desired extrapolation, the shape of the distribution and the limit value. Extremes are effective when dealing with Ceiling limits or when agents have an acute toxic response over a specific concentration (cyanide, ammonia and similar agents). The arithmetic mean is an effective measure for the mean mass for cumulating agents (asbestos, quartz and similar agents). Geometric mean and variance are essential for all extrapolation and inference statistics. Log(GM) is being used in noise exposure (in dB(A))

### Example 53 Performance of estimators of censored sample descriptive statistics

Three out of ten mice inoculated with tuberculosis did not die within 60 days (GUPTA271). Schneider (1988 p69) used this Lognormal distributed data set to illustrate the performance of different estimators of  $\mu$  and  $\sigma$  in small censored samples. The results of the rankit estimator was added.

Name of the method page in symbol Estimators Schneider (1986) GM in days GSD Ignoring censored data - - 50.7 1.16 Censored data at 65 days - - 52.8 1.17 Best linear unbiased 85 BLU 55.2 1.23 Maximum likelihood 69 ML 55.2 1.20 Restricted ML 103 RML 55.4 1.21 Dixon's 88 - 55.5 1.23 Modified maximum likelihood 104 MML 55.2 1.20 Bias corrected ML 110 MLc 55.6 1.23 Rankit regression 80 LU 56.0 1.24

Using only the non-censored data (=1/7\* $\sigma x_j$  and s={ $\sigma(x_j-)2/6$ }+1/2) or a fixed value for the censored data (Hornung 1990, Hawkins 1991 p104) underestimate both EXP( $\mu$ ) and EXP( $\sigma$ ) rather extreme. The Rankit regression estimators result in the highest values for GMg and GSDg. This is suitable for industrial hygiene purposes because of the low chance of underestimating the location and variance of the exposure

#### **Confidence d of one sided tolerance**

 $(1-\delta)$  the probability of accepting the desired compliance probability correctly (Tuggle 1982)

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#### **Confidence (in relation to a fraction)**

The chance that the tolerance interval contains the desired fraction of the population

#### **Confidence (in relation to the parameter)**

Confidence (in relation to the parameter), the chance that the confidence interval contains the parameter of estimation

#### Consistent

Consistent estimate, see <u>Asymptotic unbiased</u> estimator

#### **H** Terms and definitions

The explanations are based on Kendall (1982) or subsequently the most suitable term in literature. References between ().

• Accuracy, the difference between the measurement and the truth (Hawkins 1991), the extent in which calculations or estimations, the true value approximate

• Asymptotic unbiased or consistent estimator, an estimator which expectation equals the parameter by infinite sample size

• Autocorrelation, the phenomenon that observations in a series are dependent upon the preceding

• Averaging time, a period of time for which the measuring procedure yields a single result (prEN 482)

• Bias, systematic error (Hawkins 1991 156). Consistent deviation of the results from the true value (ISO 6879)

• Censored distribution, a distribution with a known fraction of observations outside the detection range (Hald 1949)

• Confidence  $\delta$  of one sided tolerance; (1- $\delta$ ) the probability of accepting the desired compliance probability correctly (Tuggle 1982)

• Confidence (in relation to a fraction), the chance that the tolerance interval contains the desired fraction of the population

• Confidence (in relation to the parameter), the chance that the confidence interval contains the parameter of estimation

- Consistent estimate, see Asymptotic unbiased estimator
- Degrees of freedom, the mutually independent, number of elements in a sample from the distribution
- Descriptive statistic, a number representing a probability distribution
- Dispersion, variance (Sarhan)

• Effectivity, Effectiveness the combined minimum of systematic (bias, accuracy) and random errors (efficiency, variance, precision). Increases if the systematic error of the first and second kind and the random error decrease

• Efficiency, according to Fisher (1921) an estimator is efficient if his population variance is the smallest (Kendall)

- Error of the second kind, accepting an invalid hypothesis. Also specificity (rejecting compliance)
- Error of the first kind, rejecting a valid hypothesis. Also sensitivity (detecting non-compliance)
- Error, see effectivity
- Estimate, the value of the estimator (Kendall)
- Estimator, a rule or method to estimate a constant in the population (Kendall)
- Expectation, the arithmetic mean of a probability distribution
- Extrapolation, to estimate the value a variable outside its tabulated or observed range

• Fraction, the number of elements of a population with a given property, divided by the size of the population

• Similar exposure group, a group of persons performing the same tasks and with a random exposure variability which overshadows the systematic in-between person variability (ad hoc).

• A group of workers with identical probabilities of exposure to a single environmental agent (Hawkins 1991 page 5).

• A group of employees who experience agent exposures similar enough that monitoring of any worker in the group provides data useful for predicting exposures of the remaining workers (Hawkins 1991 page 160).

• Inference, the process of deriving from assumed premises either the strict logical conclusion or one that is to some degree probable (The Random House college dictionary)

H Terms and definitions

- Interpolation, to insert, estimate or find an intermediate term (in a sequence)
- Kurtosis, the fourth moment
- Location, mean (Sarhan)
- Lognormal descriptive statistics, location and variance parameters describing a Lognormal distribution

• Maximum likelihood, one of the methods that provides estimators of the parameters of a parent population from samples. ML estimators fulfil certain criteria for consistency, efficiency and sufficiency. In fact ML estimators are consistent, tend to Normality for large sample size, have minimum variance in the limit at least, and provide sufficient statistics where such exist (Kendall 1947 volume II par. 17.22)

• Median, the most central result or, in case that sample size is even, the arithmetic mean of the untransformed two most central data.

• Minimum variance estimate, a method of calculating an estimator with the characteristic of maximum efficiency

• Modus, the value in a distribution with the highest frequency.

• Monomorphic group, A group of workers whose individual mean exposures compromise a single lognormal distribution. Term introduced by Rappaport (1991 page 66) but should be avoided. See Similar exposure group.

- Mutually independent, in opposite with autocorrelation
- non-compliance probability, the population fraction measurements over the industrial hygiene limit value
- Occupational exposure assessment, comparing exposure with the limit value (prEN 689)

• Omnibus, term used by d'Agostino (1971) to characterise tests on shape that combine aspects of both skewness and kurtosis

- Performance, general requirements on the <u>effectiveness</u> of the exposure assessment (prEN 482)
- Periodic measurements, the regular check if exposure conditions have changed (prEN 689)
- Population, collection of elements on which the conclusions of the statistical evaluation are related to
- Power, the chance of rejecting a unvalued null hypothesis
- Precision, random error

• Precision, the size of the deviation from the mean of the observations (Hawkins 1991 163) the closeness of agreement between the results obtained by applying the method several times under prescribed conditions (prEN 482)

- Random drawing, taking an element from a population with a method that is independent of all properties of the element
- Range of accuracy, the values for which the measurements are considered to be reliable
- Reliability, see confidence

• Robust, the property of a test that it works well for a wide variety of population types (Snedecor 1980 p 135)

- Rankit, the expectation of the standard normal ordering (Fisher 1938)
- Reference period, the specified period of time stated for the limit value of a specific agent (prEN 689)
- Sample, a series drawings from a population
- Scale, variation
- Selectivity, degree of independence from interferents (prEN 482)
- Skewed distribution, an asymmetrical distribution (Kendall)
- Sustainment, the capacity of individuals or groups to bear exposure

• Truncated distribution, a distribution with an unknown proportion result outside the measurement reach (Hald 1949)

• Upper tolerance limit, the upper boundary containing at least the desired fraction of the population

• Unbiased estimator, an estimator with the characteristic that the expectation equals the parameter for every sample size

• Workplace, the defined area or areas in which the work activities are carried out.

#### **Degrees of freedom**

The mutually independent, number of elements in a sample from the distribution.

#### **Degrees of freedom**

The number of degrees of freedom for the censored and non-censored case are calculated using:

```
If DetecNumAantal < M Then

Nu = (M + DetecNumAantal) 2 - 1

If Nu > 2 * DetecNumAantal Then Nu = 2 * DetecNumAantal

Else

Nu = M - 1

End If
```

With:

M is sample size DetecNumAantal is the uncensored number of measurements Nu is the Number of degrees of freedom

### **Descriptive statistic**

A number representing a probability distribution

#### **Dispersion**

Variance (Sarhan)

#### **B.1 Goodness-of-fit**

Following Geary (1947) one could say that "Lognormality is a myth. There never was and will never be, a Lognormal distribution.". Exposure data are only best represented by the Lognormal model (see <u>B.4.1</u>). Shapiro (1990 page 5) states that the reason to study the shape of a distribution is ".... whether or not it is reasonable to approximate the data with the model, not whether the data came from the hypothesized distribution". Thus studying goodness-of-fit of industrial hygiene exposure data is functional (Hawkins 1991 page 58), it can be done in samples of at least 3 exposure data and in two different ways: - graphically, with a probability plot (B.1.1),

- quantitatively, with a test on Lognormality (B.1.2).

For both it is true that the <u>effectiveness</u> increases with sample size. The interested reader in "distributional assumption testing" is referred to Shapiro (1990).

#### **B.4.1 General results**

df equals the number of sampling periods minus unity (M-1) if:

• the total exposure duration ? is much larger (up to infinity) than the total sampled time (?>>t\*M, t= sampling duration), the TWA situation,

• the number of consecutive exposure periods  $M\tau$  is much larger (up to infinity) than the number of the sampled periods M ( $M\tau >> M$ ), in the long-term compliance control situation. Most exposure assessment strategies use df=M-1 and thus extrapolate implicit to general results.

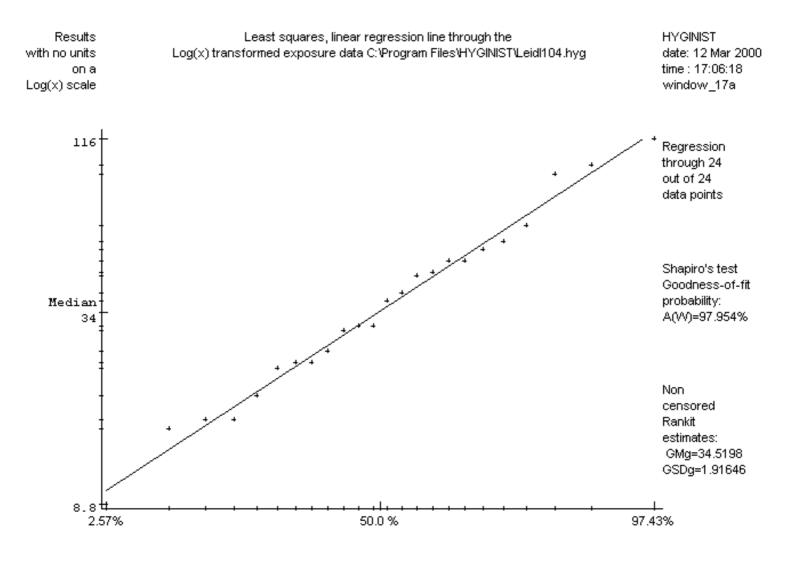
#### **B.1.1 Graphical**

The examination of Lognormal shape with probability paper has a long tradition in industrial hygiene (Oldham 1953, Leidel 1977 page 102) and other quality control situations (Morrison 1958, Snedecor 1980 4.13). In probability paper the standard normal deviates or their probabilities (the expected values) are located on the horizontal axis and the logarithmically transformed, observed exposure data c in ascending order are located on the vertical axis. In the ideal case the crosshairs form a straight line through the (non existing) origin (see Figure 22. The decision that the sample data are from a (Log)normal distribution is subjective in this case.

#### Figure 22 Lognormal probability plot on 24 TWA8 hours methyl methacrylate (LEIDL104)

Rankits Ri or `Normal Order Statistics` are estimators of standard Normal deviates (Fisher 1938 p 25, Teichroew 1956, Harter 1961 and 1970). The algorithm for calculating exact rankit values is rather laborious (Royston 1982b). HYGINIST uses 'read data statements' for MW20 (from Teichroew 1956 page 416 rounded at the fifth decimal) and for sample size of 21 through 2000 the polynomials of Royston (1982b, NSCOR2) are used. see example 49

### Figure 22 Lognormal probability plot on 24 TWA8 hours methyl metacrylate (LEIDL104)



### **Example 49 Making rankits by Monte Carlo** simulation

Rankits can be made with a Monte Carlo simulation:

- generate a sample of M random standard Normal deviates Zi (Abramowitz 1971, page 953, direct method), and arrange them in ascending order,
- repeat this procedure at least a thousand times,
- the arithmetic mean of the 1000 deviates with rank i is an effective estimate of rankit Ri.

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#### **B.1.2 Shapiro's W-test (uncensored)**

"The one major drawback of the probability plotting technique .... is the lack of objectivity" (Shapiro 1990 page 21). Statistical tests on shape are more objective, because of their reproducibility. However, the classical tests on skewness and kurtosis (Fisher 1938, Geary 1947) are only useful for samples of at least 50 measurements (see Hawkins 1991 page 58). These tests are now overshadowed by the omnibus test (= combined test on kurtosis and skewness) of Shapiro (1965).

The W-test of Shapiro (1965) estimates the <u>effectiveness</u> of the linear regression through the rankits (Schneider 1986 page 182). This special case of the <u>analysis of variance test</u> uses the following algorithm:



The coefficients Si in formula B-1 are established using:

- S1=1/sqrt(2) for M=3,
- Royston's polynomials (1995, AS R94) for M>4 and M≤2000.

The one sided probability distribution A(W) is (Royston 1995, AS R94) is calculated using:

- the exact W-distribution for M=3,
- a transformation to a standard Normal approximation for 3<M≤2000.

The power of the W-test is strongest against short-tailed (platykurtic) and skew distributions and weakest against symmetric moderately long tailed (leptokurtic) distributions (Royston 1992).

The significance level of A(W)<5% can be used to reject the Lognormal null hypothesis for MW 30. The <u>effectiveness</u> of the W-test decreases if results are rounded in grouping intervals  $\Delta C$  (Pearson 1977). The W-test needs to be adapted (Royston 1989) if  $\Delta C$ >0.1\* $\omega$  (with  $\omega$ = the arithmetic standard deviation see formula B-18).

#### note 28

formula B-1 shows that the W test statistic is the ratio of two different estimators of the variance in a sample. The F-ratio test is based on the ratio of the variances of two different samples.

#### Efficiency

According to Fisher (1921) an estimator is efficient if his population variance is the smallest (Kendall)

#### **Error**

See effectivity

#### Error of the first kind

Rejecting a valid hypothesis. Also sensitivity (detecting non-compliance)

#### Error of the second kind

Accepting an invalid hypothesis. Also specificity (rejecting compliance)

#### **Estimate**

The value of the estimator (Kendall)

•

#### **Estimator**

A rule or method to estimate a constant in the population (Kendall)

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#### 2.2.4.2 Example files \*.HYG

The program contains 36 files with industrial hygiene or quality control example data. More information on the example data files in Table 1. The name of the data files is mostly compiled from the authors name and the page number of the reference. The files in Table 1 are used throughout the text as examples. The descriptive statistics calculated for BOLEY62.HYG (see Example 57) and CHIP123.HYG will differ from those presented by the authors.

Table 1 Example data from different sources

#### **Expectation**

The arithmetic mean of a probability distribution

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#### **A. EXPOSURE ASSESSMENT**

HYGINIST is an instrument for the quantitative exposure assessment:

• Sample exposure data and the Lognormal distribution are used to draw general conclusions on exposure range, compliance with hygiene limits and inference with reference exposure characteristics.

This qualitative annex describes four aspects of exposure assessment:

- its place within the process "effective control of occupational exposure risks" (A.1),
- domains in which it can be utilized (A.2),
- different exposure assessment strategies (A.3)
- the extrapolation of sample data (<u>A.4</u>).

In Annex B the quantitative aspects of exposure assessment are discussed

## A.1 Effective control of exposure

The evaluation of exposure is part of the effective control of occupational exposure risk factors (working conditions). This is in many countries (IOHA Conference 1992) a part of Health & Safety control regulation and legislation. Effective working condition control can be schematized as a <u>nine step process</u>.

Table 13 Effective control of occupational exposure risks

1 Hazards. The static, innate health and safety aspects of an occupational agent (physical, chemical, biological and mental).

2 Limit value. The intensity of an agent over a reference period that is legally, health-based or otherwise accepted as admissible.

3 Exposure. The, at large, conductable and dynamic intensity of the occupational agent in the workplace, caused by the plant, the organization and the conduct of the employees. 4 Testing the exposure against a limit value. This leads to the decision:

- no, additional control measures are necessary,
- yes, exposure is in compliance with the limit,
- unknown, the limit is not suitable to test the exposure (<u>co-exposure</u>, restricted resistance).
- 5 Control measures. The technical, organizational and restriction of emission or immission.
- 6 Co-exposure. The controllable, but static interaction with other occupational agents.
- 7 Mental and physical resistance of an individual or a group. The result of:
- innate health, unequally distributed in the population,
- homeostasis, the tendency to maintain the internal stability in a physiological system,
- health perception, the dynamic vision of a person on its health and/or on public health, and
- health risks perception, the dynamic vision of a person or a community of hygiene hazards

#### possibly threatening health.

8 Sustainment. Testing total exposure in similar exposure groups against the physical and mental resistance by means of health examination or epidemiological analysis. This leads to the decision:

- yes, there is a state of effective control,
- no, supplementary control measures are necessary.
- In both cases this may increase the knowledge about hygiene hazards.
- 9 Effective control. A state of control in which:
- employer and employees are cognizant with and give sufficient credit to industrial hygiene risks and control measures,
- exposure is in compliance with the limit values,
- technical and measurements are in compliance with the current industry state of the art and comparable with what's usual practise in this branch of industry,
- occupation related complaints, effects and absenteeism and the industrial hygiene risk complies with the socially accepted level,
- knowledge is generated about how to control occupational exposure risks effectively.

## note 24

The nine process steps can also be applied in the effective control of environmental hygiene, process safety and quality.

### note 25

Combined exposure of several agents (WHO 1981, Scheffers 1985),

• exposure through different routes of entry (lung, mucous membranes, skin and/or intestines) (Manz 1987, Thomas 1986),

- specific sensitivity (ACGIH 1982, Stresemann 1988),
- novel work schedules (Roach 1977, Hickey 1977, Brief 1986, Eide 1990),
- physical exercise (WHO 1981),
- extreme climate (Hertig 1975, WHO 1981 p29),
- use of personal protection.

The WHO report (1981) contains a comprehensive reference list with inaccessible references from east European periodicals.

# A.2 Domains utilizing exposure assessment

The evaluation of exposure in workplace atmosphere is practiced in <u>Process safety</u>, <u>Industrial hygiene</u>, <u>health surveillance</u>, <u>Occupational medicine</u> and <u>Occupational</u> <u>epidemiology</u>. In <u>table 14</u>, the application of exposure assessment is sorted by sampling plan and domain (Corn 1985, CEN 1995).

In the red colored fields of <u>table 14</u> HYGINIST is useful for:

- the assessment of homogeneity in sample data (see chapter 3),
- the extrapolation to general results (see chapter 5),
- inference between two samples (see chapter 6),
- assessment of minimum sample size (see chapter 7).

The classification of exposure for a TWA<sub>8 hour</sub> standard (column 2 of <u>table 14</u>) is explained in detail by Leidel (1977) and many others and is therefore not included in the program.

## A.2.1 Process safety

To control the state of a production installation (i.e. reactors, appendages, seals, gaskets, extrusions, sampling points, logistics) and to detect unwanted emissions, the chemical industry utilizes routine measurement programs on fixed places and with a fixed sequences, mostly with directly readable instruments. The grab samples are directly compared to the limit value. For there is a legal framework for continuous or sequential sampling (EG directive 78/610/EEG, PB L 197/12 of July 22, 1978).

# A.2.2 Industrial/Occupational hygiene

Industrial (US) or occupational (GB) hygiene, in its classic form, deals with the working conditions at the workplace: the spot where employees meet hardware and materials. The aim is to keep risks in compliance with the current standards in order to guarantee workers a safe and healthy stay in the work environment not only during a (fraction of the) work shift but even during a lifetime. The method is to recognize, evaluate and control the agents at the workplace.

Industrial hygiene is a mature applied science: You can find basic or complete professional information of almost every present-day problem in the peer review or other literature that is produced since the forties and that can be found in hardcopy, on-line or compact disk databanks. The recognition of chemical agents risk is described by e.g. Roach (1977), Leidel (1977 chapter 2), Clayton (1978 p29-112), Oostendorp (1985<sub>ab</sub>), Boleij (1987), Guest (1993), Hawkins (1991), Mulhausen (1998) . The statistical aspects of the evaluation of workplace exposure can be found throughout the complete text.

# A.2.3 Health surveillance in similar exposure groups

In chemical process industry the evaluation of exposure is often conducted among similar exposure groups (Mulhausen 1998, Hawkins 1991 page 5, Damiano 1987, Corn 1979). Its aim is:

- assessment of long-term risk of overexposure,
- administration of exposure history.

In occupational settings the activity pattern of groups of employees is often similar throughout the year, despite the sometimes significant between-worker-variability during short observation periods (Rappaport 1993). Within a SEG the distribution of activities among the workers throughout the year should only be determined by chance. The statistical aspects of assessing exposure and risk in similar exposure groups can be found throughout the complete text.

HYGINIST strongly supports the quantitative aspects of SEG health surveillance programs as described in the appendices of AIHA's strategy for occupational exposure assessment (Hawkins 1991):

- II, descriptive statistics and plotting probability,
- III, arithmetic means tests,
- IV, tolerance limit test.

# **A.2.4 Occupational medicine**

Exposure data are sometimes used in assessing the sustainment (see table 13) of a healthy individual or in employees with a limited mental and/or physical resistance against the total of occupational exposure. According to Rempel (1990 page 435): "The principal tool for preventing work related illness should be the industrial hygiene exposure assessment (primary prevention). Unfortunately, even in the best situations, work related illness occurs. Medical surveillance in the workplace functions as a backup to exposure assessment, as a 'safety net' to catch illness early and activate interventions to prevent it from progressing (secondary prevention)." Statistical evaluation of exposure data will be of limited use in this domain.

## A.2.5 Occupational epidemiology

Occupational epidemiology (Monson 1980, Smith 1987, Checkoway 1989, Harris 1993) applies exposure assessment in similar exposure groups, to find:

- dose-response relations between exposure and health (biometrics, blood and urine values, lung function, mortality and morbidity rates),
- no-effect or accepted risk levels for industrial hygiene limit value assessment.

Table 15 Scheme for health based limit value setting in similar exposure groups

# Table 15 Scheme for health based limit value setting insimilar exposure groups

+	+								
	Complaints or								
	Medical occu-	+	-+	+		-+	+-		+
	rences			Dose/H	Response	:		Occupation	al
	+	-+	+?	?¦ relati	.on	+?		Limit	
	+	-+						Value	
	Exposure	+	-+	+		-+	+-		+
	assessment								
	+	-+							

# Table 14 Exposure assessment applications by domain

Sampling plan One grab or TWA One series D2 series exposure situa- commeassurement. exposure data. tions. Comparing differen- ment ces in regimes of control Domain Process Incident, accident Continuous and Technical measures <u>A.2.1</u> safety/emission and leakage semi-permanent Control monitoring Systems

Industrial hygiene Compliance with a Long term Technical and. <u>A.2.2</u> (workplace oriented) Standard compliance control Organisational Control charts

Health surveillance Range finding General Technical, organisational <u>A.2.3</u> Similar exposure assessment and and behaviour measures. Group compliance control Occupational Individual long term Sustainment under <u>A.2.4</u> Medicine compliance occupational load Different circumstances (single worker)

Occupational Range finding dose estimate Dose groups <u>A.2.5</u> epidemiology and industrial toxicology

# A.3 Existing exposure assessment strategies

In recent decades strategies have been developed for the long-term exposure assessment (e.g. AIHA, BIN, CEFIC, CONCAWE, EH42, Leidel 1977, TrgA 402, VDI 2450, WGD, WHO, CEN 689, Guest). In general these strategies all include four steps:

- what are the hazards (agents, routes of entry, exposure duration and frequency),
- what is the exposure (identifying similar place/group/time situations),
- what are worst-cases (ranking hazard and exposure),
- which of the ranked worst cases is in non-compliance with the limit value(s) ?

They all provide some sort of evaluation to generalize measurements performed.

In the last few decades the industrial hygiene world is flooded with alternative exposure assessment sampling strategies and statistical methods to analyze sample data. Some of these methods provide only concepts and do not even claim to improve the power of exposure control over the classical methods with fundamental basic concepts. They are ignored here.

# **A.4 Extrapolation**

The methods to generalize the measurement results in the assessment strategies are based on:

- the experience of "experts" (CEFIC, CONCAWE, TRgA 402, WGD),
- distribution free statistical analysis (VDI 2450),
- the Lognormal distribution (AIHA, BIN, CEN 689, EH42, NIOSH, WHO)
- other parametric distributions (Berry 1973, Owen 1980).

HYGINIST is based on the <u>Lognormal distribution</u>. The statistical aspects are explained throughout the manual. Other parametric distributions are explained only superficially (see <u>B.4.2</u>). Stellingwerf commented (1984, letter to the editor) the power and other statistical aspects of the first two methods.

Depending on sampling duration and limit value reference period, two types of extrapolation to unsampled periods (general results) can be distinguished:

• In number: the measured periods are considered as a fraction of the total number of exposure periods,

• In time: the sampling durations are considered as a fraction of the total exposure reference period (see <u>Example 47</u>).

For extrapolation in numbers the sampling duration should be equal to the limit value's reference period.

## A.4.1 The Lognormal evaluation

Most assessment strategies are based on Lognormally distributed workplace air concentrations (among others BIN, Bar-Shalom, EH42, Leidel, Rappaport, Tuggle, WHO, CEN 689).

According to Esmen (1977) and many others population, mutually independent, industrial hygiene measurements are best represented by the Lognormal distribution (see Figure 21). `Best` means, according to Esmen (1977), that the estimator is unbiased or consistent and efficient. `Best` also means that the estimator has the highest probability among the existing estimators. (Gamma, Weibull, Normal, exponential, Nonparametric).

Much knowledge and experience on the Lognormal distribution, extrapolation and inference has been gathered within the biometrics (Gaddum 1945), econometrics, technometrics, survival analysis, meteorology and geology (Shimizu 1988). Industrial hygiene has learned and is still learning from these applied sciences.

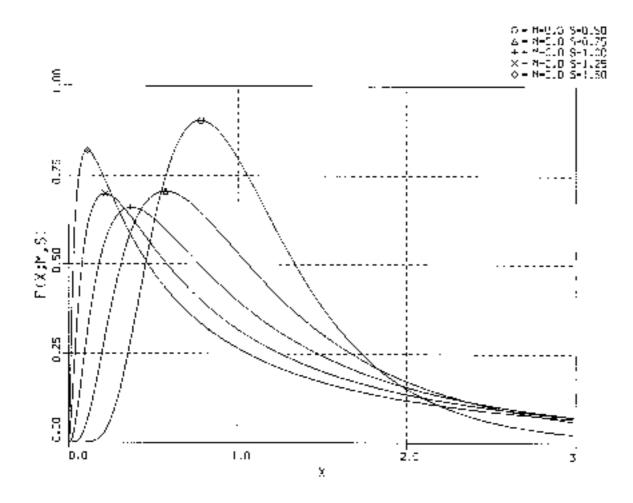


Figure 21 A family of Lognormal distributions with mean M and standard deviation s

A.4.1 The Lognormal evaluation

Example 48 Lognormal

# **Example 48 Lognormal**

The Lognormal distribution in series industrial hygiene measurements was first recognised in the fifties at the coal face (Oldham, 1953). Lognormal goodness-of-fit has been demonstrated in the distribution of concentrations of gasses, vapours, dust, fibres and enzyme-activity in workplace air, in excretion products in urine, in exhaled air, in blood values and in (untransformed) noise intensities (kPa). Leidel (1975b page 7, 1977 page 122) indicates that Lognormal goodness-of-fit is observed in American, English and German industry. The Lognormal distribution is observed in series short-term (seconds) and long-term (days) sampling periods (Leidel 1975, 1977).

# A.4.2 Other parametric distributions

The Lognormal distribution  $\Lambda$  can be approximated by a linear combination of Normal distributions (Shimizu 1988a page 9):

$$\Lambda = \eta + \frac{(\eta^2 - 1)^* \sigma}{2} + \frac{(2^* \eta^3 - 9^* \eta)^* \sigma^2}{12} + O(\sigma^3)$$

with  $\Lambda$  the Lognormal L( $\mu$ , $\sigma$ ) and  $\eta$  the Normal *N*( $\mu$ , $\sigma$ ) distribution. If  $\sigma$ <0.2 $\rightarrow$ 0, then the last three terms tend to zero and the Lognormal distribution is approximately normally distributed.

Berry (1973, cited by Leidel 1977 page 103) finds, for certain contaminants in food and drinking water, the Gamma distribution more suitable than the Lognormal. He further expands this for samples with a high proportion of censored data. This method is not further applied in industrial hygiene.

The three parameters, Lognormal Delta distribution is effective in a stationary process with a constant low level background concentration (Owen 1980, Leidel 1977 104). In contrast to the statistical point of view, the three parameter Lognormal distribution is in industrial hygiene a special case of the two parameter distribution (with  $\delta$ =0) because a random and a fixed exposure level are considered.

According to Shapiro (1991 p8, 15) many of the distributions applied are mutually dependent:

- the exponential distribution is a special case of both the Gamma (Chi-square with 2 degrees of freedom) and the Weibull distribution,

- the Weibull becomes an "extreme value distribution" through logarithmic transformation,

- the Lognormal distribution can be approximated with a Weibull or an exponential distribution.

In conclusion there is no evidence and there are no good reasons to use other distributions in stead of the Lognormal in the industrial hygiene exposure assessment.

# **Example 47 Extrapolation in time**

The reference period of the following limit values obliges you to perform (1) a variable sampling plan and (2) extrapolation:

- the Dutch limit value for lead TWA40 hour,
- the EG asbestos cumulative action level for 3 months,
- the EG vinyl chloride limit for one year.

The Dutch MAC30 min for carbon monoxide is often measured by a series grab IR registrations. Using IR or indicator tubes makes it usually impossible to sample the total reference period ( $\sigma$ ti << T), so extrapolation in time is preferred. Statistical techniques are available to evaluate the TWA from partial-period or grab sampling (see <u>5.2</u>).

# **B THE LOGNORMAL DISTRIBUTION**

The statistical evaluation of industrial hygiene sample exposure data is tied to different, implicit and explicit, conventions. Which convention or alternative HYGINIST uses, is made explicit in <u>table 16</u> and is explained in the chapters mentioned in the last column.

With good <u>Statistics</u>, population characteristics like Goodness-of-fit, location, range, and inference can be estimated from a sample, in a reliable and reproducible way. It is the task of the industrial hygienist to develop a reliable exposure assessment strategy and to choose the right statistical methods. Therefore, good exposure assessment requires both industrial hygiene and statistical skills.

Proposition 1:

# • Quantifying workplace air exposure in similar exposure groups is most effective with a random or stratified sampling strategy and with Lognormal extrapolation.

HYGINIST evaluates the following situations:

- A complete sample to a complete population (B.2),
- A censored sample to a complete population (B.3.),
- A complete or censored sample to a confined population (B.4.2.).

Proposition 2:

• Lognormal extrapolation is possible if the expert industrial hygienist decides that the model is acceptable., based on:

- the population description,
- the measurement strategy,
- the effectivity of the measurement method, and
- the goodness-of-fit,

This proposition makes a heavy appeal on the experience and expertise of the industrial hygienist. A scheme which helps to decide on conformity with Lognormality based on statistical grounds is presented in par. 3.4 . In non-experimental research, like industrial hygiene and occupational epidemiology, elements are not randomised over the populations (Miettinen, 1985) and thus the variance in observations on elements can be in part non stochastic. The bias in population selection, exposure assessment strategy and the measurement method will distort the conclusions. Checking on selection is more than just goodness-of-fit control: it means auditing the complete design of the investigation.

#### Proposition 3:

Unbiased estimators and unbiased extrapolation methods should be preferred.

This proposition deals with the industrial hygiene habit of general extrapolation from small samples (M<10). A perfect estimator is unbiased with minimum, and normally distributed, variance. The inaccuracy of maximum likelihood estimators in small samples leads to more errors of the first kind (incorrectly accepting compliance). This should be considered as more serious than the lower efficiency (with the chance of incorrectly accepting non-compliance) of unbiased estimators.

#### **Proposition 4**

# • If data are censored, estimating the descriptive statistics from the rankits plot is the method of preference.

Eliminating censored data or using a fraction of the detection limit as their value is replaced by a more effective method (see  $\underline{B.3}$ )

Proposition 5:

# • It is general practice in industrial hygiene to perform statistical extrapolation to general results.

The extent of the extrapolation and associated degrees of freedom is further elaborated in  $\underline{B.4}$ .

**Proposition 6:** 

#### • In censored samples the number of results outside the accuracy range contributes for one half to the number of degrees of freedom with a maximum equal to of the number of the uncensored results.

This proposition is a compromise between extremes (see B.4.3).

Proposition 7:

### • Extrapolation to a one-sided 95% confidence level is just tradition.

Almost every application of statistics uses 95% as default for inference and extrapolation (see 4.2).

Proposition 8:

# • Student-t based statistics should be preferred in industrial hygiene statistical inference and extrapolation.

The Student distribution is asymptotically normal, sufficiently robust to guard against violating the normal model (Boneau 1960, Heeren 1987) and relatively easy to calculate.

# Table 16 Conventions in industrial hygiene statistics

Characteristic Convention Alternative explanation propo Pragraph sition

The shape of the Lognormal Normal, Nonparametric 1 <u>A.4</u> distribution Gamma, Weibull

Test for goodness (Log)normal (median describing population homo 2 <u>B.1</u> normalorder) probability geneity, Rankit probability -of-fit paper. isher and Geary tests plot, W-test.Waters test onkurtosis and skewness

Descriptivestatis consistent, efficient Unbiased 6 B.2 tics

Coping with C<dl =  $\frac{1}{2}$  Cdl Maximum likelihood or 4 <u>B.3</u> censored data dl= accuracy limit Rankit regression through the uncensored data

Degrees of extrapolation to extrapolation to a 3  $\underline{B.4}$  freedom df generalresults. confinedpopulation df=M-1 M?:df=(M?-1)(M-1)/(M?-M)

df in censored all data df=M-1 or the the minimum value of 5 B.4.3 samples uncensored only: df=M`-1 df=(M+M`)\2-1 or df=2\*M`

Extrapolation Extent upper one sided 95% two sided, different percentages 7 4.2

Extrapolation standard Normal unbiased and 8 4 Technique Noncentral Student

# **B.3 Parametric descriptive statistics (censored sample)**

Censoring (Hald 1949) is a situation in which a part of the sample data has an unknown or a fixed value. Type I corresponds with censoring with accuracy limits (Schneider 1986 page 2). Methods based on censored samples have the advantage of resistance to outliers (Snedecor 1980 page 135): A small percentage of outliers, produced by gross mistakes in measuring, recording and copying, will hardly bias the estimators.

See:

- <u>B.3.1</u> on how Lognormal descriptive statistics are calculated using linear regression through the outcome within the detection range see
- <u>B.3.2</u> on how the other descriptive statistics are calculated

Censoring greatly complicates extrapolation and inference (Schneider 1986 p 177). With asymmetric (one sided) censoring, a case that is often seen in industrial hygiene, the estimators of the descriptive statistics  $\mu$  and  $\sigma$  become mutually dependent. The precision of censored based estimators and estimates depends on (Schneider 1986 4.7):

- the sample size,
- the symmetry of censoring.

Figure 25 500 Rivet heads (HALD151)

# **B.3.3 GMu, AM, and w<sup>2</sup> (censored)**

In a censored sample, the descriptive statistics  $\underline{GM_u}$ ,  $\underline{AM_u}$  and  $\underline{w^2}$  are calculated using  $GM_g$  in <u>B.3.1</u>,  $GSD_g$  in <u>B.3.2</u> and the degrees of freedom df of <u>B.4.3</u>.

Figure 27 Mice survival time (GUPTA271, Schneider 1986 p 69 & 88)

Example 53 Performance of estimators of censored sample descriptive statistics

# **B.3.1 Censored sample estimators for EXP(s)**

In the case of a censored sample the program estimates  $\sigma$  from the linear regression through the uncensored data M' in the rankits plot. Log(GSD<sub>g</sub>) is the regression slope (Prescott 1970, section 5):

$$GSD^{g} = EXP\left(\frac{\sum_{i=0}^{1-ui} R_{i}^{-x} x_{i}^{-\frac{\sum_{i=0}^{1-ui} R_{i} \sum_{i=0}^{1-ui} x_{i}}{\prod_{i=0}^{1-ui} R_{i}^{-\frac{1-ui}{2}}}}{\sum_{i=0}^{1-ui} R_{i}^{-\frac{1-ui}{2}} \frac{\prod_{i=0}^{1-ui} R_{i}^{-\frac{1-ui}{2}}}{M'}}{M'}\right)$$

In formula B-20 *II* and *uI* are the lowest and highest uncensored data rank and *M'* is the number of results between the accuracy limits. The formulas B.20 and B.21 are identical with the linear, alternative estimators of Gupta (1952 5.2. formulas 31 through 35) and Sarhan (1962 p208 formulas 10C.2.1 and 10C.2.2). See Example 14, 21 and 44 on the rankit estimators for mean and variance of strontium in milk.

Example 52 Comparing untransformed linear estimators

For uncensored samples the rankit estimators are as effective as the classical estimators (see <u>B.2</u>). They are more effective than classical solution where results below the detection lower limit LL receive the value .5\*LL (Hornung 1990, Hawkins 1991 p 104). <u>Example 53</u> suggest that the rankits estimators should be preferred in industrial hygiene.

# Example 44 Regression analysis in exposure control chart

### \*.HYG file Description

VINCHL## The TWA8 hour Vinylchloride VCM in a SEG polymerisation shift workers since 1987 (see Example 29) were presented in an exposure control chart (Figure 15). In contrast with the comparison of the 1989 and 1991 data, the regression line delineate a significant decrease of exposure in time. The regression slope calculated using TRUE EPISTAT indicates that the geometric mean exposure between 1987 and 1993 decreased every year with 100\*[1-exp(-.1961)]≈18%. (95% confidence bounds 12-24%).

# **B.4.3 Censored**

There is no convention in industrial hygiene on how results outside the accuracy range of (1) the sampling procedure and (2) the analytical method, should contribute to the degrees of freedom. The following methods are found (with no justification given for the choices made):

• Perkins (1990) establishes the arithmetic mean of a large, censored sample with the uncensored data only (df=M`-1).

 Schneider (1986 page 190) uses the uncensored data when sample size is small (df=M`-1).

• Schneider (1986 page 200 & 201) estimated tolerance limits (=percentile values), independent of sample size (df  $\equiv \infty$ ) on 96 locomotives of which 59 were type I censored (large samples are considered as asymptotic normally distributed).

• Hornung (1990 method 2 & 3) and Hawkins (1991 p104) use both censored and uncensored data (df=M-1),

• The most liberal is the NIOSH method for non-compliance probability in long-term exposure situations (Leidel 1977 page 65) which is independent of sample size and accuracy range (df  $\equiv \infty$ ),

lf:

- sample data show enough variance (e.g. GSD>1.4)
- the standard deviation w>>-C overshadows the grouping interval, and
- limit H lies inside the accuracy range,

then censored data can be considered as data of equal value in a continuous distribution and thus, at least in part, mutually independent (see proposition 6):

$$df = INT\left(\frac{M+M'}{2}\right) - 1$$

Ho wever, 1 :

df > 2 \* M' then df = 2 \* M

with M` the results within the accuracy range. This method is rather conservative taking into account that, for NIOHS` method of non-compliance probability in long-term exposure situations (Leidel 1977 page 65), no considerations on df have to be made (see screen 25 par.. 5.1.2). For Nonparametric (distribution free) methods dealing with censored data is more simple:

- In the one sample binomial test and Poisson test with the hygienic limit inside the accuracy range, the results outside the accuracy range are considered as independent (df=M-1),

- When the Wilcoxon rank test is applied to compare two samples and one sample contains nondetectable values, they are considered as equals and independent (df1=M1-1),

HYGINIST calculates the number of degrees of freedom for the censored and the noncensored case as follows:

```
If DetecNumAantal < M Then
    Nu = (M + DetecNumAantal) 2 - 1
    If Nu > 2 * DetecNumAantal Then Nu = 2 * DetecNumAantal
Else
    Nu = M - 1
End If
```

With:

M is sample size

DetecNumAantal is the uncensored number of measurements Nu is the Number of degrees of freedom

Example 55 Degrees of freedom in censored samples

# Example 55 Degrees of freedom in censored samples

• The 310 rivet heads with diameters (HALD151) above the lower limit of 13.4 mm (Hald 1952 page 151) in a sample of 500 (see Figure 24), provides a df=404.

• The 15 items under stress (SCHNE224) with an accelerated lifetime below the 6 time units (TU) in a sample of 50 (see Figure 5), provides a df=31 (Schneider 1988 p224).

• The 37 locomotives with failures before 135,000 Miles (SCHNE70.HYG) in a sample of 96 (see Figure 6), provides a df=65 (Schneider 1986 example 4.3 page 69).

• The 7 grab sample airborne Chlorine concentrations (OWEN716) within the range of accuracy from a sample of 15 that were taken over a working day (Owen 1980 page 716) in order to classify for the federal 8-hour TWA standard of 1 PPM (See Figure 4), provides a df=10.

# **B.5 Sample size**

In estimating exposure the following theoretical minima for the sample size exist:

- location, source strength, EXP( $\mu$ ),  $\beta$ : one measurement,
- variance, scale,  $EXP(\sigma)$ , w: two measurements,
- shape, kurtosis, goodness-of-fit: 3 measurements.

Most industrial hygienists will establish their sampling plan based on:

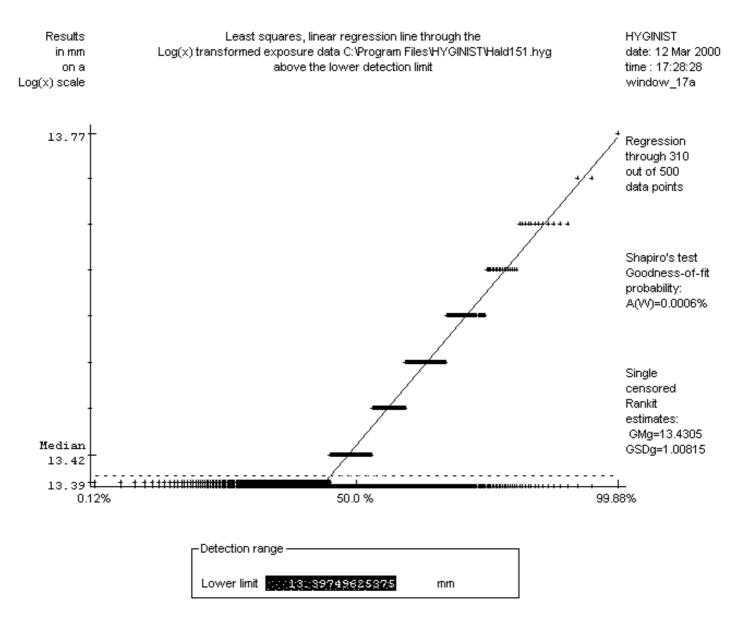
- the goal of the exposure assessment (see A.2),
- the measurement accuracy,
- the expected difference between concentration C and limit value H,
- organizational and financial considerations.

For every exposure application and domain (see A.2), sample size considerations are made in literature (Leidel 1977, page 120, The need for an action level; Leidel 1977, page 82, and Dewell 1989 accuracy based; Hawkins 1991, page 51, and Esmen 1992, long-term compliance control; Hawkins 1991, page 59; Schneider 1988, chapter 7, censored samples; Leidel 1977, pages 34 & 71, worst-case employee, cumulative binomial; Buhring 1989 and Hawkins 1991, page 59, variance based; Rappaport 1987, Ammo dose based, criticised by Evans 1988; Corn 1985, page 176 and Tait 1992).

In general the sample size should increase if:

- the population under study is large,
- the desired confidence increases,
- the exposure variability is large,
- the difference between C and H is small,
- CVt is large.

### Figure 25 500 Rivet heads (HALD151)



### **B.4 Degrees of freedom**

Degrees of freedom df are defined as the mutually independent variables of the sample in the population. If the statistical uncertainty (e.g. the extrapolation space) increases, the number of degrees of freedom decreases.

In a one dimensional sample df is established by:

- the number of measurements M (see **B.4.1**),

- the population size (expanded <u>B.4.1</u> or confined <u>B.4.2</u>).

More complex are situations with:

- censored data (see <u>B.4.3</u>),

```
- when samples with unequal GSDs are compared (see 6.2.3.2).
```

HYGINIST calculates the number of degrees of freedom for the censored and the noncensored case as follows:

The choice of the estimators of the descriptive statistics and the extrapolation methods (see <u>chapter 5</u>) are, in part, determined by the size of df.

# **B.4.2 Confined population**

If the reference period  $\tau$  of a limit value (e.g. TWA<sub>8 hour</sub>, TWA<sub>40 hour</sub> for lead,  $\tau$ =480 hours or M $\tau$ =60 shifts of TWA<sub>8 hour</sub> in a period of 3 months for asbestos) can be divided in M? consecutive sampling periods (of e.g. t=1 minute, t=15 minutes or t=8 hours) and M non consecutive periods are sampled during time t (with M<<M $\tau$ , Leidel 1977 p38), then the non-sampled periods over which extrapolation should be carried out is confined M $\tau$ -M. The number of degrees of freedom in this case is (Juda 1967):

$$df = \text{INT}\left[ (M-1) \ast \left( 1 + \frac{M-1}{M^{T} - M} \right) \right]$$

The last term in formula formula B-22 determines that df=M-1 for  $M\tau \rightarrow \infty$  and df= $\infty$ ; if  $M \rightarrow M\tau$ . The influence of a confined population on df is relevant, if both  $M\tau$  and M are small; roughly if M<20 and  $M\tau$ W3\*M.

Example 54 Degrees of freedom in confined populations

# Example 54 Degrees of freedom in confined populations

From Leidel (1977 page 63, 67):

- During 5 out of MT=16 exposure periods to **Hydrogen sulphide** during one shift, a worker's exposure is sampled df=15\*4/11≈5 (LEIDEL63.HYG).
- 10 PAS TWA<sub>8 hour</sub> **Dioxane** in a period of 6 months ( $M\tau$ =130 working days). Confined as it is, the influence on the degrees of freedom is too small: df=INT(9.67)=9 (LEIDEL67.HYG).

40 TWA<sub>8 hour</sub>'s in a confined population of M $\tau$ =200 shifts of one employee in one year results in df= 48.

5 TWA<sub>4 hour</sub>'s in a population of  $M\tau$ =13 Friday morning shift in one season results in df=6.

# 6.2.3.2. Comparing GMs while GSDs differ

The statistic for testing that both GM`s originate from the same population base is (Snedecor 1980, 6.11):

$$t_{df_{i}} = \frac{LOG\left(\frac{GM_{2}}{GM}\right)}{\sqrt{(s+s_{2})}}$$
with
$$df_{t} = INT\left[\frac{(s+s_{2})^{2}*df^{*}df_{2}}{df^{*}s^{2}+df_{2}*s_{2}^{2}}\right] s = \frac{LOG(GSD)^{2}}{df+1} s_{2} = \frac{LOG(GSD_{2})^{2}}{M_{2}}$$
Formule 6-5

Formula 6.5 follows, under the null hypothesis, the Student distribution. The two-sided probability A% is calculated using tdf and dft from 6.5 and the Student distribution.

Example 41

# Example 41 Comparing GMs while GSDs are unequal

### \*.HYG file Description

VINCHL89& Because the exposure variance between 1991 and 1989 differs VINCHL91 (see <u>Example 39</u>) the location parameters for TWA<sub>8 hour</sub> Vinylchloride in the SEG PVC polymerisation shift workers were compared using the inference test of two GM`s with unequal GSD's. Although the ratio of GM1989=0.83 PPM and GM1991=0.37 PPM is 2.2, a significant difference is not confirmed: the two-sided probability for dfpooled=27 is AGM=GM2=5.1%.

- Illustrating the influence of unequal GSD's in comparing GM. For M=M2=10, GSD=2.71828 and GSD2=7.43714 differ significantly. AGM=GM2W5% needs GM2/GMD4.6. This is 1.8 more than what is necessary if the GSD's are equal (see paragraph 6.2.3.1 and examples <u>40</u> and <u>41</u>).

#### **Example 39 Comparing two GSD's**

#### \*.HYG file Description

POSTB11I, In a plant manufacturing fibreglass reinforced polyester materials, POST08P4 14 Styrene PAS TWA8 hour concentrations were collected within a 15 days period

&POST10P5 on 7 inlayers working at 5 different presses (Post 1989, 1991). The Lognormal probability plot (see Figure 3) suggest a mixture of at least two distributions and the raw data in the base report support this (Post 1989). Four TWA8 hour concentrations from worker 8 at press 4 are compared with the five TWA8 hour of worker 10 on press 5 (measured on nearly the same days). The scale parameters GSD=1.21 and GSD2=1.14 (see screen 29b) are from the same base: the two sided change AGSD=GSD=57.4% (continued in Example 40).

VINCHL89 & VINCHL91 The exposure control chart Figure 15 of the TWA8 hour Vinylchloride in the SEG PVC

polymerisation shift workers since 1987 shows a loglinear decrease in exposure over time. To quantify the decrease the 37 data of 1991 are compared with the 20 results of 1989. The scale parameters GSDdf=36=2.73 and GSDdf=20=4.97 differ significantly with a two-sided probability AGSD=GSD2=1.5 % (continued in Example 41).

- In the 1972-1974 randomized experiment in Colorado (Crow 1977 page 973), the mean hail mass on Mn=16 nonseeded days was GMn=2.3632 with GSDn=7.9135 and on the Ms=17 seeded days GMs=3.3434 with GSDs=8.35.

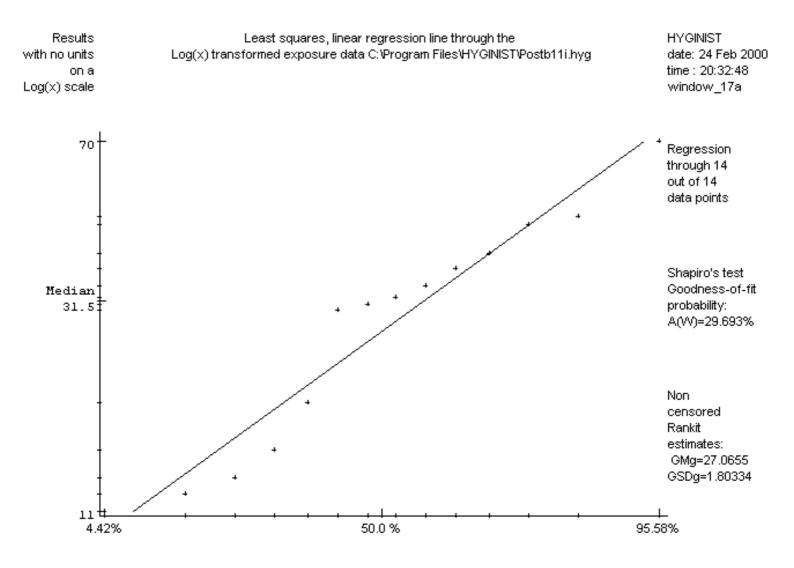
Like Crow (1977), the calculated AGSDn=GSDs=92.53% supports the conclusion that seeding does not influence the scale parameter of hail mass (continued in Example 40). - From the Variance ratio distribution table 26.9 of Abramowitz (1970), it can be derived that two GSD's differ at a two-sided significant level of A=(2\*QFldf,df2)=5% for GSD=2.71828, - df=df2=1 and GSD2=1.11\*10+11,

- df=df2=8 and GSD2=8.21,

- df=df2=30 and GSD2=4.22.

To establish differences in exposure variability with 1.4WGSDW3.5, large samples (M>30) are needed.

# Figure 3 14 TWA8 hour Styrene on inlayers working on different presses (POSTB11I)



# Example 40 Comparing GM's while GSD's are equal

#### \*.HYG file Description

POST08P4 & The Styrene PAS exposure level GM=38.6 PPM (see Example 9) from POST10P5 worker 8 at press 4, is compared with GM=12 PPM of worker 10 on press 5. Assuming equal GSD's (see Example 39) the two-sided change AGM=GM2=0.002% supports rejecting the null hypothesis: The exposure level of inlayer 8 at press 4 is D3 times higher. MOF134NS The effectivity of scavenging on the Methoxyflurane exposure in the MOF134S breathing zone of veterinarian in small private practice, animal clinics during surgeries was studied (Potts 1988 page 134). A comparison was made between two series TWA10-30 min's measurements: - 16 nonscavenged results (10 double censored data, Figure 19, df=12) GM=0.48 PPM and GSD=5.7, - 6 scavenged results (uncensored, Figure 20, df=5) GM2=0.24 PPM and GSD2=2.9.The Wilcoxon rank sum test.

used by the authors, showed no statistical differences between the two samples. Due to small sample size and large GSD the parametric analogous with matching GSD's (AGSD=GSD2=29.4 %) also supports the null hypothesis: scavenging does not influence exposure level (AGM=GM2=38.3 %).

- The median hail mass GMn=2.36 on Mn=16 nonseeded days does not differ from GMs=3.34 on the Ms=17 seeded days in the hail seeding experiment in Colorado, (Crow 1977 page 973, example 5, exponential transformation). The two sided probability A(GMn=GMs)=63.8%, based on equal GSD's (see Example 39), supports the null hypothesis.

- From the Student table 26.10 in Abramowitz (1970), it can be derived that two GM's, from samples of equal size and scale, differ significantly at two-sided A(tldft)=5% with GSD=2.71828,

- dft=2 and GM/GM2D 73.9
- dft=16 and GM/GM2D2.72
- dft=60 and GM/GM2D1.69.

With dfD10 and GSD $\approx$ 2.7 significant differences in exposure level between samples are easy to assess. See also examples <u>41</u> and <u>42</u>

### **Example 42 Comparing two GSDs**

#### \*.HYG file Description

POST08P4&POST10P5 The GM and GSD's of Styrene PAS TWA8 hours of worker 8 at press

and worker 10 on press 5 (see Example 40, Example 39 and Post 1989), are combined. The summed sample size is M+M2=9, the merged GMt=23.5 PPM and the merged GSDt=1.8. These values are exactly the same as when all raw date are combined (POST1008.HYG)

- In a hypothetical fertilizer plant the plan is to perform a routine program on total dust air sampling. In order to estimate an optimal sample size two series of dust measurements from the past are available, however, only the descriptive statistics were reported, the raw data were lost. The sample estimators are:

- M1=4, GM1=1.8 mg/m3 and GSD1=2.4

- M2=4, GM2=2.24 mg/m3 and GSD2=2.4

Combining these descriptive statistics results in the following Mt=8, GMt=2.00798 mg/m<sub>3</sub> and GSDt=2.26803. Note that with equal GSD's and GM's which are very close, the combined GSDt is smaller than in the separate samples! See Example 46 for the assessment of the optimal sample size.

#### note 27

Statistics is a belief among experts. It is based on knowledge, logic and reproducible observations. Sampling is an art. Computing is a rigid, and in essence, simple skill. Fundamental sciences, and statistics in particular, are often misused. See e.g. the commonly found booklets "How to lie with ....".

## **Extrapolation**

• To estimate the value of a variable outside its tabulated or observed range

# **Fraction**

The number of elements of a population with a given property, divided by the size of the population

### Inference

The process of deriving from assumed premises either the strict logical conclusion or one that is to some degree probable (The Random House college dictionary)

## Interpolation

To insert, estimate or find an intermediate term (in a sequence)

# Table 3 Type of distribution according to the goodness-of-fit with a transformation

Best transformation fit Distribution type Ci Normal, Gaussian log(Ci) If s/x  $\approx$  constant for every Ci, then Lognormal Sqrt(Ci) If s<sup>2</sup>  $\approx$  x for every Ci, then the Poisson distribution 1/Ci If s  $\approx$  x<sup>2</sup> for every Ci, then inverse normal

# **Kurtosis**

The fourth moment

# Location

Mean (Sarhan), the first moment

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## **Lognormal descriptive statistics**

Location and variance parameters describing a Lognormal distribution

#### **Minimum variance estimate**

A method of calculating an estimator with the characteristic of maximum efficiency

## **Monomorphic group**

A group of workers whose individual mean exposures compromise a single lognormal distribution. Term introduced by Rappaport (1991 page 66) but should be avoided. See Similar exposure group.

## **Mutually independent**

In opposite with autocorrelation

# non-compliance probability

The population fraction measurements over the industrial hygiene limit value

#### **Occupational exposure assessment**

Comparing exposure with the limit value (prEN 689)

## **Omnibus**

Term used by d'Agostino (1971) to characterise tests on shape that combine aspects of both skewness and <u>kurtosis</u>

#### Performance

General requirements on the effectiveness of the exposure assessment (prEN 482)

#### **Periodic measurements**

The regular check if exposure conditions have changed (prEN 689)

#### **Power**

The chance of rejecting a unvalued null hypothesis

# **Precision**

- Random error
- The size of the deviation from the mean of the observations (Hawkins 1991 163)
- The closeness of agreement between the results obtained by applying the method several times under prescribed conditions (prEN 482)

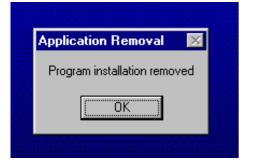
#### Uninstall or remove (earlier versions of) HYGINIST

If you have already installed a development version of HYGINIST for Windows or you want to remove the HYGINIST program from your system, then click in ascending order:

- Start,
- Preferences,
- Configuration,
- Software,
- Scroll to HYGINIST,
- Click Add/Remove.

HYGINIST Remova	d I
Application F	Removal
	Ja Nee Application Removal
	Removing all HYGINIST components from your computer Please wait.
	0%

All installed HYGINIST components are now removed.



The remove is finished. Now continue with the installation.

#### C.4 Automatic installation on a hard disk

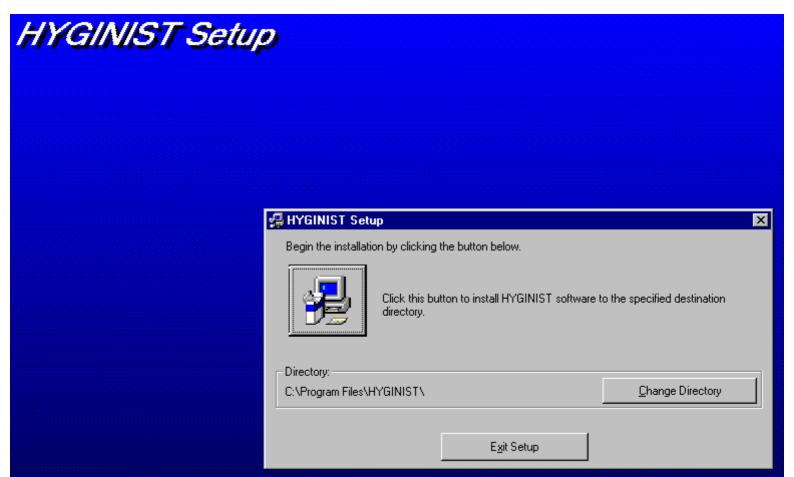
Browse with the explorer to the directory containing the extracted HYGINZIP.EXE files or:

- Click Start in the lower left corner and then click on Run,
- Browse to the directory containing the extracted files,

Now click on SETUP.EXE to start the installation. The Installation starts with the following message window:

HYGINIST Setup		
	🕵 HYGINIST Setup	×
	Welcome to the HYGINIST installation program. Setup cannot install system files or update shared files if they are in use. Before proceeding, we recommend that you close any applications you may be running.	
	OK E <u>x</u> it Setup	

Close all programs before you continue.



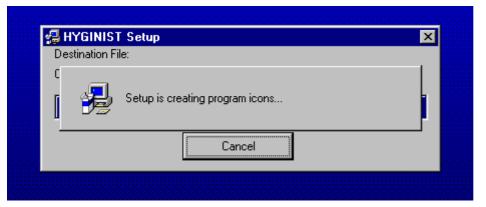
Now click the large button in the upper left corner to install the program in the default directory.

You can change the standard (sub)directory C:\Program files\HYGINIST by clicking the "Change Directory" button on the right site.

HYGINIST Setup	
	🛃 HYGINIST Setup 🔀
	Destination File: C:\Program Files\HYGINIST\POSTB111.HYG 82%
	Cancel

All HYGINIST files are copied to the destination directories.

C.4 Automatic installation on a hard disk



An program Icon to start HYGINIST is set under 'Start', 'Programs'.

HYGINIST Setup	
	HYGINIST Setup
	<u> </u>

The installation is completed successfully! You now can start HYGINIST on your system

### **C.5 Start the program**

You start HYGINIST for Windows by clicking <u>'Start', 'Programs'</u>. Now click on the HYGINIST <u>Hyginwin.exe</u> Icon.

If there is no <u>lcon</u> in your menu or on your desktop then do the following:

• By default HYGINIST for Windows is installed in the directory C:\Program files\HYGINIST\

• If you haven't accepted the default directory and don't know were HYGINIST was installed then search HYGINIST for Windows using the Explorer. If HYINIST is found then (double)click on <u>HYGINWIN.EXE</u>.

If this is the first time the program is started after installation took place, then the HYGINIST <u>Login screen</u> appears. If you already filled out Login form then only the Splash screen is displayed for a few seconds before the <u>exposure data management</u> screen appears.

## Start, Programs

Ł	EditPad Pro	
1	Hyginist	
(Chro		

# **HYGINIST** Icons

🔛 <u>Hyginwin.exe</u>



# Explorer

🗃 Hyginwin.DEP	16 kB
🖏 Hyginwin.exe	732 kB
📄 Hyginwin.GID	9 kB

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### **C.5.1 Enter name and password**

A login screen appear. The name of the system user of the computer is displayed



If you have received your password in reply to your registration then fill out:

your name

HYGINIST version 4.0.68 For Windows 95/98/2000/M and N	т
Copyright 1996-2001 Scheffers IHPC	
Login HYGINIST User information System user My System Your name George W Password	

• and the password

Press <<u>OK></u> if you entered all aivallable information.

If the information is correct the program

<u><Yes></u> to get a password or <u><Esc></u> for direct use of an unregistrered version

#### **How to Register**

Choose between a <u>stand-alone</u> or a <u>network</u> licence. To register fill out the <u>registration form</u>.

When <u>registration form</u> and the <u>"System user" and "Your name"</u> of the Login screen are received and also payment is secured, then a HYGINIST password will be returned to you by email.

Additional information may be found at the HYGINIST homepage

#### **Stand-alone license**

License structure at January 1, 2001. This license structure replaces all preceding The stand-alone license is meant for use on individual PC's.

#### The stand-alone version costs EURO 120.-.

For more than five stand-alone packages, special rates are counted. Please contact <u>Scheffers IHPC</u> for this.

#### **Network license**

Network license structure since January 1, 2002. This license structure replaces all preceding.

The network license is meant for organisations were PC's are linked to a central server and a network director provides the end-users with the software.

The base package (zero licenses) EURO 35,-

Every licence up to ten, per license EURO 85,-Eleven and more licenses, per license EURO 60,-

So the price for a single-user network license 85+35= EURO 120,-10 users 10\*85+35= EURO 855,-20 users 10\*60+10\*85+35= EURO 1485,-

For more than 50 licenses, special rates are offered. Please contact Scheffers IHPC for this.

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#### **HYGINIST** for Windows registration form

If you decide to register HYGINIST for Windows then please fill out this form and send or fax it to:

Scheffers IHPC Cramer van Brienenstr 1F 6225 BA Maastricht, The Netherlands Fax +31(0)842-201756

Your name:

Company:

Shipping address:

City, Zipcode: Country:

Your phone: your fax:

Methods of Payment. Using your Visa, Master or Euro creditcard; Please charge to my account (write here the total price):

Card Number: Name (on card): Expire date:

From within the Netherlands you can transfer the total amount to the Postbank Account 6729317 of Scheffers IHPC mentioning HYGINIST for Windows. Vanuit Nederland kunt u het totaal bedrag overmaken op giro 6729317 van Scheffers IHPC, Maastricht onder vermelding van HYGINIST voor Windows.

Product Unit price Quantity TVA Net price in Euro's ( $\P \in \blacksquare$ 

Stand-alone or single user network license  $\notin 95, - * \dots = \dots, -$ Clients within Europe add 19% TVA/VAT/BTW  $\notin 18,05 * \dots = \dots, -$ 2 to 10 network licenses add  $\notin 60, - * \dots = \dots, -$ Clients within Europe add 19% TVA/VAT/BTW  $\notin 11,40 * \dots = \dots, -$ 11 and more licenses add  $\notin 40, - * \dots = \dots, -$ 

Clients within Europe

file:///C|/Hyginwin5/Helpscribble/hs600050.htm (1 van 2) [9-6-2002 17:19:37]

Registration form

add 19% TVA/VAT/BT	₩€7,60 * 	=,-		
Total TVA	+ €,>,-			
Total amount	+ €,-			
Name:				Date
Signature			/	/

The HYGINIST Pasword will be returned if payment is guaranteed and the email with the "System User" and "Name User is received.

## **Register HYGINIST**

HYGINIST is shareware, so you have the opportunity to fully try it out before you register. Just press the <cancel> button in the Login screen every time you start the program. In the following screen the free trail period will be indicated.

If you want to use HYGINIST without shareware warnings, then you have to do two things:

fill out the <u>registration form</u> and send or fax it to:
Scheffers IHPC
Cramer van Brienenstr 1F
6225 BA Maastricht
The Netherlands
Fax +31(0)842-201756
email the "System user" and "Your name" of the Login screen to <u>ihpc@planet.nl</u>

When <u>registration form</u> is received and payment is secured, the HYGINIST password will be returned to you by email.

#### C.5.2 How to get a password

If you don't know the password or pressed the <Enter> key before filled it out, then the next message box appears:

HYGINIST	
HYGINIST User information         Incorrect Password. Do you want to receive a valid one?         Press <yes> to send email to Scheffers IHPC. Mention the 'System user' and 'Your name' in the body of th         Press <no> to re-enter your Pasword.         Press <cancel> to start the program without a Password         Press <help> to learn more on the license agreement         Ja       Nee         Annuleren       Help</help></cancel></no></yes>	×
Login         HYGINIST User information         System user         Your name         George W         Password	

- If you want to have a password because you will be using HYGINIST regularly, then press </r>Yes>. Your email program will be activated in oder to request a pasword.
- The HYGINIST help file will be activated and you will be instructed in how to obtain a password.
- If you have a valid password but you entered before you could fill out the Password textbox then press <<u>No></u>

C.5.2 How to get a password

- If you just wat to see how the program works then press <a></a></a></a>
- Do you want to know the license agreement then press <a href="https://www.elen.com"><a href="https://www.elen.com"><a href="https://www.elen.com">www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.elen.com</a> <a href="https://www.elen.com"/>www.

## **C.5.3 Use as unregistered shareware**

#### HYGINIST version 4.0.68

This unregistrered version of HYGINIST for Windows works until 2001/03/31

Check regularly the HYGINIST homepage: http://home.wxs.nl/~ihpc for newer versions Send your experiences and findings by email to ihpc@wxs.nl or by fax to +31-43-3622107



#### 2. Exposure data management

HYGINIST evaluates two types of exposure data:

- A series of M measurement results , or
- A sample size M and the Lognormal statistical descriptive statistics <u>GM</u> and <u>GSD</u>.

The program always starts with the next window.

🛋 HYGINIST Development ver	sion 4.0.53	
<u>F</u> ile <u>H</u> elp		2
Data type         Image: C Descriptive statistics	Which exposure data type? - A series measurement outcome: click menu option <u>Fi</u> le - Known values of GM and GSD: click option button ' <u>D</u> escriptive statistics'	

For context sensitive help move your cursor over the picture. Click your mouse if your cursor changes to hand with index finger and you get context sensitive help.

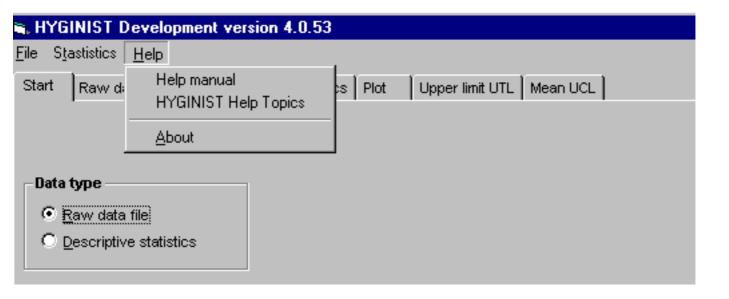
this screen offers you the possibility to choose between:

- 'Entering raw data' by keyboard,
- Entering the estimators of the Lognormal 'descriptive statistics' by keyboard,
- Loading a raw data file from disk.

HYGINIST exposure data management further includes:

- Instruction about the requirements that all exposure data should meet (par. 2.1),
- Input of exposure data (par. 2.2),
- Sorting and calculating descriptive statistics (par. 2.3),
- Error messages and handling (par. 2.4),
- Save, show and edit data files (par. 2.6 through 2.8),
- Exchange files with other database programs (par. <u>2.9</u>),
- At this moment it is not possible to import exposure data directly form a database or a spread sheet

# E.2 Online help



#### 2.2.3 Entering raw data

Click '&File', 'New \*.HYG file' to start entering raw data.

🛢 HYGINIST Development v	ersion 4.0.53	
<u>File H</u> elp		
<u>N</u> ew *.HYG file Ctrl+N		2
<u>O</u> pen *.HYG File_Ctrl+O		
<u>C</u> lose all data		
E <u>x</u> it		
Data type	Which exposure data type?	
Raw data file	- A series measurement outcome: click menu option <u>File</u>	
C Descriptive statistics	- Known values of GM and GSD: click option button 'Descriptive statistics'	

The frame 'Exposure data identification' in which you can fill out :

- <u>a name (obligate)</u>
- A sample size (obligate)
- Units of measurements
- Sampling duration

Development version 4.0.32		_ 🗆 🗵
<u>File</u> S <u>t</u> astistics Report <u>H</u> elp		
		6
– Data type –		
	Create a Raw datafile. Enter a name and the sample size.	
C Descriptive statistics		
Exposure data identification -		
Name	Measured in: 🛛 🕮	lg/m3 ▼
Sample size M=	Sampling duration	ours 🔻

If name and sample size are filled then two tabs appear and a <Continue> button. Click on tab 'Raw data' or on button 'Continue' to start entering individual measurement outcome (2.2.3.1).

S. Development version 4.0.32	
<u>File</u> S <u>t</u> astistics Report <u>H</u> elp	
Start Raw data	14
Data type	Continue
Exposure data identification	
Name Haw117	Measured in: mg/m3 💌
Sample size M= 15	Sampling duration <b>hours</b>

file:///C|/Hyginwin5/Helpscribble/hs22300.htm [9-6-2002 17:19:39]

#### 2.2.4 Loading a file

HYGINIST Developm	ent version 4.0.53				
<u>File H</u> elp	<b>Open a *.HYG del</b> Zoeken in: database DBGrid grafieken Helpscribble hyginist hygtools Swsetup * Bestands <u>n</u> aam:	imited raw data file ginwin5 tekst Acn8_9.hyg Albre220.hyg Bar_si25.hyg Bar_si25.hyg Bilan304.hyg Bilan304.hyg Acn8_9.hyg	<ul> <li>Boley85.hyg</li> <li>Boley94.hyg</li> <li>Chip123.hyg</li> <li>Cohen132.hyg</li> <li>Conov195.hyg</li> <li>Detectie.hyg</li> <li>Detectie.hyg</li> <li>Dewell24.hyg</li> </ul>	? × Dewell42.hyg Dewell44.hyg Dixon.hyg dixon2.hyg Fin2001a.hyg Fin2001b.hyg Fin2001c.hyg Fin2001c.hyg penen	2
	Bestands <u>typ</u> en:	Hyginist Files (*.hyg)		Annuleren	

#### 2.2.4.1 Select a file from disk

Click '&File', 'Open \*.HYG file' to load an existing raw data file.

Open a *.HYG	delimited raw data file		? ×		_ 🗆 ×
Look jn: 🧕 🥳	🔁 Hyginist	-	🗃 🔳		2
😫 Acn8_9.hyg	📓 Cohen132.hyg	📓 Hald151.hyg	📓 Leidel63.h		
📕 Albre220.hyg	; 🔰 Conov195.hyg	🛃 Haw104.hyg	🗾 Leidel67.h		
📕 📓 Bar_si25.hyg	) 📓 Dewell24.hyg	📓 Haw117.hyg		pn <u>Fi</u> le	
📘 📓 Bilan304.hyg	) 🛛 📓 Dewell42.hyg	📓 Ld103_10.hyg	📓 Leidl104.h	on ' <u>D</u> escriptive	
📓 Boley62.hyg	📓 Dewell44.hyg	📓 Leidel56.hyg	📓 Mof134ns.		
📓 Chip123.hyg	📓 Gupta271.hyg	📓 Leidel61.hyg	📓 Mof134s.h		
		—	_		
•			▶		
File <u>n</u> ame:			<u>O</u> pen		
Files of <u>type</u> :	Hyginist Files (*.hyg)	•	Cancel		
				1	

#### 2.8.2 Editing raw data

Change the value of a result by clicking in the grid and selecting the value.

e S <u>t</u> astistics Report <u>H</u> elp						
art Raw data Limits Descriptive statistics Plot Up	r limit UTL   Mean UCL					15
	F		CUE	lyginwin5\Acn8_9.hy	19	
Measured in: ppm 🔻	-	Number		Conentration	Unit	
		•	L =	2.0E-2		ī
Range of the sample outcome			2 =	5.0E-2		
Sample size M= 116			3 =	5.0E-2		
			1 =	5.0E-2		
Lowest outcome 2.0E-2			5 =	5.0E-2		
			5 =	5.0E-2		
Highest outcome 17.9						
Highest outcome 17.9			7 =	5.0E-2		
Highest outcome 17.9			7 =	5.0E-2 5.0E-2		
Highest outcome 17.9			·			

Now retype its value

If a series raw data from the current directory contains:

- values outside the range (1E-10 through 1E+10),
- just equals,
- too much variance,

a mesage box apears with an error messages.

This offers you the possibility to correct a file (for example to introduce detection limit values in stead of zeros).

Example 5 Show raw data file

Contents - Index

#### 2.2.1.2 Units of measurement

Enter units of measurement (=dimension):

- to prevent errors in entering a limit value
- as an aid for the report facility,

The dimension characterizes the intensity of the exposure. The sampling method decides on the denominator and the analytical methods on the numerator. Indicator tubes and direct readable devices for gasses and vapors often use 'parts per million' (ppm = ml/m3). For toxicological active gasses and vapors 'weights per volume' (like mg/m3) as the dimension is mostly undesired. The use of these measures originates, however, from the analytical laboratory procedure. According to EN 689 (CEN 1995) the following dimensions for workplace atmosphere should be preferred:

- gasses and vapors ml/m3 (ppm, independent of temperature and pressure) or mg/m3 at 20 °C and 101,3 kPa,
- fibers/m3,
- aerosols (suspended matter) mg/m3

#### 2.2.3.2 Censored data

Treat measurements outside the range of accuracy as follows:

- define an upper and/or lower limit (LL, UL) outside the range of accuracy (II through ul), so that no outcome lie outside the range of accuracy and inside the limits (LL through II and ul through UL);
- give results outside the range of accuracy the value of the limit.

Example 3 Range of accuracy

#### note 12

There is no single accepted way to handle undetectable levels (Leidel 1977 p 103). The procedure followed here is introduced to get a clear graphical presentation in the probability plot (screen 17).

#### **Example 3 Range of accuracy**

\*.HYG Description
HAW104 An 'Acid Operator' in a (hypothetical) Sodiumchlorine plant is measured for chlorine gas. 10 random TWA<sub>8 hour</sub> workplace air exposure samples were collected (Hawkins 1991 p 104). The results in ascending order are
<.1, <.1, <.1, .1, .2, .2, .3, .3, .4, .5 PPM.</li>
The lower accuracy limit of the measurement technique is .1 PPM.
Because one result is exactly .1 and three results are <.1, the lower detection limit is established at .05.</li>
The following data are entered
.05, .05, .05, .1, .2, .2, .3, .3, .4, .5 in a file called HAW104.HYG.

#### **Example 5 Show raw data file**

\*.HYG file Description

LEIDL103 To eliminate the fixed background concentration of .1 PPM HF in the file LDL103\_10 LEIDL103.HYG, subtract .1 PPM from all data and save the result as LDL103\_10.HYG SCHNE224 Items of which life time under stress is the quality characteristic, are tested (Schneider 1988 p224). The survival time of 15 items from a batch of 50 were 1.6, 2.0, 3.3, 3.3, 3.4, 3.5, 3.8, 4.4, 4.5, 4.5, 4.8, 5.0, 5.8, 5.9, 5.9. (Schneider 1988 Table 7.2.). The remaining thrityfive exceeded the survival time 6.0. Change the default value zero to 6.0

#### 2.2.2 Assign a name to the exposure data

Every file name should start with a character. The obligate name extension `.HYG` can be omitted. The name length may not exceed 255 characters

If a new file with raw data is created and saved with an existing name, then the data of that file are removed.

If only descriptive statistics will be entered, then using an existing name has no consequences for the raw data in that file.

## 2.2.1.1 Sample size

Enter the sample size. If more than two measurements are entered, then examining the shape of the sample distribution is possible.

If the goal of a HYGINIST session is the assessment of:

- The NIOSH non-compliance probability (see par. <u>5.1.2</u>), or
- The minimum sample size for long-term control (see chapter 7),

and the descriptive statistics GM and GSD will be entered, then any integer between the limits is valid.

More on sample size see 2.2.1

Example 1 Reanalyzing exposure data by adapting the number of degrees of freedom

# **3 Plot**

The tab <Plot> includes:

- the examination of the Lognormal shape of a sample exposure data, and
- descriptive statistics estimation between limits of accuracy.

<u>Table 4</u> in paragraph <u>3.4</u> helps the user to draw proper conclusions on the shape. A Lognormal shape is essential for an effective extrapolation to general results (Hawkins 1991 p58).

The tab "Plot" presents:

- a plot of the sample on Lognormal probability scale (Screen 17a, see par. 3.1),
- defining the accuracy range of the sample measurements (Screen 17bcd see par. 3.1.2)
- linear regression (Screen 17e, see 3.1.3)
- regression estimators for the descriptive statistics (Screen 17e, see 3.1.4)
- testing the shape (Screen 18, see par. 3.2),
- seven different transformations (Screen 19, see par. <u>3.3</u>).

If at least three data entries are entered by the keyboard or loaded from a file, then this tab is visible.

The exposure data in <u>example 9</u>, <u>example 10</u> and <u>example 11</u>, and the corresponding figures, are used throughout the manual to illustrate the different aspects on Lognormal extrapolation and inference in the following chapters.

#### **3.4 Decision scheme**

The following procedure, based on both industrial hygiene and statistical considerations, helps to decide if the Lognormal model is indeed the most effective model to describe this series exposure data (A.4.1 and proposition 1).

1 establish decision criteria, based on strategic 3.4.1 or compliance 3.4.2 considerations, 2 examine the assessment strategy, in particular on:

- homogeneity in the population(s) under study (see <u>A.2</u>),
- autocorrelation, if GSDTWA 8 hour<2 (Spear 1986, Francis 1989, Rappaport 1991),</li>

3 examine the sample series on outliers and remove them from the sample if there are grounds for doing so (see  $\underline{B.3}$ ),

4 establish the accuracy range and set upper and/or lower limits in Screen 17bcd (see 3.1.2), if raw data exceed the accuracy range (see B.4.3),

5 examine the conformity with the Lognormal distribution using Table 4,

6 test the results from 5 with the decision criteria in 1 and decide on the conformity. If you decide that the conformity is not rejected, then continue with extrapolation and compliance testing.

#### Table 4 Lognormal goodness-of-fit decision scheme

Decide on situations not covered by Table 4, through an evaluation of the exposure assessment strategy.

# **3.4.1 Strategic considerations**

Lognormal goodness-of-fit:

- is of minor concern in range finding research,
- should not be rejected in long-term compliance control and/or routine monitoring programs,
- is important in first establishing similar exposure groups (see <u>A.2.3</u>).
- is important if the NIOSH method for long-term TWA control is used (see <u>5.1.2</u>).

If the observed shape is not in compliance with the goal of the exposure assessment, then both sampling plan and the strategy should be reconsidered.

#### **3.4.2 Compliance considerations**

Goodness-of-fit is:

- important if the limit H lies in the central region of the exposure distribution, that is:
- C1≤H and См≥0.1\*H, or
- GM<H and GM\*GSD<sup>2</sup>>H.
- less important if robust extrapolation distributions are used, like the (Noncentral) Student
- of only academic importance if GSD<1.4, or
- if limit H is an outlier in the exposure distribution, that is:
- extremely high,  $GM \ge H$  or  $C_{M/2} \ge H$ , or
- extremely low, GM\*GSD₂≤H or Cм≤0.1\*H,

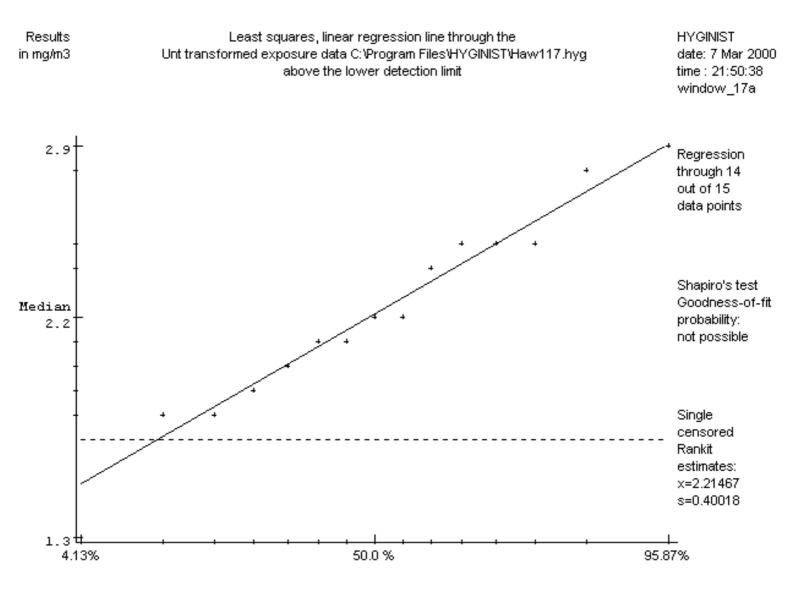
Figure 11 15 Untransformed TWA8 hours Figure 12 Total dust 12 TWA8 hours dust (HAW117) (BOLEY62)

Example 16 Conformity with the Lognormal model. 28 files with A(W)logD5%

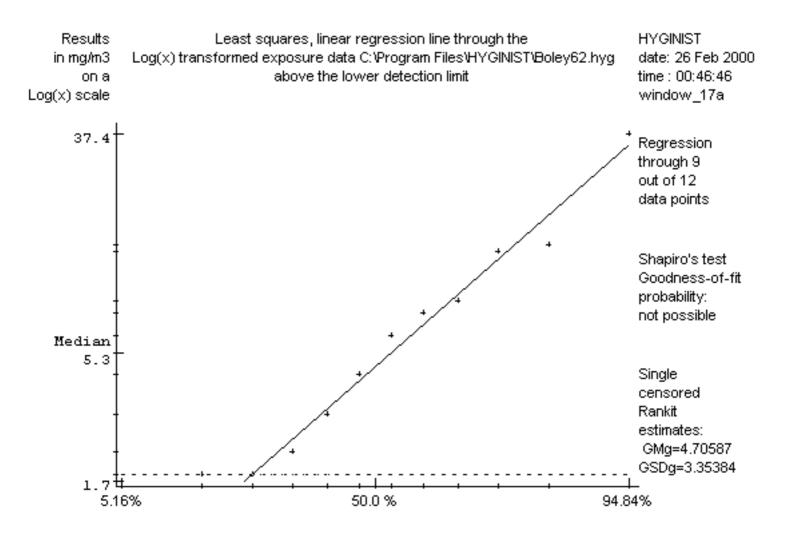
Example 17 Conformity with the Lognormal model based on the graph. Complete files with <u>A(W)</u>log<5%

Contents - Index

# Figure 11 15 Untransformed TWA8 hours dust (HAW117)



#### Figure 12 Total dust 12 TWA8 hours (BOLEY62)



# Example 16 Conformity with the Lognormal model. 28 files with A(W)>=5%

\*.HYG file Description of the exposure data Shapi A(W) Lognormal name ro W in % Conformity

LEIDEL67 10 one worker TWA8 hour PAS Dioxane (Figure 1) 0.99 99.5 Good LEIDL104 24 TWA8 hour PAS Methyl Methacrylate (Figure 21) 0.99 97.3 Perfect LEIDEL63 5 one worker, one shift TWA10 min PAS CS2 0.99 94.8 Good LEIDEL61 35 random, momentary workplace Ozone read off's 0.98 92.1 Good POST10P5 4 one worker, one press TWA8 hour PAS Styrene 0.98 90.4 Good RANDOM20 2000 Standard Lognormal deviates 0.99 87.5 Good BAR SI25 6 Carbon monoxide grab samples 0.94 64.4 Rejected DEWELL44 11 SEG TWA8 hour PAS welding [MIG] fume 0.94 51.4 Acceptable POST08P4 5 one worker, one press TWA8 hour PAS Styrene vapour 0.92 50.8 Acceptable LD103\_10 12 corrected grab sample HF correction (Figure 13) 0.94 50.7 good\* COHEN132 20 maximum flood levels (Figure 14) 0.96 49.4 good\* BILAN304 5 TWA8 hour Methylene bisphenyl isocyanate. (Figure 9) 0.91 43.7 Acceptable LEIDEL56 8 TWA20 min PAS Ethyl alcohol vapour (Figure 10) 0.92 41.8 Acceptable CHIP123 10 TWA8 hour PAS lead dust 0.93 40.0 Acceptable MOF134S 16 TWA10-30 min Methoxyfluorane. Scavenged (Figure 20) 0.90 37.2 Acceptable\* HAW117 15 SEG, random TWA8 hour PAS total dust 0.94 35.7 Acceptable\* DEWELL24 8 one worker TWA8 hour PAS on foundry respirable dust 0.91 34.3 Rejected SOLV198 45 housepainter TWA8 hour PAS Hydrocarbon (Figure 2) 0.97 33.9 Acceptable BOLEY62 12 one worker TWA8 hour PAS total dust (Figure 12 page 38) 0.93 33.4 Acceptable\* ALBRE220 4 PAS TWA8 hour Aspartame total dust 0.87 29.2 Acceptable POSTB11I 14 TWA8 hour PAS Styrene vapour (Figure 3) 0.93 29.0 Rejected X07-10 35 concentrations of chemical X 0.94 17.6 Rejected GUPTA271 10 mice, survival (Figure 26) 0.89 14.8 Acceptable\* HAW104 10 random TWA8 hour PAS Chlorine (Figure 8) 0.87 10.1 Rejected POST1008 combination of POST08P4 and POST10P5 0.85 7.6 Rejected MOF134NS 16 TWA<30 min Methoxyfluorane. Nonscavenged (Figure 19) 0.90 7.6 Acceptable\* DEWELL42 10 TWA10 min PAS on formaldehyde 0.86 6.6 Rejected

LEIDL103 12 stationary, grab sample HF, one hour sequence 0.87 6.6 Rejected \*conformity decision after censoring

# Example 17 Conformity with the Lognormal model based on the graph. Complete files with A(W)log<5%

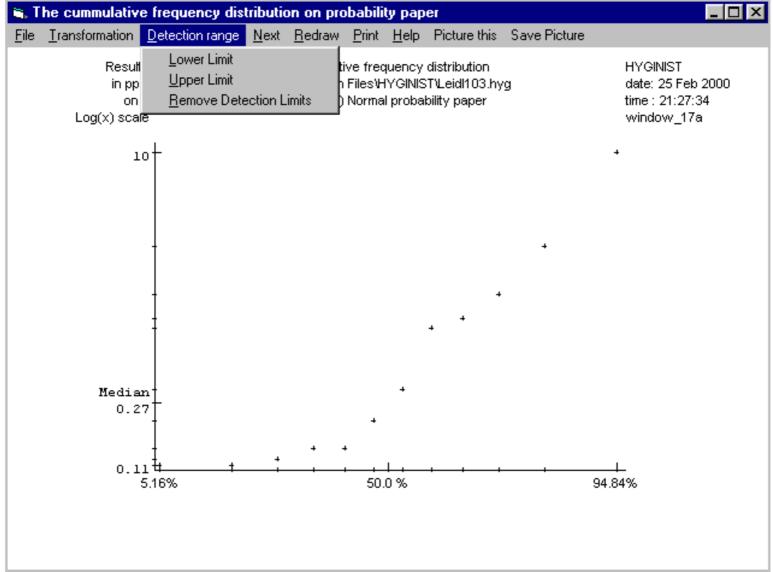
\*.HYG file Description of the exposure data Shapi A(W) Lognormal name ro's W in % Conformity

SCHNE70 failure distance of 96 locomotives (Figure 6) 0.62 1.27D-37 very good SCHNE224 survival of 50 items under stress (Figure 5) 0.54 8.6D-16 Good OWEN716 15 grab sample airborne Chlorine (Figure 4) 0.83 0.97 Acceptable

#### **3.1.2 Accuracy limits**

With menu option "detection limits", upper and lower limits can be introduced and removed. A accuracy range prevents that outlier data that cannot be excluded from the sample, bias the estimation of the location and the variance. Using the data within the range of accuracy and the corresponding rankit values:

- the shape is examined (<u>3.1.3</u>),
- the descriptive statistics are estimated (<u>3.1.4</u>).
- See par. <u>2.2.3.2</u> on how to enter censored exposure data.



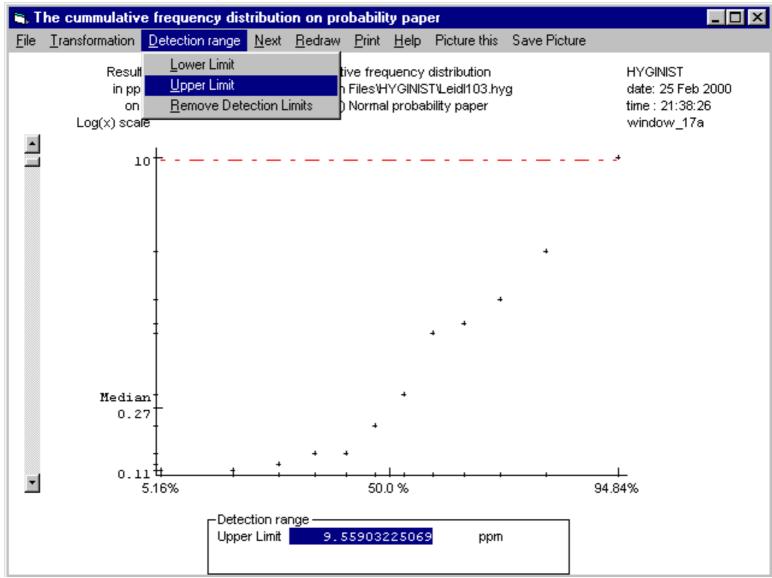
Screen 17b Should accuracy limits be entered?

The range of accuracy is always limited:

• All air sampling- and/or analytical methods do have a detection upper and lower limit. TWA8 hour PAS total dust measurements have an accuracy range of about 1.8 to 15 mg/m3 as will be shown in the examples. For aerosols and fibers PAS sampling accuracy limits are narrower than for and gases.

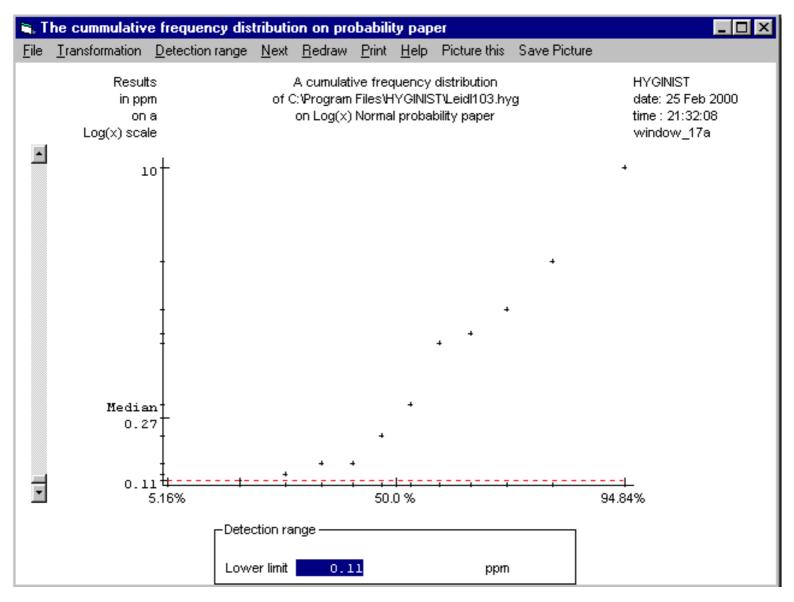
• Non-traceable errors in the strategy execution, the sampling, analysis and/or report procedure, or just by chance, can cause one or more of the extreme result(s) to behave like outliers. To prevent bias on the estimators without eliminating these data, upper and lower limits should be introduced.

Almost all Health and Safety organizations provide analytical methods for the determination of workplace air contaminants (AIHA, ISO, CEN, DFG, EPA, HSE, WHO etc.). They are often based on the manuals from OHSA (1985 and 1987) and NIOSH (Eller 1984). Voice (Dräger), Supelair (Supelco) and DOHS-Base (DOHSBase VOF) are data retrieval, Windows computer programs with industrial hygiene limit values and the detection range of the corresponding measurement methods.



A value of 1.1\*C(M) is displayed as default upper limit in Window 17c.

A value of 0.9\*C(M) is displayed as default upper limit in Window 17d.



Example 10 Upper limit

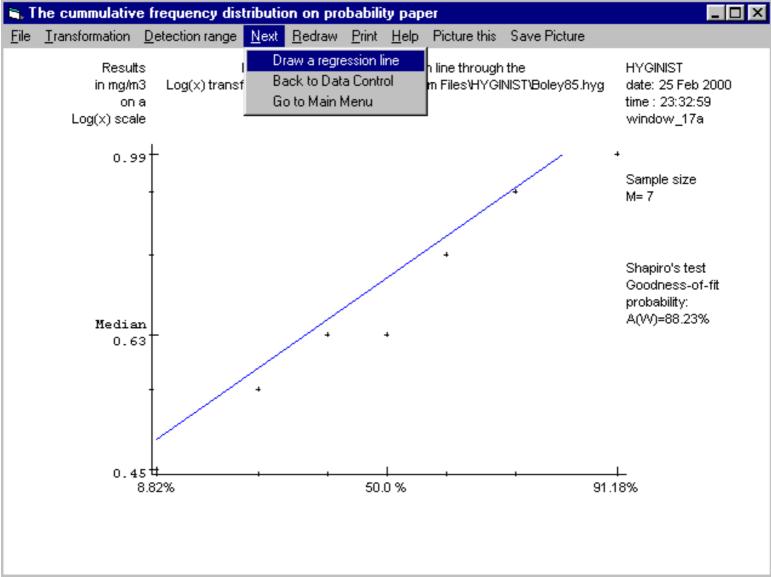
Example 11 Lower limit

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#### 3.1.3 Linear regression

Screen 17e, displaying the linear regression line, is specifically made for:

- Graphically examining the goodness-of-fit,
- Selecting the most effective transformation,
- Making reports



Window 17e Lognormal regression. 7 TWA8 hour ZnCl2 total dust on one worker

The linear regression line is calculated by using the method of least squares (Snedecor 1980 chapter 9). If:

- at least one limit is entered, or

- the transformation is "untransformed",

then Window 17e shows the number of data pairs in the regression ("Regression through #### out of #### datapoints") in the left margin. For the Lognormal case the upper limit Cu% can be estimated by:

3.1.3 Linear regression

$$C_{U\%} = GM^{g} \times (GSD^{g})^{Z_{U\%}}$$
 Formula 3-1

With GMg and GSDg calculated using the Formula 4-10 and Formula 4-9.

# **3.1.4 Regression estimators for the descriptive statistics**

lf:

- at least one limit is entered, and
- the transformation is logarithmically or untransformed,

then Screen 17f shows in the right margin:

- the number of data pairs in the regression ("Regression through #### out of #### datapoints"),
- the censoring type ("Single" of "Double") to indicate that one or two limits are introduced,

• the rankit estimators for location and variance based on the data pairs in the regression if the data are logarithmic transformed ( $GM_g$  and  $GSD_g$ ) or untransformed ( $x_{cg}$  and  $s_{cg}$ )

The use of the rankit regression estimators is recommended:

- if a fixed background concentration exceeds the lower variance (see Leidel 1977 p103),
- if the strategy used is based on it (Leidel 1977 p107, WHO 1984, Travis 1990),
- in reanalyzing historical references where it was used.

See <u>B.3.1.</u> for the algorithms of  $GM_g$  and  $GSD_g$  and their properties.

Example 12 Rankit versus direct estimators

#### **Example 12 Rankit versus direct estimators**

To show the effectivity of the rankit estimators a lower limit of 30 PPM was introduced in the 10 TWA<sub>8 hour</sub> (LEIDEL67.HYG) PAS Dioxane sample (Figure 1). Because this limit is between the default .9\*C1 and C1 the rankit estimators are calculated from the complete sample:  $GM_g$ =78.4 and  $GSD_g$ =1.67.  $GSD_g$  is about 2% higher than the direct estimator GSD=1.63 (see Example 17).

#### **Example 10 Upper limit**

#### \*.HYG files Description

SCHNE224 The survival of items under stress is Lognormal distributed (Schneider 1986 page

224). When the (accelerated) lifetime is above 1 time units (TU) an item conforms the quality limit. 35 items out of a sample of 50 survived 6 time units (TU). The results with an upper limit at 6 TU are plotted in Figure 5.

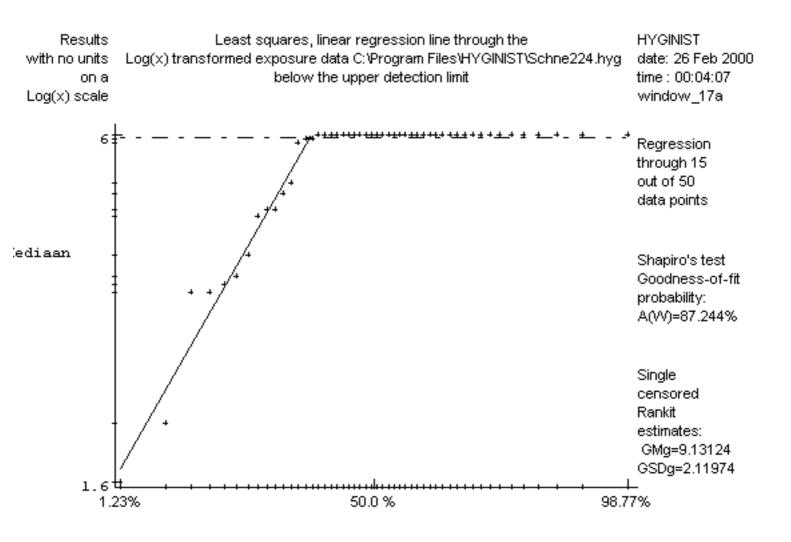
SCHNE70 Schneider (1986 example 4.3 page 69) used a sample of 96 locomotives with 37 failures before the (type I) upper censor point of 135,000 miles, assuming a Lognormal distribution. This seems to be justified by the rankit Figure 6.

OWEN716 In order to classify the TWA8 hour exposure using 15 grab sample, detection tube

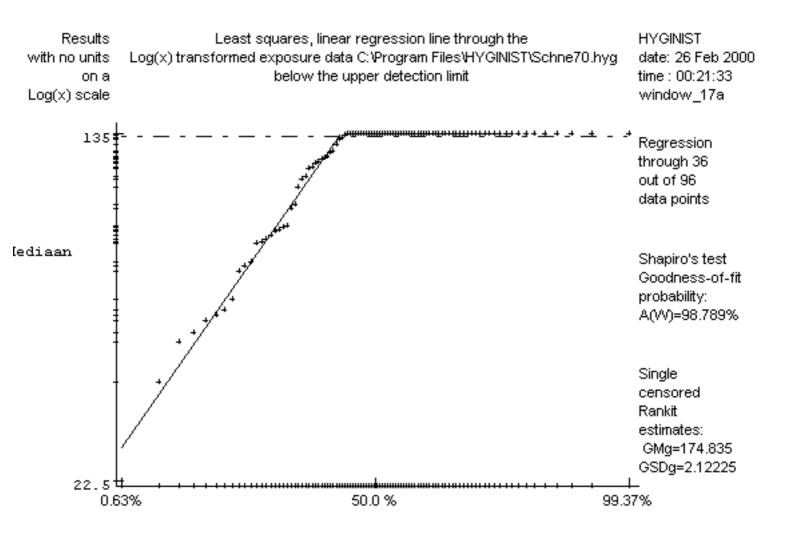
Chlorine concentrations both upper (9 PPM) and lower limit (.25 PPM) should be used (Owen 1980 p716). See <u>Example 19</u> for more files with upper limits.

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#### Figure 5 50 Items under stress (SCHNE224)



# Figure 6 The mileage of 96 locomotives (SCHNE70)



# Example 19 df, GMg and GSDg of censored Lognormal samples

\*.HYG file Description of the exposure data Sample units LL UL uncen-df GMg GSDg Name Size sored M M` BOLEY62 TWA8 hour PAS papermill total dust 12 mg/m3 2.0 - 9 9 4.71 3.35 COHEN132 maximum flood levels 20 106 0.27 - 18 18 0.40 1.34 ft<sub>3</sub>/sec DEWELL24 TWA8 hour respirable dust in 8 mg/m3 1.3 2 6 6 1.22 1.56 foundry DEWELL44 TWA8 hour PAS welding [MIG] fume 11 mg/m3 - 18.0 9 9 11.12 1.74 GUPTA271 mice survival after inoculation 10 days - 65.0 7 7 56.0 1.24 with tuberculosis HAW117 TWA8 hour PAS total dust 15 mg/m3 1.7 - 14 13 2.19 1.19 LEIDL103 stationary, grab sample, 12 PPM 0.14 - 7 8 0.29 8.27 one hour sequence HF OWEN716 grab samples airborne Chlorine 15 PPM 0.25 9.0 8 10 0.88 6.81 SCHNE224 survival of items under stress 50 TU - 6.0 15 30 9.1 2.12 SCHNE70 failure distance of locomotives 96 103 - 135.0 37 65 174.2 2.12 miles SCHNE224.HYG the number of degrees of freedom is established as df=2\*15=30 [because (50+15)/2-1D2\*M]. All others df=(M+M`)\2-1.

## **Example 11 Lower limit**

#### \*.HYG file Description

LEIDL103 Hydrogen Fluoride exposure near a control panel in a production unit was measured

using a stationary grab sampler with a one-hour sequence (Leidel 1977 page 103).

The results are 0.11, 0.11, 0.12, 0.14, 0.14, 0.21, 0.33, 0.8, 0.91,

1.3, 2.6 and 10.0 PPM. The cumulative frequency distribution lacks

Lognormality in the left tail (see Screen 17a). Continued in Example 20.

HALD151 The diameter of population rivet heads follows a Gaussian distribution with  $\mu$ =13.426 mm and  $\sigma$ =0.111 mm (Hald 1952 p148). A device with a lower detection limit of 13.4 mm was used to measure a sample of 500 rivet heads (.HYG). 190 diameters were below the detection limit.

The shape of the untransformed results are displayed in

Figure 24 (grouping interval 0.05 mm). Because of the small scale,

the shape of the sample conforms to both the Normal and Lognormal distribution.

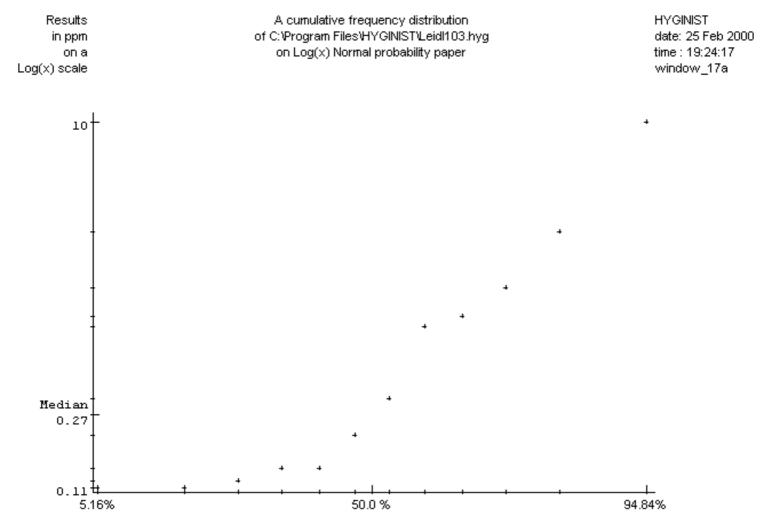
## **3.1 Graphical examination**

Graphical examination includes:

- a Rankit plot (Screen 17a, par. <u>3.1.1</u>),
- the assessment of the accuracy range (optional, Screen 17bcd, see 3.1.2),
- a linear regression fit (Screen 17e, see <u>3.1.3</u>) within the accuracy range,
- the estimation of the descriptive statistics (Screen 17ef, see par. 3.1.4 and 3.1.5),
- plots can be captured and saved, see E.3

## 3.1.1 The rankit plot

In the picture box the ascending ordered concentrations are plotted against their expected places (see <u>B.1</u>) within a normal distribution. The (un)transformed concentrations are displayed on the vertical Y-axis. For more information on normal probability plots see <u>B.1.1</u>.



Screen 17a Probability plot of exposure data on rankits scale

The <u>median</u> is displayed in Screen 17a if its value falls within the range of 5-95% of the vertical axis.

Rankit plots are made from all exposure data described in example 9, example 10 and example 11. <u>Example</u> <u>19</u> contains censored data files. How the rankit plot is used in the evaluation of shape is explained in paragraph <u>3.4</u>.

Example 9 Description of rankit plots 1 through 4

Figure 1 Ten TWA8 hours <u>Dioxane (LEIDEL.67)</u> Figure 2 45 TWA8 hours total hydrocarbons among <u>maintenance painters (Solv198)</u>

Figure 3 14 TWA8 hour Styrene on inlayers Figure 4 15 grab sample airborne working on different presses (POSTB11I) chlorine concentrations (OWEN716)

## **Example 9 Rankit plots**

#### \*.HYG file

LEIDEL67 This example (Leidel 1977 p67) is used in this manual to explain the NIOSH method for the calculation of geometric mean of long-term exposure and the use of the probability of non-compliance when deciding whether to install engineering control (see 5.1.2). On 10 different days in a period of 6 months an employee's TWA8 hour Dioxane (H=100 PPM) concentration was measured (see Figure 1)

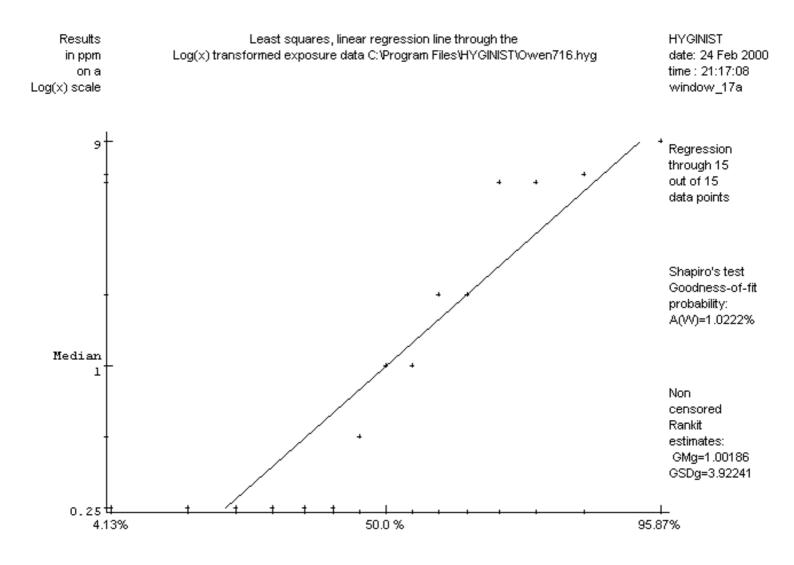
SOLV198 In a Health Hazard Survey among maintenance painters a stratified sampling programme was performed in order to estimate the current range of total Hydrocarbon exposure (in mg/m<sub>3</sub>) during solvent based paint rolling and spraying (Scheffers 1987). 45 TWA<sub>8 hours</sub> were measured.

Although there was no randomisation by purpose, the goodnessof-fit with the Lognormal model is appropriate (see Figure 2). The two-sided tolerance limits  $(1-2\alpha)$  are compared with the one-sided tolerance lower  $(1-\alpha)$  and upper  $(\alpha)$  limit (continued in Example 31).

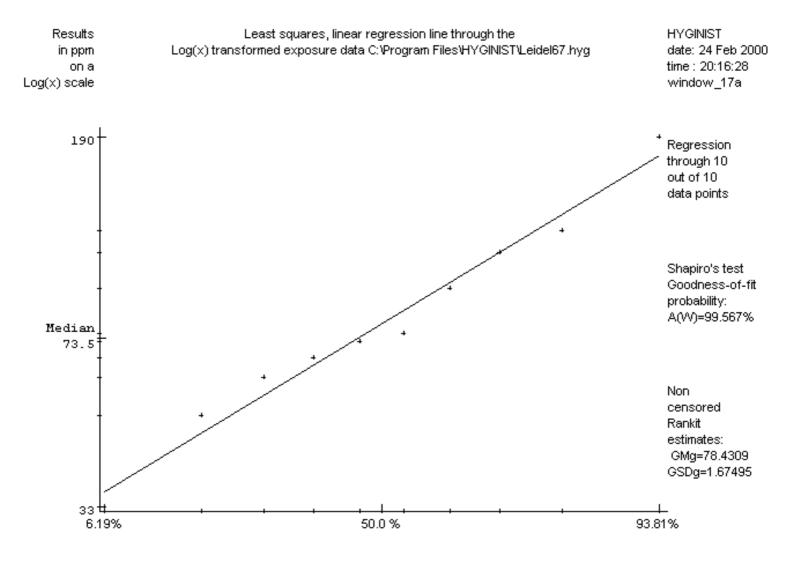
POSTB11I Among a group inlayers in a fibreglass reinforced polyester product manufacturing plant (Post 1989, 1991) 14 TWA<sub>8 hour</sub>'s styrene vapour were measured. Figure 3 shows the characteristics of a mixed population situation: two curved lines linked at an angle. The study report confirms that the five lowest measurements were taken at a different press than the highest nine. To compare both populations see Example 39.

OWEN716 At an industrial site in the US, 15 grab sample airborne Chlorine concentrations were gathered over a working day (Owen 1980 p716) in order to classify for the federal TWA<sub>8 hour</sub> standard of 1 PPM. The results are 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.50, 1.00, 1.00, 2.00,2.00, 6.00, 6.00, 6.50, 9.00 PPM. The goodness-of-fit is poor (see Figure 4).

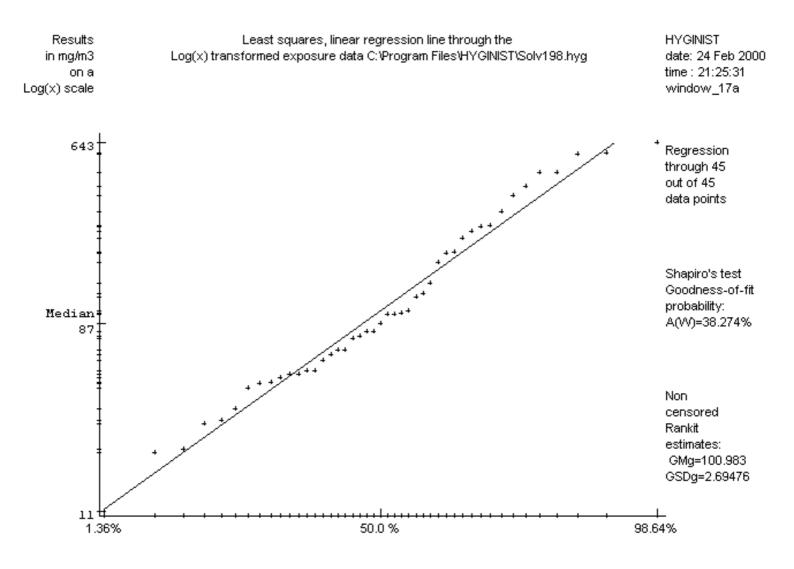
## Figure 4 15 grab sample airborne chlorine concentrations (OWEN716)



### Figure 1 Ten TWA8 hours Dioxane (LEIDEL.67)



## Figure 2 45 TWA8 hours total hydrocarbons among maintenance painters (Solv198)



# **3.1.5 Rankit estimators for Normal descriptive statistics**

If you selected the option "untransformed" in Menu Transformation, then the rankit estimators for location and variance (xcg and scg respectively), based on the data pairs in the regression, are displayed.

Table 2 Rankit estimators for Normal descriptive statistics

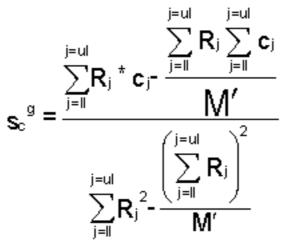
- **Example 13 Normal distributions**
- Example 14 Comparing xcg and scg with estimators from literature
- Figure 7 10 Chlorine TWA8 hour. Logarithmic transformed and uncensored (HAW104)
- Figure 8 10 Chlorine TWA8 hour. Untransformed and censored (HAW104)

## Table 2 Rankit estimators for Normal descriptive statistics

**Estimator Description** 

M' the number of results between M' = ul - llFormula 3-2 the accuracy limit

xcg arithmetic mean of the Formula 3-3 untransformed data, estimated



using the data pairs between the accuracy limits

scg standard deviation of the Formula 3-4 untransformed data, estimated

$$\overline{\mathbf{x}}_{c}^{g} = \frac{\sum_{j=1}^{j=u} \left[ \mathbf{c}_{j} - \mathbf{s}_{c}^{g} * \mathbf{R}_{j} \right]}{\mathbf{M}'}$$

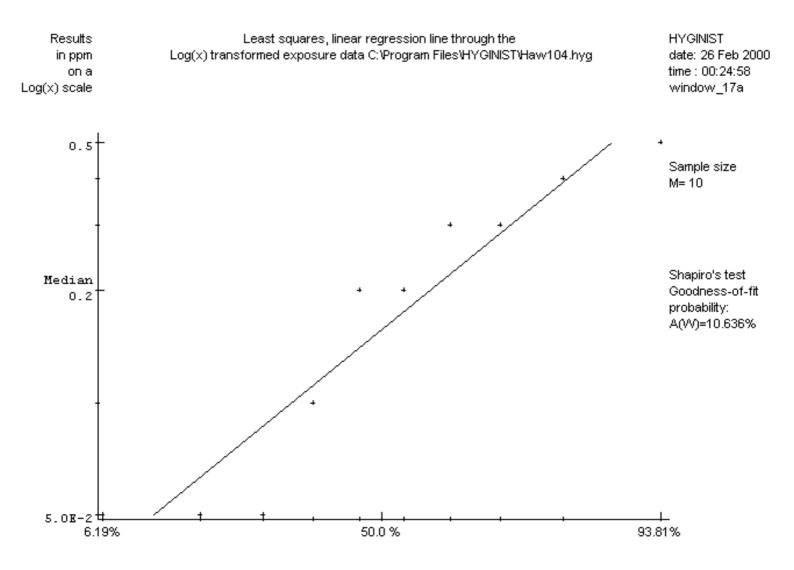
using the data pairs between the accuracy limits

## **Example 13 Normal distributions**

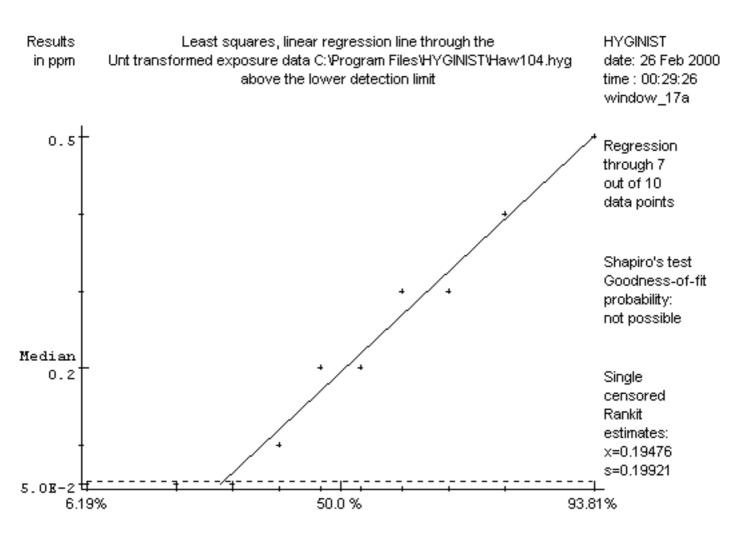
Conformity with other than the Lognormal distributions is found in the following examples from Table 1:

\*.HYG file Description A(W)log A(W)unt
in % in %
BAR\_SI25 Carbon monoxide grab samples 64.4 79.5
HAW117 15 TWA8 hour total dust (Figure 11, Example 57), 35.6 85.5
DEWELL42 10 Formaldehyde grab samples 6.6 39.9
LEIDEL56 8 TWA<sub>20</sub> min Ethyl Alcohol (Figure 10) A(W)x<sup>2</sup>=99.2% 41.8 94.9
X07-10 30 concentrations of chemical X. Aunt is 17.6 25.9
equivalent to Gustafson (1991 chapter 7)
who finds Aunt(0.9541)=25.2%,
CONOV195 50 two-digit numbers from telephone book. 2.9 23.1
Wunt=.964 is exactly the same as calculated
by Conover (1980 p365)
LEIDEL63 5 Short period exposures Hydrogen sulphide 94.8 95.5 (see Example 57).

## Figure 7 10 Chlorine TWA8 hour. Logarithmic transformed and uncensored (HAW104)



## Figure 8 10 Chlorine TWA8 hour. Untransformed and censored (HAW104)



## **E.3.2 Capture graphics**

You can copy bitmaps of all tabs and the 'log-Normal frequency distrbution' using the follwing keys on your keyboard:

- the 'Print Screen' button
- the combination of 'Alt' + 'Print Screen'.

If you then open a picture editor program (like Paint, Photo Editor etc.) or a professional word-processing program, you can paste, edit, select and save the full screen ('Print Screen') or only HYGINIST window ('Alt' + 'Print Screen').

## **3.2 Tests for normality**

The W-test of Shapiro & Wilk (1965) for normality is the most effective one among the existing omnibus tests (see  $\underline{B.1.2}$ ). Shapiro (1990 p21), however, warned: "No single [goodness-of-fit] test statistic can give you as much information as a graphical display which shows the extent and types of departures from the hypothesized model".

## **3.3 Other transformations**

Try different transformations if the Lognormal shows a poor fit. It is not possible to combine two or more of the seven transformations. Different transformations will show similar figures if the variance is small (GSD<1.4).

Menu options "Transformation"

Option Comment Double Double logarithmic transformation, log{log(ci)}. If c1<=1, then all results are multiplied with EXP(1)/c1 to keep log(ci) positive Log The natural logarithm of the result, log(ci), the standard transformation in HYGINIST Sqrt The square root, %ci Untranformed Untransformed, ci Squared Squaring, (ci)<sup>2</sup> Exponential The exponential transformation on base e=2.71828.., EXP(ci)=ec. If c1>44, then all results are first multiplied by 1/c1 to prevent overflow Reciprocal Reciprocal transformation, 1/ci

Transformations 1 to 6 influence the skewness (asymmetry). The first two decrease the variance and stabilize distributions with high extremes. Transformations 4, 5 and 6 increase variance and stabilize a sample with low extremes. All transformations except the double logarithmic are independent of the location. In Table 3 some distributions and transformations are related.

Table 3 Type of distribution according to the goodness-of-fit with a transformation

Best transformation fit Distribution type Ci Normal, Gaussian log(Ci) If  $s/x \approx constant$  for every Ci, then Lognormal Sqrt(Ci) If  $s^2 \approx x$  for every Ci, then the Poisson distribution 1/Ci If  $s \approx x^2$  for every Ci, then inverse normal

Figure 9 5 TWA8 hour MDI during indoor spraying. Figure 10 8 TWA20 min Ethyl Alcohol. LogLog transformed (<u>BILAN304</u>) One worker, one shift, untransformed (<u>LEIDEL56</u>)

Example 15 Other transformations

## Figure 9 5 TWA8 hour MDI during indoor spraying. LogLog transformed (BILAN304)

#### Figure 10 8 TWA20 min Ethyl Alcohol. One worker, one shift (LEIDEL56)

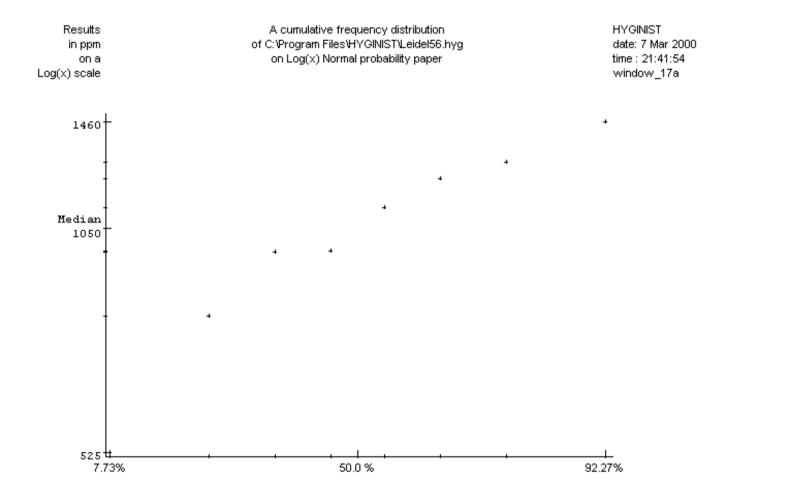


Figure 10 8 TWA20 min Ethyl Alcohol. One worker, one shift (LEIDEL56)

## 2.1.1 Range of sample sizes

The sample size M is restricted to integer values between 2 and 2000. Two unequal and uncensored data are at least necessary to calculate a sample variance. The maximum of 2000 arises from the accuracy in calculating rankits (see B.1.1). Also with >2000 data the estimators GM and GSD differ hardly from their descriptive statistics EXP( $\mu$ ) and EXP( $\sigma$ ). Three or more measurements makes it possible to examine the shape of the sample distribution. More on sample size see 2.2.1.1

## Example 1 Reanalysing exposure data by adapting the number of degrees of freedom

\*.HYG file Description

HAW117 To make a file of the 15 TWA<sub>8 hour</sub> total dust measurement results from Hawkins (1991 page 117), enter the sample size M=15. SCHNE224 To estimate the survival duration of items under stress, based on only the 15 items (Schneider 1986) who failed before the end of the observation duration (6 TU's), enter M=15 and the rankit estimators  $GM_g$ =9.1 and  $GSD_g$ =2.12 (see Figure 5)

## **2.2.1.3 Sampling Duration**

This is the time period the sampling measurements represent:

- a ten seconds sampling period may represent instantaneous sampling,
- a five hours sampling period is often sufficient for a full shift exposure assessment.

## 2.2.3.1 Raw data (uncensored)

Fill the cells of the grid with the individual measurement outcome. Use the arrows up and down to move through the grid.

<b>a, HYGINIST Raw data</b> <u>F</u> ile Report <u>H</u> elp					
Start Raw data					1
		Haw117			
Measured in: mg/m3 💌		Number		Conentration	Unit
		1	=	2.9	mg/m3
		2	=	1.3	ng/n3
		3	=	2.8	ng/n3
		4	=	1.8	ng/n3
		5	=	0	ng/n3
		6	=	0	ng/n3
		7	=	0	ng/n3
		8	=	0	ng/n3
Limiting the detection range		9	=	0	ng/n3
		10	=	0	ng/n3
		11	=	0	mg/m3
		12	=	0	ng/n3
		13	=	0	mg/m3
		14	=	0	ng/n3
		15	=	0	ng/m3
	*				

A measurement result is >1D-10 and <1D+10, and consists of: at most 16 digits (double precision) and optional, a floating point and/or an exponent. Enter a positive natural number within the range. The decimal point followed by an E or D, a + of - and one or two digits is recognized as an exponent

After pressing the <Enter> key a result is stored. After the last result is entered the file is sorted (Screen 10, par. 2.3.1). Next transaction is Show and Edit ( par. 2.8).

Example 2 Entering raw data

## **Example 2 Entering raw data**

\*.HYG file Description

HAW117 Enter the 15 TWA<sub>8 hour</sub> random collected total dust samples (OEL 10 mg/m3) from a similar exposure group (Hawkins 1991 page 117) in an arbitrary order 2.9, 1.3, 2.8, 1.8, 2.1, 2.5, 2.1, 2.2, 1.9, 2.0, 2.5, 1.8, 2.2, 2.4, 2,5

#### 2.2.5 Descriptive statistics

If you click the option button 'Descriptive statistics' in frame 'Data type' then the frame 'Exposure data identification' appears:

🖷 HYGINIST Development ver	sion 4.0.53	
<u>F</u> ile <u>H</u> elp		
		За
Data type		
◯ <u>R</u> aw data file	Analyze a Lognormal distribution using his descriptive statistics. Enter a name and the sample size.	
Descriptive statistics		
Exposure data identification -		
Name	moOsigl	
Sample size M=	10	

In the frame 'Exposure data identification' you can fill out :

- a name (obligate)
- <u>A sample size (obligate)</u>

If name and sample size are entered then the frame 'Estimators of Lognormal geometric descriptive statitics' appears.

, HYGINIST Development version 4.0.53	_ 🗆 ×
File S <u>t</u> astistics <u>H</u> elp	
Start Limits Descriptive statistics	14
Data type	
Name mu0sigm1	
Sample size M=	Je
Estimators of Lognormal geometric descriptive statistics Degrees of Freedom df= 2 GM max. likelihood= GSD= 2.71828	
ow you can fill out:	

• <u>a Geometric mean</u> value between  $0.0001 \le GM \le 10000$ 

2.2.5 Descriptive statistics

• <u>a Geometric standard deviation</u> value between 1.001≤GSD≤1000

Entering estimators of the Lognormal descriptive statistics:

- assumes the exposure data originate from a Lognormal distribution,
- prohibits the evaluation of shape (chapter 3)

Example 4 Enter GM and GSD

Form more information on GM and GSD see **B.2** 

## **Example 4 Enter GM and GSD**

#### \*.HYG file Description

- To demonstrate "minimise sample size" in routine long-term compliance control, GSD=EXP(1)=2.71828 and GM=1 are entered using the file name MU0SIG1.HYG. OWEN716 Reanalyse the airborne Chlorine TWA<sub>8 hour</sub> (Owen 1980 p716) using only the 8 uncensored grab sample data within the accuracy range of .25 and 9 PPM. Enter (See Figure 4) in Screen 3a M=8 and in Screen 7ab the estimators  $GM_g$ =.88 PPM and  $GSD_g$ =6.81 (Continued in Example 10).

## **2.1 Sample requirements**

The numerical requirements on exposure values prevent random errors and the sample range (in numbers and numerical values) from influencing the validity and exceeding the range of accuracy.

Requirements are given for:

- sample size (2.1.1)
- measurement outcome (<u>2.1.2</u>)
- Rounding and grouping interval (2.1.3)

## 2.1.2 Range of valid exposure data outcome

Sample measurement values are restricted:

- between c(1) >= 0.000000001 and c(M) <= 10000000000.
- in the ratio of their extremes: 1.0001 < c(M)/c(1) < 1000000000.

Sample measurements and the Lognormal descriptive statistics are further restricted in the range of the:

- geometric mean  $0.000000001 \le GM \le 10000000000$ ,
- geometric standard deviation  $1 < GSD \le 10000$ .

A GSD=1 indicate that all exposure data are equal. The presence of variance within a series measurements is a requirement for performing statistical analysis

## 2.1.3 Rounding and grouping interval

The measurement method or the coarse rounding of measurement outcome may overshadow the workplace variance and thus influence the shape of sample distribution and the validity of the evaluation. To prevent this the arithmetic standard deviation w should be much larger than the rounding and grouping interval  $\nabla C$ .

## 2.2 Data entry

Choose between descriptive statistics or raw data (2.2.3). In that way it is possible to analyze:

- new series of measurement results,
- series of measurement results that are exported from exposure databases,
- literature or historical data from which only sample size and the estimators GM and GSD of the Lognormal descriptive statistics are reported.

You can enter exposure data :

- by keyboard (2.2.1),
- from a file in a directory (2.2.4).

## 2.2.1 Keyboard

Entering exposure data involves:

- sample size (<u>2.2.1.1</u>),
- the units of measurement (2.2.1.2),
- the sampling duration of measurement (2.2.1.3),
- characterization of the exposure by a name (2.2.2),
- the choice between raw data and descriptive statistics entry (2.2.3).

## 2.9 \*.HYG file editors

Many software programs can create, read, write, expand, compress and edit \*.HYG files. For example spread sheet Programs like Lotus or Excel, database programs like Access and dBase, Text editors like Notepad, Editpad, wordprocessing programs like Word and WordPerfect and many others (e.g. SPSSPC, Basic, C). They can, like HYGINIST, process one column (field), numerical SDF or DELIMITED files with the extension \*.HYG.

Example 6 Making a \*. HYG file with an other program

Example 7 Generating a Lognormal Monte Carlo \*.HYG file using Basic

Example 8 Making a \*.HYG file using dBase

# Example 6 Making a \*.HYG file with an other program

HAW104.HYG is made (<.05, <.05, <.05, 0.1, 0.2, 0.2, 0.2, 0.3, 0.3, 0.4, 0.5) using Word. The following numbers are typed on an empty page:

.05, .05, .05, .1, .2, .2, .2, .3, .3, .4, .5

The file is saved by clicking the mouse on menu button <File>, <Save as>

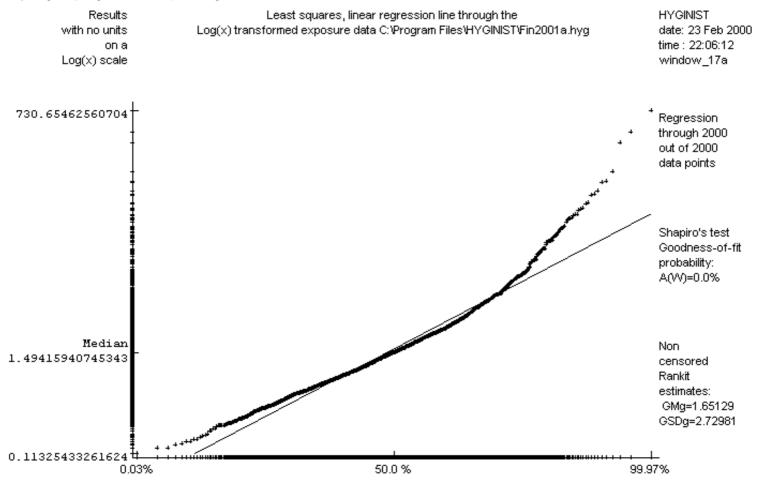
Now choose option <text file> and type HAW104.HYG<Enter>

More convenient is entering the data in a column using the <Enter> key and save it as an text file.

- .05
- .05
- .05
- .1
- .2
- .2
- .2
- .3
- .3
- .4
- .5

#### Example 7 Generating a Lognormal Monte Carlo \*.HYG file using Basic

The file HALD151 with 500 rivet head diameters is easily made using dBase because outcome were allocated in only 9 grouping intervals (see Figure 24



The dBase control centre was left using F10 and 'Exit to the dot prompt'. The following command lines were used:

).

- Command CREATE <database name>
- Field Name (W10 characters),
- Field type <Numeric>,
- Width 10 digits (including the decimal point and sign),
- Dec 5 decimal places,
- Index N,

Press <Ctrl> + <End> to stop CREATE database. Command a MODIFY COMMAND <program name> and program the following lines: DO WHILE RECNO()<=500 APPEND BLANK ENDDO Press <Ctrl> + <End> to stop MODIFY COMMAND,

Command DO <program name>. Now command the following lines from the dBase prompt REPLACE <Field name> WITH 13.39 FOR RECNO()=>1 .AND. RECNO()<191 Example 7 Generating a Lognormal Monte Carlo \*.HYG file using Basic

REPLACE <Field name> WITH 13.42 FOR RECNO()=>191 .AND. RECNO()<287 REPLACE <Field name> WITH 13.47 FOR RECNO()=>287 .AND. RECNO()<359 REPLACE <Field name> WITH 13.52 FOR RECNO()=>359 .AND. RECNO()<427 REPLACE <Field name> WITH 13.57 FOR RECNO()=>427 .AND. RECNO()<468 REPLACE <Field name> WITH 13.62 FOR RECNO()=>468 .AND. RECNO()<468 REPLACE <Field name> WITH 13.67 FOR RECNO()=>468 .AND. RECNO()<486 REPLACE <Field name> WITH 13.77 FOR RECNO()=>486 .AND. RECNO()<498 REPLACE <Field name> WITH 13.77 FOR RECNO()=>498 .AND. RECNO()<500 REPLACE <Field name> WITH 13.77 FOR RECNO()=>500 for entering the measurement results in the \*.DBF file. Finally command a COPY TO HALD151.HYG FIELD <Field name> DELIMITED for making the HALD151.HYG file.

## Example 8 Making a \*.HYG file using dBase

With the algorithm of Abramowitz (1971, p 953, direct method) the 2000 deviates of the standard Lognormal distribution were generated and stored in the one-field ASCII delimited file (<u>RANDOM20.HYG</u>) using the following BASIC subroutine:

```
DIM C(2000)
L% = 0
RANDOMIZE CDBL(TIMER)
FOR I% = 1 TO 2000
 IF L\% = 1 THEN
  Z = EXP(Y2 * V): L\% = 0
 ELSE
  DO
   DO
    Y1 = 2\# * CDBL(RND) - 1\#
    Y2 = 2\# * CDBL(RND) - 1\#
    W = Y1^{2} + Y2^{2}
   LOOP WHILE W >= 1#
   V = SQR(-2 * LOG(W) / W)
   Z = EXP(Y1 * V): L\% = 1
  LOOP WHILE Z <= 1D+300# AND Z >= 1D-300#
 ENDIF
 C(I\%) = Z
NEXT I%
```

#### **Getting Started (Summary)**

A statistical tool like HYGINIST is useful if the <u>effectiveness</u> of working condition control measures is assessed using discontinuous exposure measurements.

HYGINIST includes 6 transactions:

- 1. data entry and mutation,
- 2. examining distribution shape,
- 3. estimating the descriptive statistics,
- 4. extrapolation to unsampled periods and compliance test against a limit value,
- 5. comparing the exposure data with other sets of descriptive statistics,
- 6. establishing the minimum sample size for an unbiased estimate of long-term compliance control.

This Help further explains:

- · How to apply the HYGINIST statistical methods in working conditions control
- The many aspects of the <u>Lognormal distribution</u>
- Installing and running the program
- Program operations
- Register for regular use.

If HYGINIST is <u>started</u>, then the following Splash screen appears. After installation it will include the next Login box.

HYGINIST version 4.0.68 For Windows 95/98/2000/M and NT				
	Copyright 1996-2001 Scheffers IHPC			
Login				
HYGINIST User information				
System user My S <mark>i</mark> /st	tem			
Your name				
Password				
ок				

See <u>Annex C.5.1.</u> on how to fill out this form is

If the Login form is filled out correctly then the HYGINIST start page appears after a few seconds, in which all form and constants are loaded. Now you can start with the <u>exposure data management</u> and analysis.

HYGINIST Development ver	sion 4.0.53	
<u>F</u> ile <u>H</u> elp		2
Data type		
Raw data file	Which exposure data type? - A series measurement outcome: click menu option <u>File</u>	
C Descriptive statistics	- Known values of GM and GSD: click option button ' <u>D</u> escriptive statistics'	

I hope this program support your needs.

Please inform me by mail <u>ihpc@planet.nl</u> on your experience and don't forget checking regularly on <u>the HYGINIST homepage</u> for updates of the program and the helpfile.

Regards Theo Scheffers

<u>Click here</u> for a summary on the Goodness-of-fit methods used. <u>Click here</u> for a summary on the Extrapolation methods used.

## **4 Sample characteristics**

Tabs 3 ("Limits") and 4 ("Descriptives") makes it possible to:

- overview all sample descriptive statistics (see 4.1)
- change the environmental factors (see 4.2)

## **4.1 Descriptive statistics**

This tab gives you an overview of different descriptive statistics. It is assumed the exposure data are sampled from a population that can be described using Lognormal descriptive statistics. All calculations are done using the sample estimators GM and GSD of Lognormal descriptive statistics  $\text{EXP}(\mu)$  and  $\text{EXP}(\sigma)$  respectively, and the number of degrees of freedom df. Window 20abc shows data from:

- a complete sample (<u>4.1.1</u>),
- a censored sample (<u>4.1.2</u>),
- the entered values for M, GM and GSD ( 4.1.3)

### 4.1.1 Complete sample

This tab gives you an overview of different descriptive statistics calculated from <u>GM</u>, <u>GSD</u> and sample size M.

🐂 The exposure sample data and th	e unbiased Lognorma	al descriptive sta	atistics	_ 🗆 ×
<u>File</u> Report <u>H</u> elp Picture this				
Start Raw data Descriptive statistics	S Plot			20a
Exposure data identification				
Name C:Program Files/HYGINIST	")Leidel67 hva		Measured in: ppm	
	2cidcior inyg		measureu in. ppm	
Sample size M= 10				
Estimators of Lognormal geometry	ric descriptive statisti	cs		
GM max. likelihood=	78.43089264750	ppm		
GM unbiased=	77.58176339151	ppm		
GSD=	1.63095039328			
Four estimators of arithmetic mea	n			
AM max. likelihood=	88.39877075201	ppm		
AM unbiased=	87.25742718823	ppm		
AM mean sqr. err.=	84.22908720757	ppm		
XM normal arithmetic mean =	87.4	ppm		
Two estimators of arithmetic stan	dard deviation			
SD normal standard deviation =	43.49560608820	ppm		
SD unbiased=	44.78888751068	ppm		

Table 5 Characteristics of the complete sample estimators of the Lognormal descriptive statistics

Example 18 Comparing samples with literature data

# Table 5 Characteristics of the complete sampleestimators of the Lognormal descriptive statistics

Estimator Description and properties

df The number of degrees of freedom df = M - 1 Formula 4-1

 $GM = EXP(\bar{x})$ 

GM Estimator of the geometric mean EXP( $\mu$ ). Formula 4-2 Measure of source strength (Seixas 1988, Rock 1982)

$$\bar{x} = \frac{\sum_{i=1}^{M} x_i}{M}$$

0 < GM < ∞ Dimension ci

If GM > H, then at least one ci> H.  $X_i = log(c_i)$ Biased estimator of EXP( $\mu$ ): If M≤10 and GSD>2.7, then GM overestimated at least 5% on average.

GMU Like GM (see above) with the following exceptions: Formula 4-3 Unbiased estimator of  $\text{EXP}(\mu)$ 

$$\mathbf{GM}^{\mathsf{u}} = \mathbf{GM}^{*} \phi \left( - \frac{\mathbf{s}^{2}}{\mathbf{4}} \right)$$

with

$$\Phi(\mathbf{t}) = \sum_{k=0}^{\infty} \left( \frac{\Gamma_{M}}{\Gamma_{k,M}} * \frac{\mathbf{t}^{k}}{\mathbf{k}!} \right)$$

GMU<GM for all values of M and s If GSD/M2>6, then "Cannot calculate unbiased estimator GMu!" is displayed. Relevant for the noise level pressure kPa.

GSD Estimator of the geometric standard deviation  $\text{EXP}(\sigma)$ Formula 4-4 Measure of scale in a Lognormal distribution

Table 5 Characteristics of the complete sample estimators of the Lognormal descriptive statistics

$$s = \sqrt{\frac{\sum_{i=1}^{M} (x_i - \bar{x})^2}{M - 1}}$$

Unbiased estimator with minimum variance. Normal values in the workplace atmosphere ranges between 1.4 and 3.5.

AM Estimator of the arithmetic mean  $\beta$ Formula 4-5 Calculated using the following formula.

 $AM=GM^* \phi \left(\frac{s^2}{2}\right)$ 

$$\Phi(t)=1+\frac{(M-1)^{*}t}{M}+\frac{(M-1)^{3}t^{2}}{M^{2}*(M+1)^{*}2!}+\frac{(M-1)^{5}t^{3}}{M^{3}*(M+1)^{*}(M+3)^{*}3!}+\dots$$

Unbiased minimum variance estimator TWAreference period from series short period measurements within a reference period (Bar-Shalom 1975) The mean dose of a cumulating agent (Seixas 1988) from series of more days TWA8 hour Dimension ci> 0

w2 Unbiased minimum variance estimator

Formula 4-6 of the arithmetic variance w2 (the 2nd moment)

$$w^{2} = GM^{2} * \left[ \phi \left( \frac{s^{2}}{2} \right) - \phi \left( \frac{M - 2}{M - 1} * s^{2} \right) \right]$$

Dimension ci2

Inverse proportional with ventilation rate and the square of the volume (Roach 1977 p67).

w/AM The sample coefficient of variation, to be compared with CVt, rounding error and grouping interval ratio -C/AM.

# **Example 18 Comparing samples with literature data**

#### \*.HYG file Description

LEIDL104 24 TWA8 hour Methyl Methacrylate results in GM=34.5 PPM and GSD= 1.89 LEIDEL67 10 TWA8 hour Dioxane (see Figure 1) result in GM=78.4 PPM and GSD= 1.63. CHIP123 10 TWA8 hour lead result in GM=2.19 and GSD=1.78.

The first two series provide estimators of the descriptive statistics which are equal to the literature values (Leidel 1977 pages 67 and 104). Booher (1988) calculated GM=2.36 and GSD=1.76 from the lead exposure data among chippers. The difference cannot be explained.

## 4.1.2 Censored sample

This tab gives you an overview of different descriptive statistics calculated from the regression estimators of  $\underline{GM}$  and  $\underline{GSD}$ .

## 4.1.3 Entered values of GM and GSD

Not yet filled

## **4.2 Environmental factors**

Not yet filled

## 6 COMPARING EXPOSURE DATA

The fifth transaction compares the exposure estimators GM and GSD with:

- estimators from a <u>second sample</u>,
- true population descriptive statistics,

Valid reference data are the true Lognormal descriptive statistics  $EXP(\mu)$  and  $EXP(\sigma)$ , or the sample estimators GM and GSD and the sample size.

To compare more than two data sets, apply ANalysis Of VAriance on log-transformed exposure data (Snedecor 1980). ANOVA techniques are included in standard software like Microsoft® EXCEL.

The current developments in occupational health and safety care makes that:

- more exposure data are collected in industrial hygiene (surveys, routine programs etc.),
- (one or multi) year Health and Safety plans and engineering directives, plant lay-out, control measures ask for more quantified exposure information,
- dose assessment becomes more important in occupational epidemiology.

This leads to an increasing need to collect, analyze and compare exposure data, not against limit H, but against other location and scale data:

- in time (changing control measures, in longitudinal epidemiology),
- between workplaces (different technical, organizational or behaviors control measures),
- between exposure groups (differences in dose in epidemiology),
- within exposure groups ({dis}homogeneity, identifying worst cases, time trends),
- against true population values ("gold" standards).

This chapter explains with a lot of examples how this is done. For more information see <u>chapter 6.1</u>

## 6.2 Two sample difference

Sample size M<sub>2</sub> (see <u>6.2.1</u>) and the estimators  $GSD_2$  (<u>see 6.2.2</u>.) and  $GM_2$  (see <u>6.2.3</u>) of a second sample should be entered. It should be established first, however, that these data are from a Lognormal distribution. Use the raw data and the goodness-of-fit transaction described in <u>chapter 3</u>.

## 6.2.1 Reference sample size

The maximum size of the reference sample (M<sub>2</sub>=30000) is more than is permitted in data entry from disk or by keyboard (see 2.2.1.1).

## **6.2.2 Difference in scale**

The statistic for testing if both GSD's originate from the population is (Snedecor 1980):

$$F_{dfdf_2} = \left(\frac{\text{LOG(GSD)}}{\text{LOG(GSD_2)}}\right)^2 * \frac{df_2}{df}$$
Formule 6-1

Under the null hypothesis follows F the variance ratio or Fisher distribution (Abramowitz 1970 26.6):

$$A_{F|df_{f},df_{2}} = \frac{df_{1}^{\left(\frac{df_{2}}{2}\right)} * df_{2}^{\left(\frac{df_{1}}{2}\right)} * \Gamma\left(\frac{df_{1}+df_{2}}{2}\right)}{\Gamma\left(\frac{df_{1}}{2}\right) * \Gamma\left(\frac{df_{2}}{2}\right)} * \int_{\frac{1}{F}}^{F} x^{\left(\frac{df_{1}-2}{2}\right)} * \left(df_{2}+df_{1} * x\right)^{\left(\frac{df_{1}+df_{2}}{2}\right)} dx$$

$$\text{with } F \ge 0$$
Formule

6-2

F df1 df2 AGSD=GSD2=100\*AF|df,df2 % W10-31 < $\infty$  0 % D10+31 < $\infty$  0 % ABS(F-1)W10-10 df1=df2 100 % other values odd odd Algorithm 26.6.8 other values even odd or (even & df1>df2) Algorithm 26.6.4 other values odd or (even & df1Wdf2) even Algorithm 26.6.5 other values df1\*df2D32768 Normal approximate 26.6.15

All algorithms are from Abramowitz (1970)

Example 39

# 6.3 Differences with population descriptive statistics

Reasons to compare sample estimates with true values of  $EXP(\mu)$  and  $EXP(\sigma)$  are:

- the sample size van reference data are large or unknown (e.g M2D100),
- testing against program goals or golden standards in industrial hygiene,
- finding the confidence range for  $\text{EXP}(\mu)$  and  $\text{EXP}(\sigma)$ , using trial and error.

## 6.1 Sample or population reference values

This transaction establishes differences and trends in exposure data when at least one of the following sets of reference values are known:

- GSD<sub>2</sub> and size M<sub>2</sub> of a second sample (see <u>6.2</u>),
- EXP(σ) (<u>see 6.3.1</u>),
- EXP(µ) (<u>see 6.3.2</u>).

To compare GM's it is important to know if GSD's:

- are equal (see <u>6.2.3.1</u>), or
- differ significantly (see <u>6.2.3.2</u>).

Combining the exposure data from two samples is described in 6.2.4. To compare three or more data series see 6.4. To append the worksheet in the <file name>.LOG file (for the report function see) press <file> and <print> after the calculations took place.

Location and scale are compared using the classical parametric Student methods and formulas (see Snedecor 1980, chapters 5 and 6). The subjoined table 12 combines names found in literature for inference statistics, and displays the used names (in bold) and symbols.

# **6.3.1 EXP(**σ**)**

The test statistic that compares  $\log(GSD)^2$  with  $\sigma^2$  is (Snedecor 1980 5.11):

 $\chi^2 = df * \left(\frac{\text{LOG(GSD)}}{\sigma}\right)^2$  Formule A-8

The test statistic  $\chi^2$  follows, under the null hypothesis, a Chi-square distribution with a number of degrees of freedom df=M-1 (df=(M+M`)\2-1 or df=2M` for censored samples). For the theory on the confidence interval of GSD, see Land (1988 page 98-99).

$$Q_{\chi^2,df} = \frac{\frac{\chi^2}{\int_{-\infty}^{\infty} t^{\left(\frac{df}{2}-I\right)} e^{-\frac{1}{2}} dt}{2^{\frac{df}{2}} * \Gamma\left(\frac{df}{2}\right)}$$
 Formule A-9

Calculating the chi-square probability distribution

ABS( $\chi$ ) Df Agsd= $\sigma$ 

all values < $\infty$  if Q $\chi^2$ ,df<0.5, then AGSD= $\sigma$ =200\*Q $\chi^2$ ,df % else AGSD= $\sigma$ =200\*(1-Q $\chi^2$ ,df) % <10-16 < $\infty$  0 %

W24 and W200 and even Algorithm 26.4.4 (Abramowitz 1970)

W24 and W200 and odd Algorithm 26.4.5 (Abramowitz 1970)

>24 or >200 Normal approximate Algorithm 26.4.14 (Abramowitz 1970)

# **6.3.2 EXP(**μ**)**

The test statistic that compares log(GM) with  $\mu$  is (Snedecor 1980, 5.7):

 $t_{df} = \sqrt{df + 1} * \frac{\mu - \text{LOG(GM)}}{\text{LOG(GSD)}}$ Formule 6-10

Formula 6.10 follows, under the null hypothesis, the Student distribution. The two-sided probability A% is calculated using tdf and dft from 6.10 and the Student distribution. The theory on the confidence interval of GM is described by Land (1988 page 93-95 3.1.2 and 3.2).

Example 43 Censored sample confidence limits

## **Example 43 Censored sample confidence limits**

#### \*.HYG file description

GUPTA271 In Example 53 (mice, inoculated with tuberculosis) different estimators of EXP( $\mu$ ) and EXP( $\sigma$ ) are compared. Using the rankit estimators, df=7 and the confidence factors the two-sided 95% CI is 46.7<EXP( $\mu$ )<66.1 and 1.15<EXP( $\sigma$ )<1.56, which is comparable with Schneider`s (1988 p196 example 6.1) two-sided 95% CI's: 48.1<EXP( $\mu$ )<66.7 and 1.13<EXP( $\sigma$ )<1.59. HAW110 Hawkins (1991 Appendix III p133) uses defective formulas for the upper (GUCL) and lower (GLCL) "confidence limits on the true geometric mean" (AMmI in stead of GM based). For total dust (GM=2.6 mg/m3, GSD=1.77) he calculates two-sided 95% confidence interval for EXP( $\mu$ ), of GLCL=2.28 and GUCL=4.1 mg/m3. A more appropriate interval, using

the inverse of formula 6.10, is 1.94-3.49 mg/m3.

## 6.2.3.1 Comparing GMs with matching GSDs

The statistic for testing if both GM's originate from the population sample base is (Snedecor 1980, 6.9):

$$t_{df_1} = \frac{\text{LOG}\left(\frac{\text{GM}_2}{\text{GM}}\right)}{\text{S}_w} * \sqrt{\frac{(\text{df+1})*\text{M}_2}{\text{df+1}+\text{M}_2}}$$
Formule 6-3

The weighted logarithmic standard deviation sw is calculated using:

$$S_{gew} = \sqrt{\frac{df * S + df_2 * S_2}{df_t}}$$

with

$$s = LOG(GSD)^2$$
  $s_2 = LOG(GSD_2)^2$  and  $df_t = df + df_2$  Formule 6-4

Formula 6.3 follows, under the null hypothesis, the Student distribution. The two-sided probability A% is calculated using tdf and dft from formula 6.3, and the Student distribution (see formula 5.6).

Example 40

#### 6.2.4 Combining two samples

If two samples originate from the same population base and:

- the two samples are mutually independent, or
- the two samples were separated from one main sample,

then the number of degrees of freedom and the estimators GM and GSD of both samples can be combined into new estimators GMt and GSDt for that population base, using the next logical formulas:

$$GM_{t} = EXP\left(\frac{(df+1)*LOG(GM)+M_{2}*LOG(GM_{2})}{M_{t}}\right)$$
  
with  $M_{t} = df+M_{2}+1$  Formule 6-6

$$GSD_{t} = EXP\left(\sqrt{s_{t} + x_{t} - \frac{M_{t}}{M_{t} - 1} * LOG(GM_{t})^{2}}\right)$$

with

$$s_{t} = \frac{df^{*}LOG(GSD)^{2} + df_{2}^{*}LOG(GSD_{2})^{2}}{M_{t} \cdot 1} x_{t} = \frac{(df+1)^{*}LOG(GM)^{2} + M_{2}^{*}LOG(GM_{2})^{2}}{M_{t}}$$

Formule 6-7

If the two samples are mutually independent, then GSDs and GMs may not differ significantly. If the samples were separated from one main sample, then individual raw data may not be included in both samples.

Example 42 Comparing two GSDs

## 6.4 Comparing three or more samples

To compare three or more data series, use:

- parametric analysis of variance (ANOVA) and regression analysis,
- distribution free methods (Snedecor 1980 chapters 6 & 10.9, Siegel 1956 chapter 5) like:
- Wilcoxon (two samples),
- Kruskall-Wallis (non parametric ANOVA, three and more samples),
- Page (1963, trend in three and more samples), and
- Spearman or Kendall (rank correlation).

These methods are available in stat/graph packages like BMDP, GLIM, TRUE EPISTAT, SAS-PC, SPSSPC and BMDP.

Example 44 Regression analysis in exposure control chart

## 7. SAMPLE SIZE

The tabs <Upper Limit UTL> and <Mean UCL> may help to calculate the smallest sample size for which a series TWA measurements will estimate compliance ( $A_{C>H} \le \alpha$ ) or non-compliance ( $A_{C>H} \ge 100-\alpha$ ) using the unbiased method of Wilks, the upper confidence limit .

The sample size M<sub>2</sub> is calculated using:

- the desired percentage U%=100- $\alpha$ ,
- the industrial hygiene limit value H,
- the estimators GM and GSD or  $GM_g$  and  $GSD_g$  and the proportion results within the accuracy range (screen 20b),
- the inverse algorithm of the standard normal and the unbiased Student .

Values for GM, H and GSD can be derived from:

- calculations on emission and ventilation (A.2.1),
- exposure assessment programs or inventories done before (A.3),
- data from literature.

The standard normal estimator Az (formula 5.3) and the unbiased Student estimator At,df=1 of formula 5.5, are compared with the desired the noncompliance probability  $\alpha$ C>H=100-U%. If H/GM>1, U%>50 and

 $A_Z \leq 100$ -  $U\% \leq A_{t_{dij \geq l}}$  Formula 7-1

are true, then a minimal sample size M<sub>2</sub>=1,2,3,...? for the unbiased estimate of the compliance probability  $\alpha$  exist.

If a value of df<sub>2</sub> exist, then the smallest sample size  $M_2$  for an unbiased estimation of the compliance probability in a complete sample (M'=M) can be calculated using the formula 7.2 or 7.3 dependent if the sample is censored:

if 
$$\frac{\mathbf{M}'}{\mathbf{M}} = 1$$
 then  $\mathbf{M}_2 = \mathbf{df}_2 + 1$   
Formula 7-2

In a censored sample (with M' the number of results within the accuracy range):

7. SAMPLE SIZE

if 
$$\frac{\mathbf{M}'}{\mathbf{M}} < 1$$
 then  $\mathbf{M}_2$  is the integer value for which :

$$df_2 = INT \left( \frac{M_2 + INT \left( \frac{M'}{M} * M_2 \right)}{2} \right) - 1$$

however if

$$df_2 > 2*INT\left(\frac{M'}{M}*M_2\right) then df_2 = 2*INT\left(\frac{M'}{M}*M_2\right)$$
Formula 7-3

Because df<sub>2</sub>, M' and M are known, M<sub>2</sub> can be derived iteratively. For GM/H<1 this routine is also useful to calculate the sample size for an unbiased estimate of  $A_{C>H} \ge 95\%$  for being in non-compliance on the average.

The following situations are :

- <u>7.1</u> Compliance for every sample size.
- <u>7.2</u> Compliance for a specified number of samples.
- <u>7.3</u> Compliance for only a large number of samples.
- <u>7.4</u> Non-compliance for every sample size.

## 7.2 Two through 100 degrees of freedom

Tab 34c displays the increase of M<sub>2</sub> and the decrease  $A_{t,df=i}$ . It stops at the first integer value of M<sub>2</sub> for which  $A_{t,df=i} < \alpha$  or if dfD99.

Tab 34b displays one of three messages:

- if M<sub>2</sub><M, then: "even for a smaller sample size than the current."
- if M<sub>2</sub><M, then: "for the current sample size."
- if M<sub>2</sub>>M, then: "if sample size increases."

The minimal degrees of freedom df2 is calculated using:

$$\text{if } t_{100\text{-}U\%, df=i+1} \leq \frac{\text{LOG}\!\left(\frac{H}{GM}\right)}{\text{LOG}(GSD)} * \sqrt{\frac{i+1}{i+2}} \leq t_{100\text{-}U\%, df=i}$$

then 
$$df_2 = i$$
 formula 7-5

#### 7.3 More than 100 degrees of freedom

In practise it seems of little value to perform more than 100 measurements to show noncompliance with a limit value. The money involved which such a program could better be used to improve the working conditions. Screen 34c displays a situation that  $A_{t,df} < \alpha$  for 99<df< $\infty$ .

The minimal degrees of freedom df2 is calculated using:

$$\text{if } _{Z_{100 \cdot U\%}} < \frac{\text{LOG}\left(\frac{\text{H}}{\text{GM}}\right)}{\text{LOG(GSD)}} * \sqrt{\frac{\text{i+1}}{\text{i+2}}} < t_{\alpha, \text{df}=100}$$

then 
$$df_2 = i > 100$$

formula 7-6

For GSD=1.20 and GM/H>0.7344, more than M2=50 samples are necessary to establish the desired probability  $\alpha$  unbiased on the average. The bottom line of table 1 in Scheffers (1987) provides, for different GSD's, ratio GM/H values for which sampling is not useful. for 99<df< $\infty$ .

## 7.4 Noncompliance

Tab 34d shows the state of being in permanent noncompliance: At,df> $\alpha$  for df $\rightarrow \infty$ .

if 
$$\frac{LOG\left(\frac{H}{GM}\right)}{LOG(GSD)} < Z_{\alpha}$$
 then df<sub>2</sub> does not exist

This situation is in noncompliance, even if the sample size is infinite. You can estimate that for  $\alpha$ =5%, EXP( $\sigma$ )=3.00 and EXP( $\mu$ )/H>0.1642 there is no sample size M2 that estimates  $\alpha$  unbiased. The bottom line of table 1 of Scheffers (1987) provides for different GSD's, the EXP( $\mu$ )/H ratios over which measuring is ineffective.

## C How to get the program (running)

Follow the next steps to get a copy of HYGINIST running on your computer:

- C.1 Download HYGINZIP.EXE from the internet,
- C.2 Extract the HYGINIST setup files from HYGINZIP.EXE ,
- C.3 Remove earlier versions of HYGINIST for Windows from your computer,
- <u>C.4 Install</u> the program in your computer,
- C.4 Start the program .

Other items included here are:

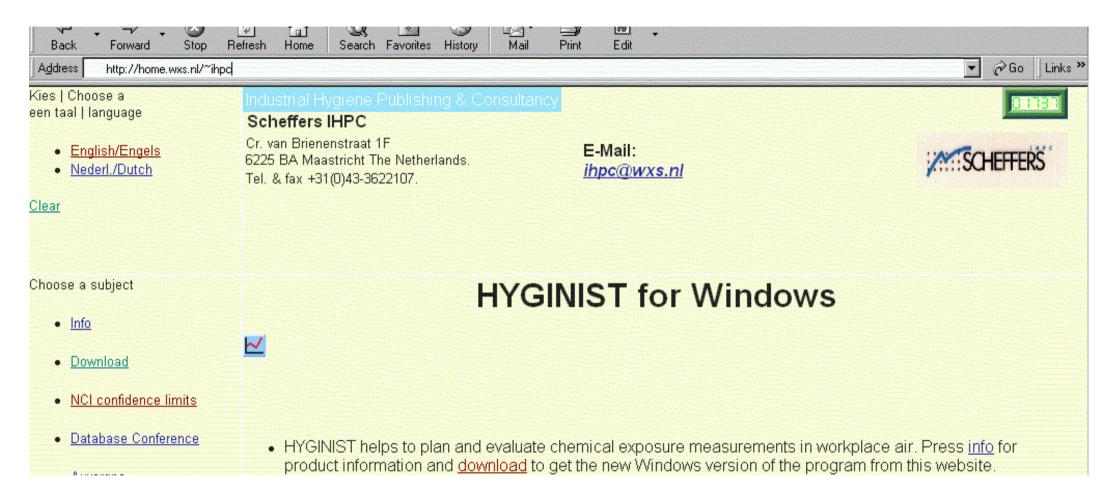
- Register the program for continuous use,
- <u>Stop</u> execution.

## **C.1 Download from the HYGINIST homepage**

- Go to the HYGINIST internet homepage http://www.planet.nl/~ihpc
- Click in the frame on the left on <u>download</u> and subsequently in the frame on the right on HYGINZIP.EXE
- Now save <u>HYGINZIP.EXE</u> in a temporary <u>directory</u> and
- Wait while file is downloaded in the <u>directory for temporary files</u> on your system. To do this in real press on <u>http://www.planet.nl/~ihpc</u>.

Continue with extracting the HYGINIST setup files from HYGINZIP.EXE

#### The HYGINIST internet site



#### **Download frame on the HYGINIST internet site**

Choose a subject	Download HYGINIST for Windows
• Info	
Download	HYGINIST for Windows is now distributed as shareware. Shareware means that :
<u>NCI confidence limits</u>	<ul> <li>you can use the program during a 60 days free trail period,</li> <li>if you want to continu the use after that period, you need to register.</li> </ul>
Database Conference	This 32 bits Visual Basic 5.0 version runs only in a Windows 95/98/ME/2000 or NT environment. HYGINIST for Windows contains the same functionallity as HYGINIST 2.2 (the DOS version) except for the comparison of two
<u>Auvergne</u>	samples. It has many new features like:
<u>Auvergne weather</u>	<ul> <li>Windows object oriented,</li> <li>Paralel and interactive analysis,</li> <li>Shapiro and Wilk goodness-of-fit testing for censored samples,</li> <li>Exact confidence limits for and compliance probability with the Lognormal mean.</li> <li>Frequecy distribution plots.</li> <li>An extension on the non-Central Student Upper tolerance limits</li> </ul>
	Click on <u>HYGINZIP.EXE</u> to start the download. The file with the current version (4.0.6#, date December 31, 2000) is 3.4 MB, so downloading may take some time. Start the self extracting WinZip program HYGINZIP.EXE. Continue by executing SETUP.EXE and follow the instructions. The distribution of HYGINIST 2.2 (the DOS version) has stopped. You can however still download HYGINIST 2.2 free of charge.

# Handling HYGINZIP.EXE

Bestand downloaden	×
	U wilt een bestand downloaden vanaf deze locatie. hyginwin.exe van home.wxs.nl
	Wat wilt u doen met dit bestand?
	O Dit programma starten vanaf de huidige locatie
	<ul> <li>Dit programma opslaan op schijf</li> <li>Wgarschuwen voor het openen van dit type bestand</li> </ul>
	OK Annuleren <u>M</u> eer informatie

# Saving HYGINZIP.EXE

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Opslaan als <u>type</u> :	Toepassing	ŀ	-	Annuleren

# **Downloading HYGINZIP.EXE in your computer**

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	5% of hyginwin.e	e Completed			
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ou can use i you want te	Saving: hyginwin.exe from home.wxs.nl				
oits Visual I the same fi like:	Estimated time left: 4 min 27 sec (131 KB of 3.26 MB copied) Download to: D:\Unzipped\hyginwin.exe Transfer rate: 12.8 KB/Sec			NT environment. H.	
	Close this dialog box when download completes he comparison				
indows ob aralel and im	<del></del>	<u>O</u> pen	Open <u>F</u> older	Cancel	
napiro and V	Vilk goodness-o	f-fit testing for (	censored sample robability with th		mean.

equecy distribution plots.

# **C.2 Extracting HYGINZIP.EXE**

Start the self-extracting program HYGINZIP.EXE. It does the following:

- it will come with a suggestion to place the extracted files in a directory for temporary files
- Accept the suggestion or choose an alternative
- Keep the directory of choice name in mind.



extracted

Continue with installing HYGINIST for Windows

If a HYGINIST for Windows (development) version was allready installed on this system <u>remove</u> it first.

# Unzip

To unzip all files in hyginzip.ex folder press the Unzip button.	<u>U</u> nzip	
Unzip to <u>f</u> older:		Run <u>W</u> inZip
CINTEMP	<u>B</u> rowse	<u>C</u> lose
Overwrite files without pro	About	
		Help

#### C.6 Stop and Exit the program

🐂 HYGINIST Development ve	rsion 4.0.53	_ 🗆 ×
<u>File</u> <u>H</u> elp		
<u>N</u> ew *.HYG fileCtrl+N		2
<u>O</u> pen *.HYG File Ctrl+O		
<u>C</u> lose all data		
Exit		
Data type		_
	Which exposure data type?	
Raw data file	<ul> <li>A series measurement outcome: click menu option <u>File</u></li> <li>Known values of GM and GSD: click option button <u>'Descriptive</u> statistics'</li> </ul>	
O <u>D</u> escriptive statistics	- Thown values of ow and obb, click option button peschiptive statistics	

Click your cursor on the upper right corner [x] or the menu option exit.

# **E PROGRAM OPERATION**

This chapter provides detailed information on:

- operating the program,
- screen lay-out,
- report making,
- on line help.

## E.1 Operating the program

In the next table the most important key functions and commands are explained.

<key> Comment See further

<Pause> Screen fixation. Press any key to continue -

string<Enter> Type and enter text (file name, dimension; W 8 characters) E.1.4, E.1.4.1 & E.1.4.2

digits<Enter> Type and enter a number E.1.4, E.1.4.1 & E.1.4.2

(sample size, exposure data, limit value, desired percentage)

<Delete> Delete typed or imported characters from the left hand side of the cursor E.1.4

<Backspace> Delete typed or imported characters from the right hand side of the cursor E.1.4

<Prt Sc> Sends current screen to clipboard E.3

 $\leftarrow,\uparrow,\rightarrow,\downarrow$  Stirs reverse video block 2.2.4.1

# **Goodness-of-fit (Summary)**

(2) Sample air concentrations from similar exposure groups, will in general fit the Lognormal model if:

- sufficient data lie within the accuracy range of the measurement method,
- sampling procedures prevent random or systematic errors (outliers),
- the measurement coefficient of variation CVt is smaller than the sample coefficient of variation  $\omega/\beta$ , and
- the grouping interval  $\nabla C$  is small compared to the arithmetic standard deviation  $\omega$ ,

Goodness-of-fit with the Lognormal distribution is assessed by:

- (2A) visual inspection of the probability plot of the logarithmic transformed data within the accuracy range.
- (2B) the <u>W-test for Normality</u> (Shapiro 1965), the most effective, complete sample test for shape.

## **Extrapolation (Summary)**

To deal with the common industrial hygiene practice of extrapolation from small (M<20) sample size sampling plans to general results, unbiased statistical estimators are calculated.

• (3A) In complete samples unbiased estimators are calculated for the geometric mean  $EXP(\mu)$ , the geometric standard deviation  $EXP(\sigma)$ , the arithmetic mean  $\beta$  and the arithmetic variance  $\omega_2$  (Finney 1941, Laurent 1963).

• (3B) If at least two results lie inside and one outside the range of accuracy, then the estimators  $GM_g$  and  $GSD_g$  are derived from the Lognormal probability plot and the least squares linear regression through the data points within the range of accuracy (Gupta 1952). The M-M' data outside the accuracy range, contribute for one half to the total degrees of freedom df=(M+M')\2-1, however, for at most twice the number of the uncensored data df<2M'.

(4A) From a series full reference period Time Weighted Average (TWA) measurements, the "long-term non-compliance probability" (NIOSH 1977, page 65) or the "acute health hazard" (Hawkins 1991 page 56) can be assessed using:

- the standard Normal method (Leidel 1977),
- the unbiased method (Wilks 1941), or
- the Noncentral Student method (Tuggle 1982).

The standard Normal method is most efficient, but biased on the average and requires large sample size, small GSD's and very good Lognormal conformity. Wilks (for routine programs) and Tuggle (for first exposure assessment) have a higher sensitivity of in detecting non-compliance.

(4B) If the series exposure data are from within a reference period (e.g. grab or partial period, non consecutive measurements), then TWA compliance probability and confidence upper limit can be estimated using:

- the unbiased minimum variance method (Land 1971),
- the approximate, consistent Student test (Jahr 1987) used in HYGINIST version 2.2.

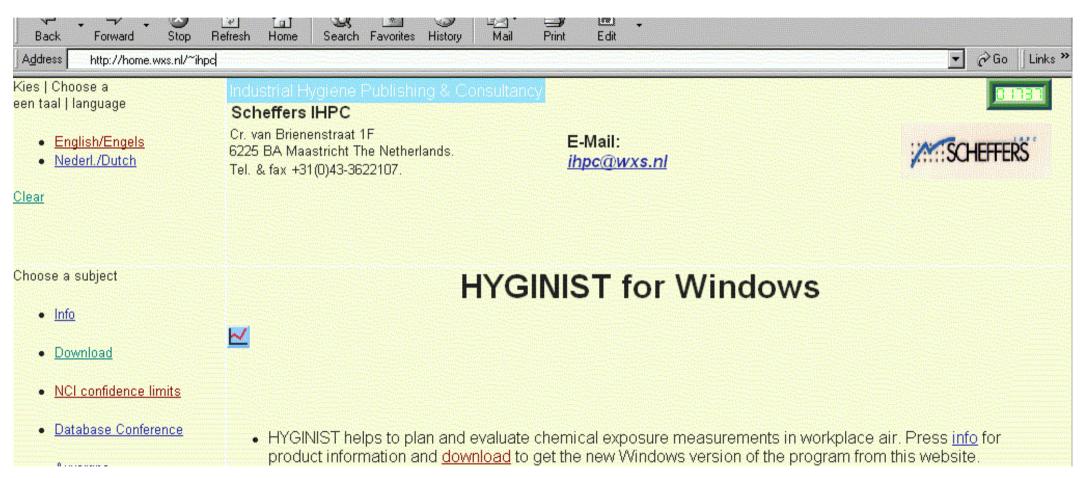
(4C) From a series TWA measurements "The chronic health hazard" (Hawkins 1991 page 56) or the "Cumulative dose" (Seixas 1988) are assessed with the same methods as in (4B). (4D) If Ceiling compliance is defined as no more than  $\alpha$ % exceeding the limit using grab or partial period sampling, then the confidence  $\delta$  can be calculated using the <u>Noncentral Student method</u>.

# **HYGINIST** email address

If you have any question please send an email to ihpc@planet.nl

#### **HYGINIST Homepage**

For additional information see the HYGINIST homepage



# 2.3 Using the data grid

# 2.3.1 Append

# 2.3.2 Edit

#### **2.3.3 Delete**

Still no text

### 3.1.2.1 Error messages

Tab "Plot" can display one of the following messages:

- "Less than 2 data points are within the limits.".
- "There is no variance between the limits": the relative difference of the highest and lowest value between the limits is below 10E-10.
- "There is too much variance between the limits": the ratio of the highest and lowest value between the limits is more than 10E+10.

Click "OK" and fill in a valid limit to continue.

# **3.2.1 The W-test for uncensored samples**

The picture box displays the chance A(W) that the (transformed) complete sample is drawn from a normal distribution.

Test statistic W is calculated using Formula B-1 . W values vary between 0 and 1. The probability distribution A(W) results in a value for goodness-of-fit between the 0 and 100%. Increasing values for A(W) suggest an increasing conformity with the shape of the Normal distribution.

In <u>Example 16</u> and <u>Example 17</u> W-values are tabulated and its influence the final Lognormal conformity conclusion is shown.

### **3.2.2 Censored sample**

In case of a censored, logarithmic transformed sample Screen number 18b appears.

Screen 18b Goodness-of-fit for censored Lognormal sample

In the case of a censored non-Lognormal transformed sample Screen number 18c appears.

#### **4.2.1 Units of measurement**

# 4.2.1.1 Sampling units

# 4.2.1.2 Sampling duration

# 4.2.2 Exposure limit

#### 4.2.2.1 Value

## 4.2.2.2 Reference period

### **4.2.3 Percentiles**

### 4.2.3.1 Confidence D

## 4.2.3.2 Cover U

# 4.3 Lognormal frequency distribution

#### 5.1.1 Comparing the 3 TWA extrapolation methods

To assess long-term compliance with hygiene limit H, 3 statistical extrapolation methods are presented and ranked (Screen 23a options 1, 2 & 3) in the increasing probability that H is considered as being an element of the exposure distribution. Use <u>table 7</u> to choose the appropriate method.

🛢 HYGINIST Developme	nt version 4.0.53 Compar	ing the exposure distribution	on with the Hygienic limit		_ 🗆 ×	
<u>File</u> S <u>t</u> astistics <u>H</u> elp						
Start Raw data Limits	Descriptive statistics Plot	Upper limit UTL Mean UCL	]		23	
– The exposure sample	data and the Lognormal de	scriptive statistics				
	-		C:\Hyginwin5\Acn8_9.hyg			
		Sample size M=	116 samples of 8 hou	rs		
		Degrees of Freedom df=	85			
		GM max. likelihood=	5.493294E-2	ppm		
		GSD=	7.29821938154485			
Noncompliance/percer	t exceedance.					
		Hyginic Limit Value H=	4 ppm \ 8 hours			
- Pre - Pre	<ul> <li>3 Extrapolation techniques to estimate the population exposure range. The sampling duration of exposure data must be representative for the reference period of the limit value.</li> <li>Press <leidel> for the maximum likelhood estimate</leidel></li> <li>Press <wilks> for an unbiased estimate of the percent exceedance. The method of preference</wilks></li> <li>Press <tuggle> for a fixed confidence estimate</tuggle></li> </ul>					
	Leidel	<b>Wilks</b> Tuggle				

The workplace air concentration distribution C in a homogeneous exposure situation is best described by the Lognormal distribution, If the population mean is  $\mu$  and variance is  $\sigma^2$ , then the standard Normal deviate Z is the logarithm of C expressed in a standardized form:

## 5.2.1.1. Nomograms

To test the sample based arithmetic mean against the hygiene limit H, plot the values of 10log(GSD) and:

- 10log(GM/H) in the nomograms of Bar-Shalom (1975 part II page 10 and 11), Bar-Shalom (1976 page 472) or Leidel (1977 page 58), for  $\alpha$ =1% and  $\alpha$ =5%, 10log(GSD)<0.5 (approximately GSD<3) and GM/H>.16,
- GM/H in the nomograms of Coenen (1978 page 405), for  $\alpha$ =5%, 0.05<10log(GSD)<0.95 (approximately 1.12<GSD<9) and GM/H>0.02 and M<1000, and conclude:
- there is non-compliance with the limit value H,
- there is no decision possible; possible overexposure,
- there is compliance with the limit value H.

## **6.2.3 Differences in location**

Comparing sample GM's:

- is exclusively possible if sample GSD2 and size M2 are known,
- is performed with different test statistics for GSD<>GSD2 and GSD=GSD2.

The option button frame "GSDs from the same population" demands your conclusion on the population base of both GSD's. Are they from one or from two different populations?

- Compare GM's while GSD's are from same base (<u>6.2.3.1</u>)
- Compare GM's while GSD's differ significantly (<u>6.2.3.2</u>)

The power to detect differences in GM's is larger if the GSD's are considered as from the same base.

# **B.1.3 Shapiro's W-test (censored sample)**

For one-sided censored samples a adapted W-test is developed by Royston (1993,1995). The censoring must be:

- less the 80% and
- the sample size more than 20.

This test, extended to two sided censored samples, is included in HYGINIST for Windows. It was not available in HYGINIST version 2.2 and earlier.

The less <u>effective{linkID=140140}</u> Monte Carlo based test for Lognormality of Waters (1991) is easily expanded towards censored samples but this will lead to a mounting number of tables.

#### **B.5.1 Sample size using Wilks method**

HYGINIST calculates the minimum sample size for long term compliance control and general exposure assessment based on the expected values for  $EXP(\mu)$  and  $EXP(\sigma)$  and limit value H. Like Hawkins (1991 page 51) the robust Student distribution is used (see chapter 7). If formula 7-1 is true, then also:

$$Z_{100U\%} \leq \frac{\mathrm{LOG}\left(\frac{\mathrm{H}}{\mathrm{GM}}\right)}{\mathrm{LOG}(\mathrm{GSD})} * \sqrt{\frac{\mathrm{df}_{2}+1}{\mathrm{df}_{2}+2}} \leq t_{100\cdot U\%} df_{2} \geq 1$$

with  $Z_{100 \text{ U}\%} > 0$ ,  $t_{100 \text{ U}\%} > 0$  (because U% > 50%)

is true. Rearranging formula 5.24 so that df2 becomes a function of the other parameters results in:

$$\begin{split} \frac{l}{\left(\frac{Z_{100-U\%}}{X}\right)^2 - l} & -l \leq df_2 \leq \frac{l}{\left(\frac{t_{100-U\%}dy=l}{X}\right)^2 - l} - l \\ & \text{with } \mathbf{X} = \frac{\mathrm{LOG}\left(\frac{\mathrm{H}}{\mathrm{GM}}\right)}{\mathrm{LOG}(\mathrm{GSD})} \end{split}$$

# C.6.1 MenuExit

The HYGINIST program stops and asks you if you want to exit.

### **C.6.2 Exit Button**

## **E.1.4 Entering characters or numbers**

Text or numbers entered by keyboard, are completed if the object in which the are placed losses the focus.

Comma's <,> in a series characters or digits are replaced automatically by a decimal point
 <.>

• Use <Backspace> or <Del> to remove undesired characters or digits.

• Text (name data file or dimension) may exceed 8 characters, however the text may be less visible. Upper and lower case characters are both accepted.

# E.1.4.2 Numbers

The decimal sign differs between and within the US and Europe. Comma's <,> in a series digits are replaced automatically by a decimal point <.>

Any number between 10000 and 1D+100 or between 1D-100 and 0.1 is displayed with at most 8 digits and with a fixed decimal point combined with an exponent `D±NN`. The real value of the number is the mantissa multiplied by 10 raised to the ±NN power. ##.######D±NN

Numbers >= D+100 or <=1D-100 who do not exceed the extremes, are displayed with at most 7 digits and with a fixed decimal point combined with an exponent `D $\pm$ NNN`. The real value of the outcome is, the mantissa multiplied by 10 raised to the  $\pm$  NNN power. ##.#####D $\pm$ NNN

#### **Context sensitive help**

#### **Tool tips**

#### Internet

Visit the HYGINIST homepage

#### **E.3 Report facility**

All HYGINIST screens are easily incorporated in text editor programs. Since standard text and picture processing programs have extended facilities to manipulate text and figures in reports HYGINIST screens are only made available for these programs

#### E.3.1 \*.LOG report text file

🖱 Development version 4.0.32	
<u>File Stastistics Report H</u> elp	
Start Descrip Form to printer UTL Mean UCL	21
Data type To file Mu0.LOG	
C Raw data file	Modify
Descriptive statistics	
Exposure data identification	
Name Mu0Sig1	Measured in: ppm 💌
Sample size M= 10	Sampling duration 8 hou: 💌
Estimators of Lognormal geometric descriptive statistics	
Degrees of Freedom df= 9	
GM max. likelihood=	ppm
GSD= 2.17828	
Environmental factors	
Hyginic Limit Value H=10	Reference Period 8 hou: 💌
U exceedance percentage= 95% D confidence ;	percentage= 95

If Report is displayed in the menu bar, then you can append the information of the current screen to the TEXT data file \*.LOG.

If HYGINIST.LOG does not exist in the current directory, then it is created automatically. To report exact figures, use HYGINIST.LOG. The file can be imported in any word processing program.

MuOSig1.LOG		
Exposure data identification		A
Name	MuOSig1	
Sample size M=	10 over 8 hours	
GM max. likelihood=	1 ppm	
GSD=	2.17828	
Environmental factors		
Hyginic Limit Value H=	10 ppm over 8 hours	
U exceedance percentage=	95 %	
D confidence percentage=	95 %	

#### **E.3.3 Printer**

#### **F** References

#### **F.1 Computer program and quantitative evaluation**

F.2 The example data in Table 1

**F.3 Further readings** 

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#### F.2 The example data in Table 1

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#### **F.3 Further readings**

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#### **G** Symbols and abbreviations

Greek letters  $\alpha, \beta, \gamma, \delta$ ... are population parameters. Latin letters A,D.... are sample estimates. Symbol name description  $\alpha$  alpha Change, probability, A Sample estimator of chance ? Agem Arithmetic mean of a series probabilities A(W) Probability distribution of Shapiro's W-test (1965) AM Finney's estimator of  $\beta$ AMam Direct, simple or arithmetic estimator of  $\beta$ AMmI Maximum likelihood estimator of  $\beta$  $\beta$  beta Arithmetic mean of the Lognormal distribution. First moment BLU Best linear unbiased estimators (Schneider 1986 p57) ci Measured concentration in workplace air in period i Ci True concentration in the workplace air in period i CT True concentration in workplace air in reference period T  $C(\delta,\alpha)$  Calculated concentration overlying at least U% of the Lognormal distribution  $C(\delta,\alpha)$  Estimator of  $C(\delta,\alpha)$ CI Confidence Interval (two sided upper and lower limit) CVt Sampling an analytical measurement coefficient of variation (Leidel 1997 p78)  $\delta$  delta Confidence, reliability  $\Delta C$  Grouping interval D Sample estimator of the confidence  $\delta$ d Noncentrality parameter df Degrees of freedom E() epsilon The expectation, the theoretical arithmetic mean of the probability distribution EXP() De exponential distribution with base e=2.71828...  $EXP(\mu)$  Geometric mean of the Lognormal distribution  $EXP(\sigma)$  Geometric standard deviation of the Lognormal distribution F Deviate of the Fisher or variance ratio distribution GM Direct sample estimator of  $EXP(\mu)$ GMU Unbiased sample estimator of  $EXP(\mu)$ GMG Regression sample estimator of  $EXP(\mu)$ GSD Unbiased sample estimator of  $EXP(\sigma)$ GSDG Regression sample estimator of  $EXP(\sigma)$ H Industrial hygiene limit value SEG Similar exposure group INT() Integer, a function to establish the value before the decimal point  $\Lambda(\mu,\sigma^2)$  Lambda Lognormal distribution with descriptive statistics EXP( $\mu$ ) and EXP( $\sigma$ ) LCL Lower confidence limit of a descriptive statistic UTL Lower tolerance limit of a distribution LOG() The natural logarithm with base e=2.71828... μ mu The mean of a Normal distribution

M The total sample size (censored and uncensored data)

G Symbols and abbreviations

M' The number of results within the detection limits  $M\tau$  The population size (confined or expanded) ML Maximum likelihood MM Method of moments (Schneider 1986 p39) MML Modified maximum likelihood (Schneider 1986 p97) N(0,1) Standard Normal distribution with  $\mu=0$  and  $\sigma=1$ OTL One-sided tolerance limit  $\Pi$  Product of a series results Ri Rankit, normal order statistic, standard normal order expectations RML Restricted maximum likelihood (Schneider 1986 p100) RSD see CVt and  $\omega$ /AM  $\sigma$  sigma Standard deviation of the normal distribution s Sample estimator of  $\sigma$ Si Coefficient for the normal W-test  $\Sigma$  Sum of a series results SQR() The square root t Deviate of the Student distribution ti A sampled period within reference period T tj An unsampled period within reference period T T The duration of the reference period Toi The sum of all sampled periods within the reference period T Td Deviate of the Noncentral Student distribution ? tau The sum of all reference periods T TI Tolerance Interval (two sided upper and lower limit) TWA The arithmetic, time weighted average concentration within the reference period U% The desired percentage for confidence and tolerance limits UCL Upper confidence limit of a descriptive statistic UTL Upper tolerance limit of a distribution W The probability density function of the analysis of variance test for Normality (Shapiro 1965) ω2 Variance of the Lognormal distribution. Second moment  $\omega$ /AM The relative arithmetic standard deviation xi log(ci) The natural logarithm of concentration ci Direct estimator of the arithmetic mean  $\mu$  of the Normal distribution  $\chi$  Chi Square root of the deviate of the Chi-square distribution Z Deviate of the standard Normal distribution N(0,1).

file:///C|/Hyginwin5/Helpscribble/hs135000.htm (2 van 2) [9-6-2002 17:20:28]

#### **Detection range**

see range of accuracy

#### **Range of accuracy**

The values for which the measurement values are considered to be reliable.

#### HEG

• A group of workers with identical probabilities of exposure to a single environmental agent (Hawkins 1991 page 5).

• A group of employees who experience agent exposures similar enough that monitoring of any worker in the group provides data useful for predicting exposures of the remaining workers (Hawkins 1991 page 160). see also <u>Similar Exposure Group</u>

#### **Population**

Collection of elements on which the conclusions of the statistical evaluation are related to

#### **Random drawing**

• Taking an element from a population with a method that is independent of all properties of the element

#### Reliability

See confidence

#### Robust

The property of a test that it works well for a wide variety of population types (Snedecor 1980 p 135)

#### Rankit

The expectation of the standard normal ordering (Fisher 1938)

#### **Reference period**

The specified period of time stated for the limit value of a specific agent (prEN 689)

#### Sample

A series drawings from a population

#### Scale

Variation

#### SEG

See Similar exposure group

#### **Selectivity**

Degree of independence from interferents (prEN 482)

#### **Skewed distribution**

An asymmetrical distribution (Kendall)

#### **Sustainment**

• he capacity of individuals or groups to bear exposure

#### **Truncated distribution**

A distribution with an unknown proportion result outside the measurement reach (Hald 1949)

#### **Upper tolerance limit**

• The upper boundary containing at least the desired fraction of the population

#### **Unbiased estimator**

An estimator with the characteristic that the expectation equals the parameter for every sample size.

### Workplace

The defined area or areas in which the work activities are carried out.

#### J About the author

HYGINIST has been quite a solo project. Research, developing and writing the approach, the program and the enplaning manual started in 1985. I was born in 1953 in Voorburg (the Netherlands). Awarded in Environmental Health and Hygiene in 1979 at the Agricultural University in Wageningen based on a study on the concentrations of tetrachloroethylene in the breathing air of neighbors of dry-cleaning shops. In 1979 I joined the occupational health research organization TNO-MBL. There I performed a two-year health hazard survey among painters working in the Dutch construction industry. In 1981 I joined the DSM Chemical company to co-ordinate the industrial hygiene activities on a site of 750 ha with 51 chemical plants and 7000 employees. I followed several post-doc courses on biostatistics and epidemiology and performed and co-operated in several epidemiology studies. The exposure assessment in health and hygiene surveillance became my main branch of interest and from both that and the passion for industrial hygiene, statistics, computers and communication, the computer program HYGINIST evolved. In 1989, I joined the Dutch Occupational Hygiene Society's Limits and Measurement Methods Group, of which I was the chair between 1991 and 1997. I am full member of the American Industrial Hygiene Association AIHA's Exposure Assessment Strategies Committee and the WEEL committee. In 1994 I incorporated the industrial hygiene education, consultancy and publishing activities in Scheffers IHPC I'm living with wife and daughter in Maastricht, one of Europe's finest cities.

# Table 6 Characteristics of the complete sample estimators of the Lognormal descriptive statistics

Estimator Description and properties additional to Table 5

M' the number of results between

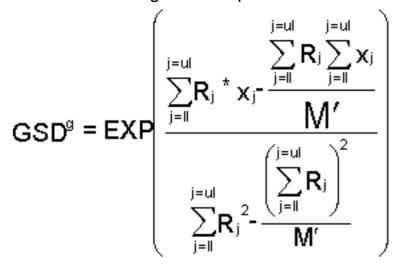
Formula 4-7 upper and lower limit  $\mathbf{M'} = \mathbf{ul} \cdot \mathbf{ll}$ 

df the number of degrees of freedom

If 
$$df \le 2 \times M'$$
 then  
 $df = INT\left(\frac{M+M'}{2}\right) \cdot 1$   
else if  $df \ge 2 \times M'$ 

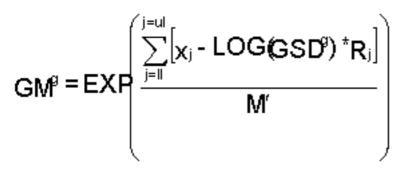
Formula 4-8 of a censored sample: 
$$M' < M$$
 then  $df = 2 \times M'$ 

GSD<sub>g</sub> Geometric Standard Deviation estimated Formula 4-9 using the data pairs between the accuracy limits.



GMg Geometric mean estimated using the Formula 4-10 data pairs between the accuracy limits.

Table 6 Characteristics of the complete sample estimators of the Lognormal descriptive statistics



## Table 9 Statistical properties of 3 methods which assess the effectiveness of control

Method-> Standard Normal Unbiased Noncentral Student

Characteristic Chapter 5.1.2 Chapter 5.1.3 Chapter 5.1.4

Expectation of A%: E(A%)> $\alpha$  E(A%)= $\alpha$  E(A%)< $\alpha$ - increase of the bias if: GSD  $\uparrow$ , Unbiased GSD  $\downarrow$ , H/GM  $\uparrow$  or df  $\downarrow$  H/GM  $\downarrow$ , or df  $\uparrow$ 

\_\_\_\_\_

Efficiency of Variance High Moderate Lowe  $\sigma(A\%)$  estimate

Shape of A% Skewed, but asymptotic Normal if GSD°1 or H/GM°1

- outlier incidence Frequent and extreme Moderate lowest

- kurtosis shape Tapering Moderate flattest

Leptokurtosis platykurtosis

Confidence  $\delta$  of finding non-compliance. If Ca=H, then  $0 < \delta_{A>=\alpha} < 50\% 50 < \delta_{A>=\alpha} < 100\% d_{A>=\alpha} = U\%$  if df->0, then  $\delta_{A>=\alpha} - >0\% \delta_{A>=\alpha} - >100\% \delta_{A>=\alpha} = U\%$ 

#### Table 11 Methods to test Ceiling limits using TWAshort period

Lognormal conformity kc>H Sample size M Statistical method Chapter Rejected D0 and Wp\*M >1/p (cumulative) Binomial/Poisson 5.3.1 Dacceptable n.r W1/p adapted Binomial/Poisson 5.3.2 Dacceptable n.r >2 Lognormal Noncentral Student 5.3.3

# Table 12 Notations and terms used for inference test statistics.

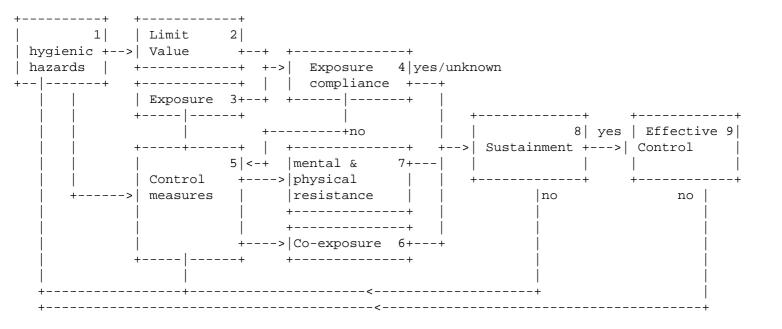
Name Population sample chapter parameter estimate Two-sided probability, GSD = GSD2I  $\alpha$ GSD=GSD2 AGSD=GSD2 6.2 nference of two sample Geometric Standard Deviations Two sample difference in scale Two sample analysis of variance

Two-sided probability,  $GM = GM2 \alpha GM = GM2 AGM = GM2 6.2.3$ Inference of two sample Geometric Means Two sample difference in location

Two-sided probability, GSD = EXP( $\sigma$ ) Inference with population Geometric Standard Deviation  $\alpha$ GSD=EXP( $\sigma$ ) AGSD=EXP( $\sigma$ ) 6.3.1

Two-sided probability,  $GM = EXP(\mu) \alpha GM = EXP(\mu) AGM = EXP(\mu) 6.3.2$ Inference with population Geometric Mean

# Table 13 Effective control of occupational exposure risks



# Example 20 Correcting exposure variability for a fixed background

#### \*.HYG file Description

LEIDL103 The Lognormal probability plot on M=12 successive Hydrogen fluoride concentrations (Leidel 1977 p103-104) clearly shows the fixed background exposure level of about 0.1 PPM additional to Lognormal variation.

LD103\_10 If 0.1 PPM is subtracted from all results of LEIDL103.HYG, then GM=.18 PPM and GSD=9.75: exactly the same as the values calculated by Leidel (1977 p103). The probability plot, however suggest the need to introduce a lower limit of .01 PPM and this results in rankit estimators of M'=10, GMg=0.16 PPM and GSDg=13.9: somewhat more accurate Than the estimators read by Leidel (1977, figure I-4 page 104) from the Probability plot GM=.16 and GSD=(84% value)/(50%value)=12.8.

# Example 22 How to establish sample size from GM and GSD

6 TWA8 hour total dust samples from a hypothetical homogeneous population (with known  $\mu$ =-0.1,  $\sigma$ =1) results in the GM and GSD values which are displayed in Screen 7ab. The gravimetric total dust TWA8 hour method has a CVt=0.25 (Leidel 1977 table D-1) which is smaller than the displayed sample relative standard deviation w/AM=1. Thus, Lognormality is not overshadowed by measurement error. The minimal sample size for long-term compliance control with H=10 mg/m3 and U=95% is estimated in chapter 7.

### Example 23 Exceeding the limit (censored nonparametric)

#### \*.HYG file Description

HALD151 If one wishes to know what percentage of diameters of rivet heads (Hald 1952) are below 13.3 mm, then Screen 21a will respond "Between 0 and 38%" because of the lower detection limit of 13.40 mm

SCHNE224 The upper accuracy limit at 6 Time Units (Schneider 1988 page 224) for the items under stress, inhibits the Nonparametric estimation of the number of items exceeding 10 TU (see Figure 5).

### **Example 24 Using 95% as default**

Nearly every application of statistics uses 95% as default extrapolation value, or its complement 5% as significance level:

• Leidel (1977 page 69) uses in the compliance control  $\alpha$ >0.05 to indicate that control measures are necessary.

• The European-based Dutch legislation on Vinylchloride requires 95% confidence that the average annual concentration in the workplace air, calculated from sequential measurements, is below the limit value TWA1 year.

• According to Leidel (1977 page 118) an employer should try to attain 95% confidence that no more than 5% of the employee days are over the limit value.

• The one-sided tolerance (OTL) approach of Tuggle (1981 page 497) questions "Are we 95% confident that less than 5% of all exposures received in the workplace are above the PEL?"

• In the 8 hour labour service,  $\alpha$ =0.05 corresponds with a 24 minutes period and with 1 out of 20 shifts.

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### **Example 25 Two-sided interval**

In order to calculate the two-sided 95%:

• confidence interval of the arithmetic mean by using the method of Jahr while running the procedure "Classification for TWA limit/Cumulative dose." (Screen 24, par. <u>B.2.</u>),

• tolerance interval running the procedures "<u>effectiveness</u> of control measures" from NIOSH or Wilks (Screen 25 and Screen 26),

the desired percentage should alternate between U=2.5% and U=97.5%

### **Example 34 Estimation of the average daily dose**

#### \*.HYG file Description

ACN8\_9 In a retrospective cohort mortality study (Swaen 1992) among Dutch workers occupational exposed to Acrylonitrile (ACN), the average daily dose was assessed using the exposure control chart (Figure 17) of the similar exposure group (=SEG) ACN production workers. The M=116 PAS TWA8 hour ACN, sampled in 1977 and 1978, fit the Lognormal model (see Figure 18) when a lower detection limit of LL=0.05 PPM is introduced. The M`=56 uncensored data provides df=85 degrees of freedom. Using the rankit estimators  $GM_g$ =0.05 PPM and  $GSD_g$ =7.3, the average daily dose in 1977/1978 is, for this SEG, estimated as AM1977-1978=0.37 PPM (90% confidence range of 0.25-0.53 PPM).

VINCHL91 The M=37 results of the Vinylchloride PAS sampling in a SEG PVC polymerisation shift workers (see Example 29) sampled in 1991 fit the Lognormal model (see Figure 16). With df=36, GM=0.36, GSD=2.90 the average daily dose is estimated as AM<sub>1991</sub>=0.60 PPM. The compliance against the European Community exposure limit of HEC=3 PPM (a one year average of all TWA<sub>8 hour</sub>'s) is A( $\beta$ >H)=10-9, indi cating that the long term control measures are effective for this SEG.

HAW117 From 14 random TWA8 hour PAS total dust above LL=1.4 mg/m3 the chronic health hazard was assessed (see Example 57). With AM=2.2 mg/m3 and H=10 mg/m3 the approximate probability that  $\beta$  exceeds limit H is A( $\beta$ >H)=7\*10-12%. The two-sided 95% confidence interval including  $\beta$  is 2.0-2.47 mg/m3. Though the algorithms for the interval calculation by Hawkins (1991 page 130-133 approach 1 and 2) are quit different, the result (Hawkins 1991 page 134 table III.2 two last lines) are comparable (Normal approach 1.97-2.43 mg/m3, Lognormal approach 1.93-3.42 mg/m3).

- From formula 5.13, the Student table (Ciba-Geigy 1980) and GSD=2.71828 it follows that:

for df=1,  $\zeta\beta,\delta>=95\%/\beta=552.1$ 

for df=9,  $\zeta\beta$ , $\delta$ >=95%/ $\beta$ =6.311.

If sample size increases, then  $\zeta\beta$ , $\delta/\beta$  decreases towards unity.

# Example 35 Estimation of grab sample based TWA

\*.HYG file Description

OWEN716 From GMg=.88 PPM, GSDg=6.81 and df=10 of the series grab sample airborne Chlorine , the two-sided confidence interval is 1.3-11.7 PPM, indicating real overexposure against H8 hour=1 PPM (Owen 1980 p716).

BAR\_SI25 From GM=47.5 PPM and GSD=1.675 on carbon monoxide grab samples a TWA8 hour=53.0 PPM is estimated. The probability that  $\beta$ =TWA8 hour exceeds H8 hour=50 PPM is AßDH=59.4% (90% confidence interval 33.3-84.3 PPM) indicating possible overexposure (Bar-Shalom 1975 page I-25).

LEIDEL61 From 35 direct reading Ozone concentrations, the estimators of the untransformed descriptive statistics  $\mu$  and  $\sigma$  are =.0831 and s=.023 PPM. The one-sided 95% upper confidence limit is calculated as UCL=.089 and the situation was concluded to be in compliance with the H8 hour=.1 PPM (Leidel 1977 p61-62). Using formula 5.12 the 95% UCL of  $\beta$  is  $\zeta\beta$ ,U%=95=0.090, which leads to the same conclusion.

# **Example 36 Compliance with a ceiling limit value (distribution free)**

#### \*.HYG file description

- After grab sampling M=480 (8 hours of 60 minutes) consecutive periods on a shift with a non-Lognormal exposure distribution, the confidence  $\delta$  that Ceiling noncompliance probability is Ac>HW1% is:

- for k=0 -> D(480,0,0.01)D99.2%

- for kW1 -> D(480,1,0.01)D95.3%

using the cumulative binomial test in TRUE EPISTAT.

Using the Poisson distribution on these data (p is small, n is large), with the number of cases expected 480\*.01=4.8 and the number of cases observed 1, results in DPoisson=99.23%. As could be expected the Poisson value is similar to the cumulative binomial.

### **Example 37 Compiance with a ceiing limit value** (distribution free)

#### \*.HYG file Description

LEIDEL63 5 short period exposures to Hydrogen sulphide were sampled and tested against a ceiling of 20 PPM (Leidel 1977 page 65). With A(W)=95%, GM=13.9 PPM and GSD=1.12 the NIOSH noncompliance probability (screen 25) is  $A_{C>H}=0.00073$ . Because all 5 sampled periods were below the ceiling, Leidel (1977 page 65) calculates the chance that the 16-5=11

nonsampled periods in the population are also in compliance as  $P_c=(.9993)_{11}=.992$ . In this example the following methodological shortcomings can be stipulated:

- GSD is (almost) completely determined by CVt (see Example 57),

- The Normal shape is superior over the Lognormal,

- The standard normal method is biased for small sample size. However, because the GSD is extreme small and overestimated, the chance on exceeding the ceiling value in the 11 nonsampled periods of this work situation, can be neglected.

- A M=25 grab sample, exposure sampling plan from a complete Lognormal distribution results in GM=1 and GSD=2.71818. With limit H=10 the NIOSH noncompliance probability is calculated as Ac>H/100=0.01065 indicating that k=1 out of M=93 is in noncompliance. The confidence that ceiling compliance is  $\alpha$ C>HW5%, is estimated as D(93,1,0.05)=95%.Using the Poisson distribution on these data with the number of cases expected .05\*93=4.65 and the number of cases observed 1, results in D(4.65,1)=94.6%. As could be expected the Poisson value is similar to the cumulative binomial. To get compliance with the Poisson test the sampling plan should be increased to at least 95 grab samples.

### **Example 38 Compliance with a ceiling limit vaue** (Noncentral Student)

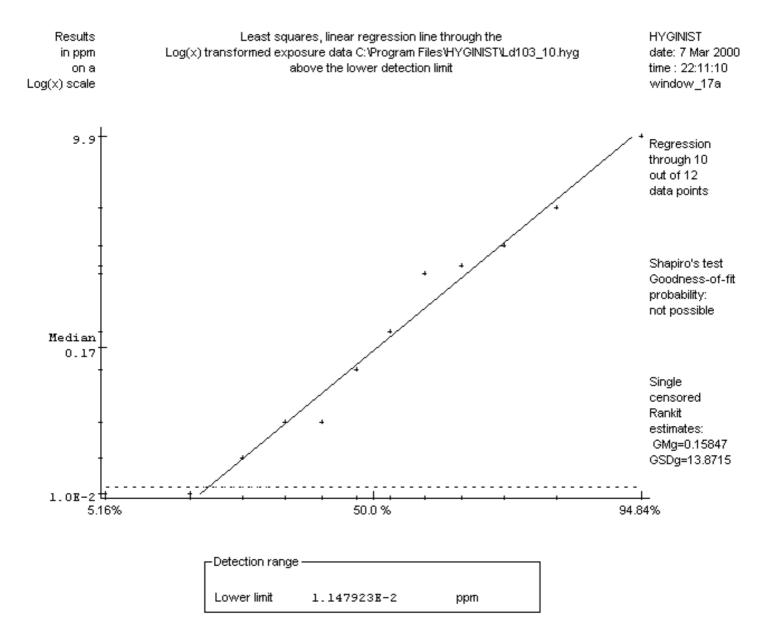
#### \*.HYG file Description

LD103\_10 The unbiased probability that a grab sample Hydrogen fluoride concentration (Leidel 1977 pages 103-104) is above the ceiling limit of 3 PPM HF, based on M`=10, LL=.01 PPM, GMg=.258 PPM and GSDg=13.87, is AC>H=19.9%. The confidence  $\delta$  that Ceiling H is exceeded  $\alpha$ <1% of the times is estimated as D(C $\alpha$ <1%>H)=7.89% using the Noncentral Student (method 6 table 11). Since  $\delta$  should be more than 95%, control measures are necessary to get in compliance with the ceiling.

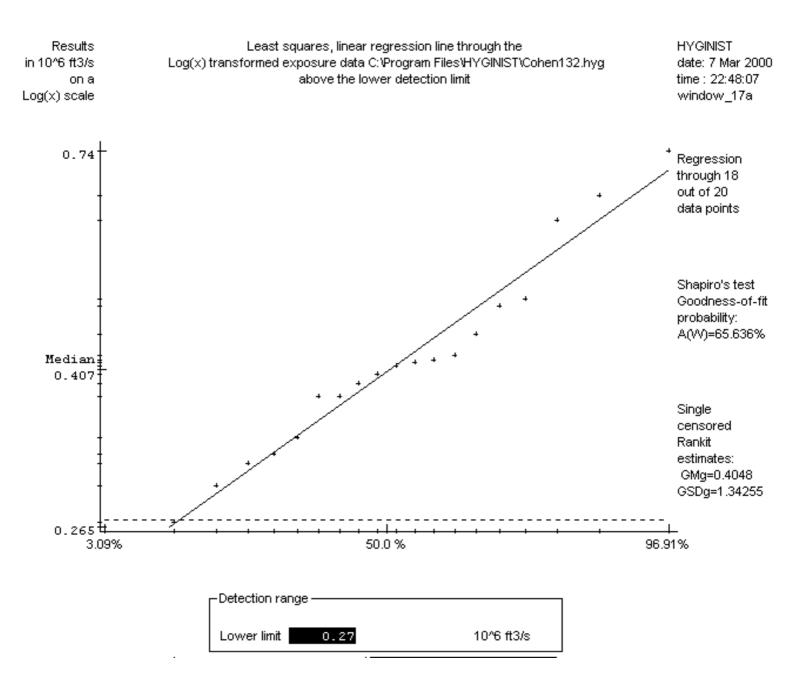
LEIDEL63 5 TWAshort period Hydrogen sulphide were sampled and tested against a ceiling of H=20 PPM (Leidel 1977 page 65). With M=5, GM=13.9 PPM and GSD=1.12 the confidence  $\delta$  that Ceiling H is exceeded  $\alpha$ <5% of the times is estimated as D(C $\alpha$ <5%>H)=87.7%, indicating noncompliance with the ceiling. Because the population is confined (see Example 54) recalculating the confidence with df=5 is permitted and results in D(C $\alpha$ <5%>H)=91%. Since, however, the sample variance is completely determined by CVt the compliance conclusion can be drawn solely based on GM<H.

- Using an imaginary, grab sample, exposure sampling plan with GM=1, GSD=2.71828 and Ceiling H=100. If ceiling compliance is defined as  $100-\delta=\alpha W1\%$ , then MD13 grab samples are sufficient: D(C $\alpha$ <1%>H)=99.2%

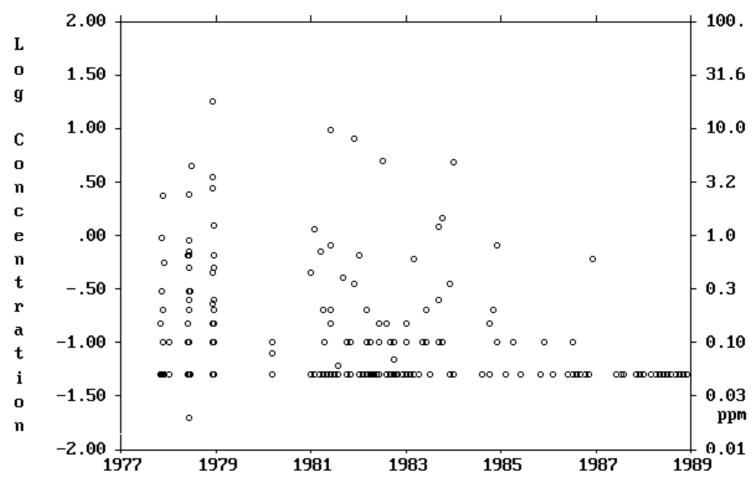
## Figure 13 Susquechanna river maximum flood levels in ft3/sec (COHEN132)



## Figure 14 12 CHF grab samples corrected for .1 PPM fixed background (LD103\_10)

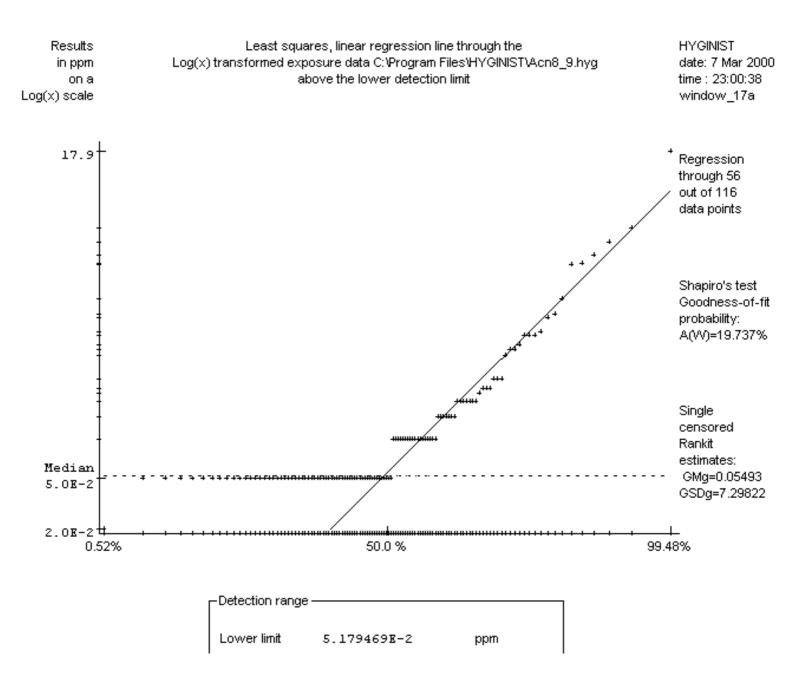


#### Figure 17 283 TWA8 hour ACN in a SEG production

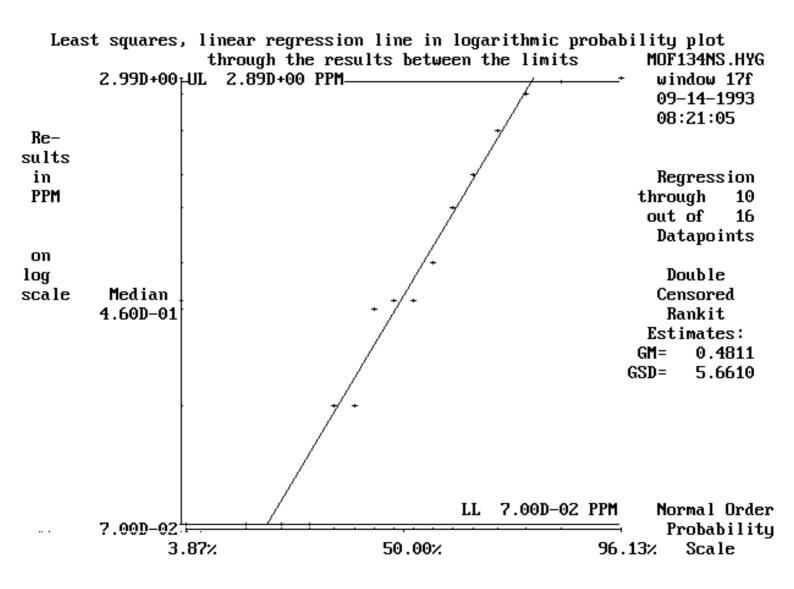


Calender years

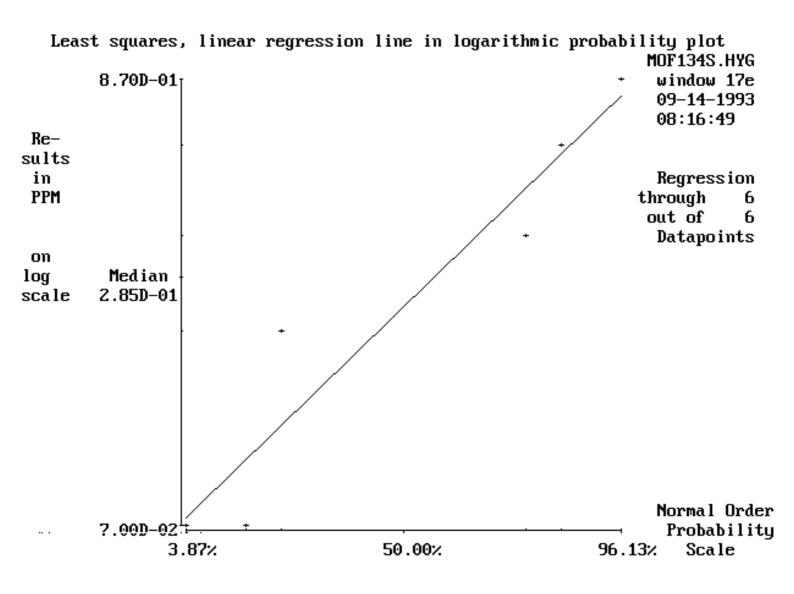
#### Figure 18 116 TWA8 hour ACN in a SEG production 1977-78



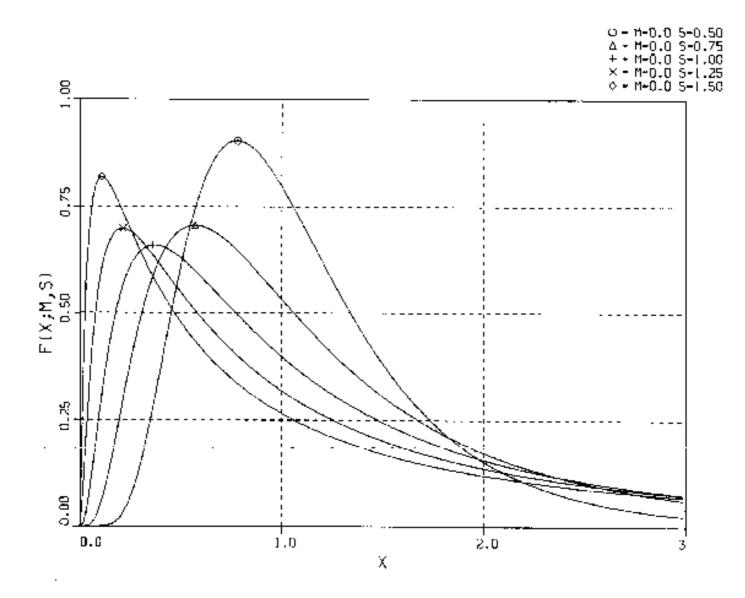
#### Figure 19 16 TWA10-30 min Methoxyfluane. Nonscavenged results (MOF134NS)



## Figure 20 6 TWA10-30 min Methoxyfluane. Scavenged results (MOF134S)



## Figure 21 A family of Lognormal distributions with mean M and standard deviation s

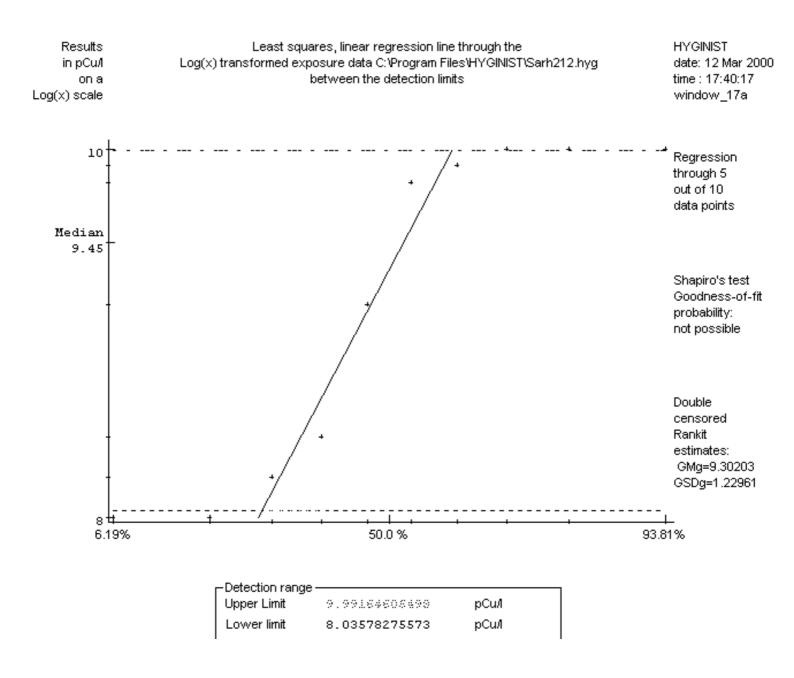


0

GM=exp(M) GSD=exp(s)

M=0; GM=1
s=0.25; GSD=1.284
s=0.50; GSD=1.649
s=0.75; GSD=2.117
s=1.00; GSD=2.718
s=1.25; GSD=3.490
s=1.50; GSD=4.482

## Figure 26 10 measurements of Strontium-90 in milk (SARH212)



## Figure 27 Mice survival time (GUPTA271, Schneider 1986 p 69 & 88)

