Quantitative quality control and compliance testing

Session M: The new (draft) EN 689 (part II)

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What’s covered in these slides?

Don’t expect a general overview like in the first session but rather:

- Some real worked examples of procedures cited in the prEN689
- Some illustrations of calculations and links
  - to papers explaining their origin
  - to tools automating them

- Some thoughts on the text as it stands right now
- Let’s start with the title:

Draft prEN 689 : 2016

“Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values”

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Reliable quantitative information about exposure of workers

2/8 p of the body of the standard dedicated to the basic characterization

5.1.4 Estimation of exposure

The estimation of potential exposures should permit the appraiser to obtain reliable quantitative information about exposure of workers concerned, taking particular account of tasks with high exposures (see Annex A).

The possible sources of information include

- earlier measurements,
- measurements from comparable installations or work processes,
- reliable calculations based upon relevant quantitative data, and
- exposure modelling.

The estimation of potential exposures shall determine whether it is necessary to perform measurements especially when exposure is apparently much higher than the OELVs. In this case, it is better to implement a program to reduce exposures, and then proceed to action before conducting exposure measurements.

The information collected on the expected exposure levels shall also verify the adequacy of the measurement techniques and analysis that are implemented

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Overview of approaches

Example 1

Table A.1 — Overview of approaches to exposure assessment in different workplace situations

Workplace situation	Exposure measurements (according to Clause 5)	Reasonable worst case measurements (under control)	Measurement of technical parameters	Calculation of exposure (using validated models or algorithms)	Comparison with other workplaces	Control Banding approaches	Good practice guidance for defined branches or tasks
A.2 constant conditions	x	x	x	x	x	x	x
A.3 shortened exposure with constant conditions	x	x	x	x	x	x	x
A.4 occasional exposure	x	x	x	x	x	x	x
A.5 stationary with irregular exposure	x	x	x	-	x	x	x
A.6 mobile with irregular exposure	x	x	-	-	x	x	x
A.7 unpredictable, constantly changing exposure	x	-	-	-	x	-	x
A.8 outdoor	x	-	-	x	x	-	x
A.9 underground	x	-	x	x	x	-	x
A.10 unforeseen occurrences	-	-	x	x	x	-	x

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Use technical and physicochemical parameters in e.g. IHMod

https://www.aiha.org/get-involved/VolunteerGroups/Pages/Exposure-Assessment-Strategies-Committee.aspx

- IH MOD is a mathematical modeling Excel spreadsheet used for estimating occupational exposures. It is a supplement to the book "Mathematical Models for Estimating Occupational Exposure to Chemicals". Multiple languages are available.
- Click on this link for IH MOD General Help

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First contact

Basic information immediately supplied by the customer

- Theme park, new installation:
  - Room in which an employee is reading a story. Meanwhile, smoke and flames (fake) are produced. The smoke is captured immediately with an exhaust ventilation.
  - A first employee complained about “lack of oxygen”. A second employee replacing him experienced similar complaints. The attraction was closed.
  - The theme park ordered “immediate and urgent measurements”
- Material
  - Fake flames product: SDS, manual
  - Smoke machine: machine

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Second contact

We phoned back to gather additional quantative information to evaluate if (immediate and urgent) measurements were needed

- Room volume: 180m³
- Exhaust:
  - 2 fans, max 2400m³/h per fan, used at +/- 1600m³/h per fan
  - 3200 m³/h total exhaust
- A can of the chemical "fake flames" (2.5l) is sufficient for 60 - 80 hours of aerosolisation (continuous usage)
- Actual usage per cycle of 6 min:
  - aerosolisation during 40 sec
  - clearance time of 45 sec
- 50 people per cycle of 6 min; 3 to 4 minutes with people present
- Operators change each hour
- No specific OEL ➔ Particles not classified elsewhere: OEL 8h 10mg/m³

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Evaluation if measurements are necessary

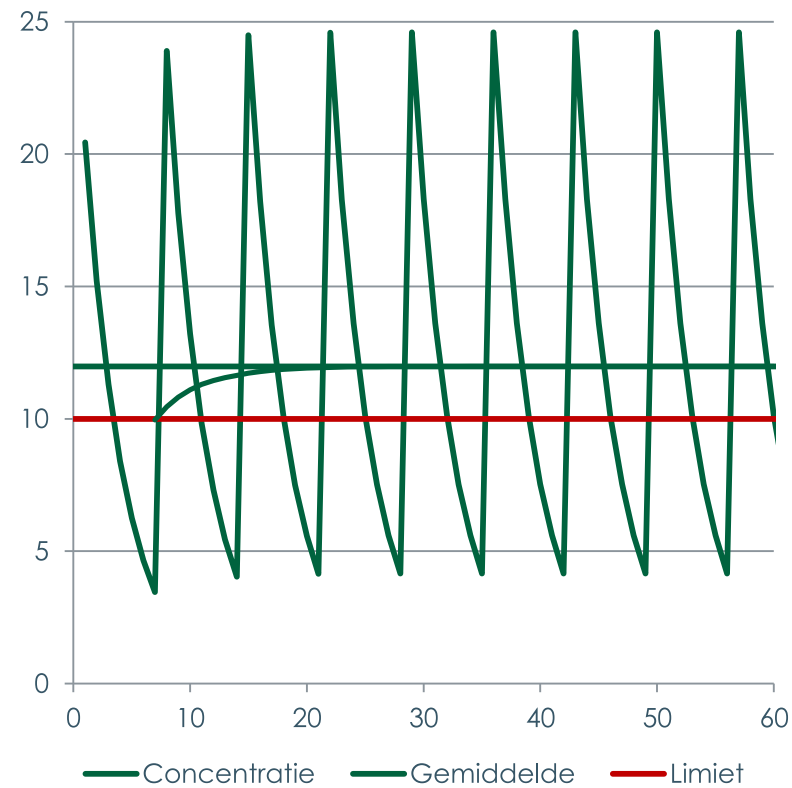
Estimation of the steady state aerosol concentration (constant emission)

- IHMod and calculation details
  - Start a first cycle from steady state: well mixed room purge equation (5 min 20 secs)
  - Use left over concentration as starting point for second cycle well mixed room model with constant emission rate (40s)
  - Copy paste the values from IHMod to excel, plot the pattern and calculate the TWA

Conclusion

Exposure peaks up to 25 mg/m³, mean exposure of 12 mg/m³ expected

value	unit	quantity
3200	m³/h	exhaust
53,33333333	m³/min	exhaust
180	m³	volume room
2500	ml	volume chemical product
70	h	max total usage time product
35,71428571	ml/h	mean consumption rate (continuous use)
40	s	usage time product
360	s	cycle time (6 min)
0,111111111		usage time factor per cycle
3,968253968	ml/h	real consumption rate (intermittent use)
1,03	g/ml	mass density
4,087301587	g/h	mass flow per machine
9	m	numer of machines
36,78571429	g/h	total mass flow (intermittent use)
613,0952381	mg/min	total mass flow (intermittent use)
0,396825397	ml	consumed volume per machine per cycle
0,408730159	g	consumed mass per machine per cycle
3,678571429	g	consumed mass per cycle
0,020436508	g/m³	steady state concentration
20,43650794	mg/m³	steady state concentration



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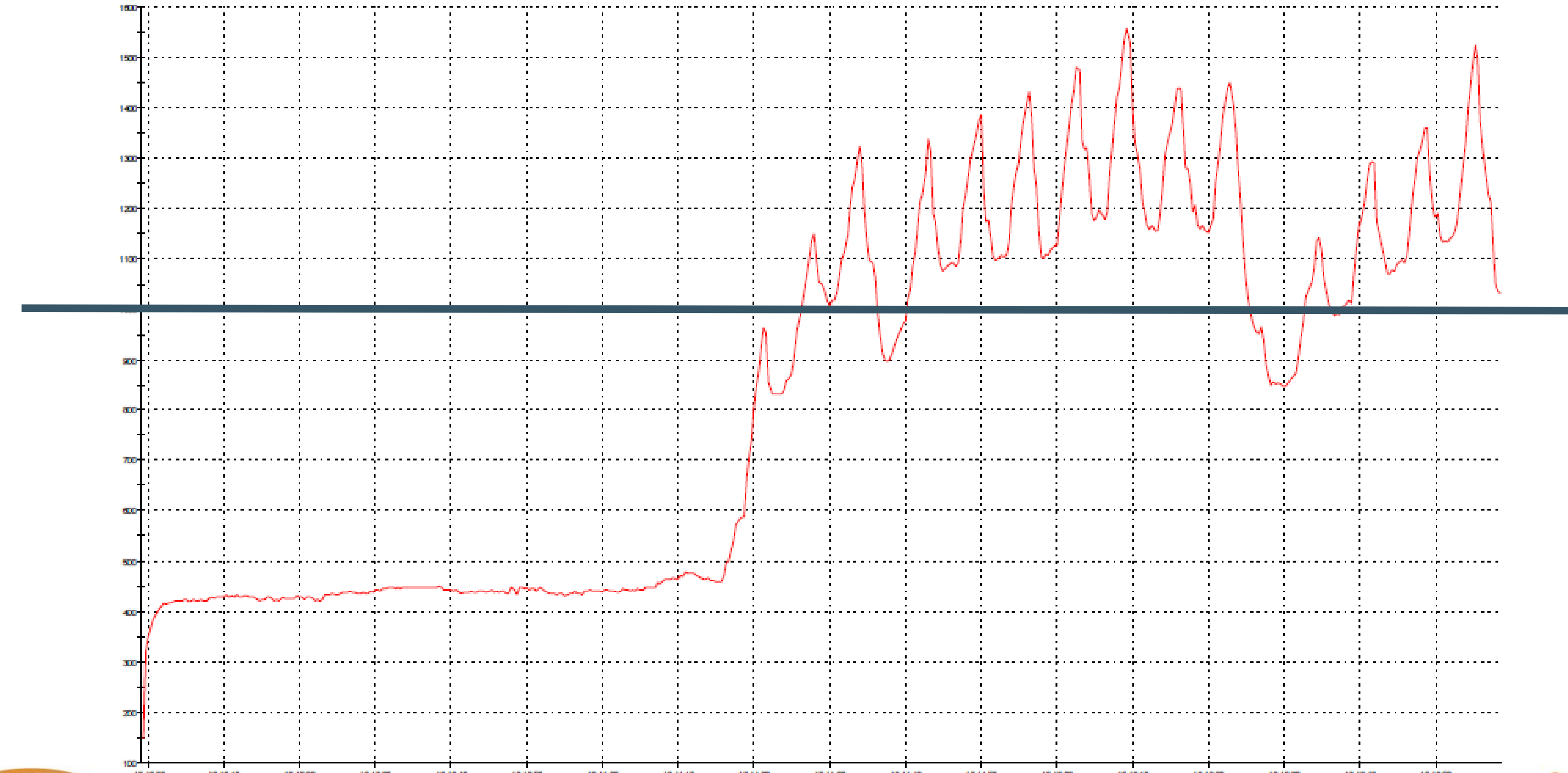
Conclusion: insufficient ventilation

Detailed measurement not necessary, illustrate with CO_2 as proxy



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Overview of approaches

Example 2

Table A.1 — Overview of approaches to exposure assessment in different workplace situations

Workplace situation	Exposure measure-ments (according to Clause 5)	Reasonable worst case measurements (under control)	Measurement of technical parameters	Calculation of exposure (using validated models or algorithms)	Comparison with other workplaces	Control Banding approaches	Good practice guidance for defined branches or tasks
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A.7 unpredictable, constantly changing exposure	x	-	-	-	x	-	x
A.8 outdoor	x	-	-	x	x	-	x
A.9 underground	x	-	x	x	x	-	x
A.10 unforeseen occurrences	-	-	x	x	x	-	x

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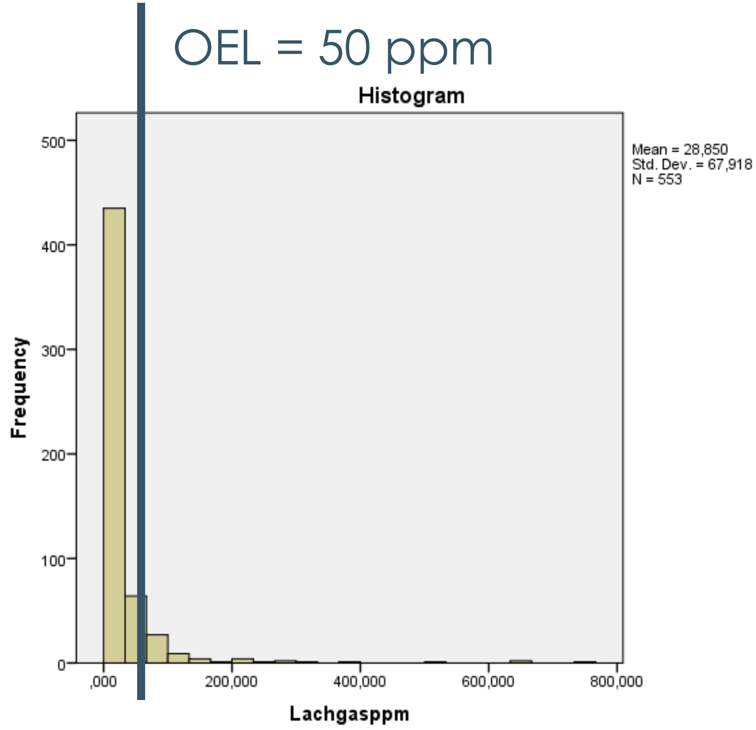
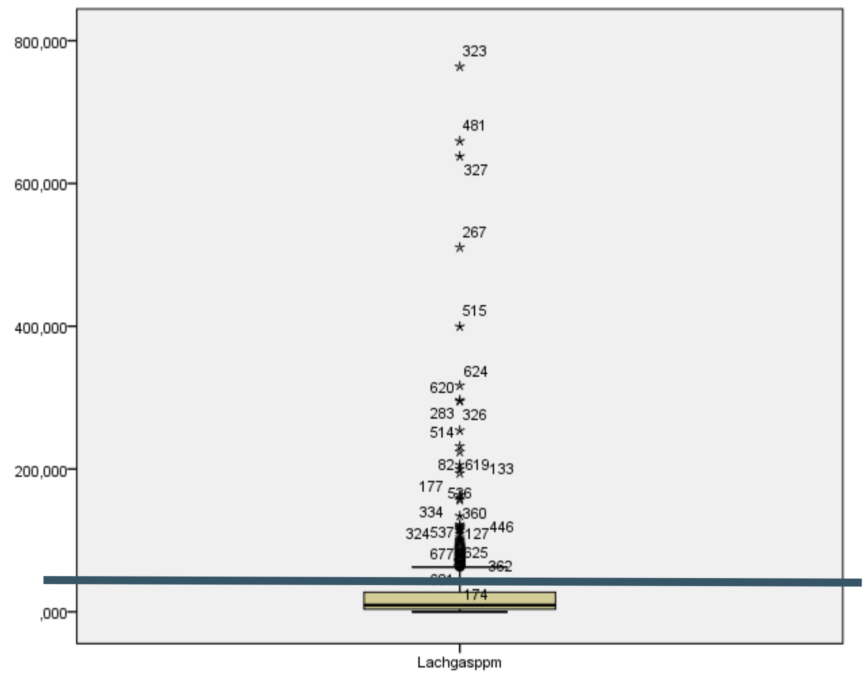
Use knowledge from other workplaces

Example 2: with a huge nitrous oxide exposure dataset

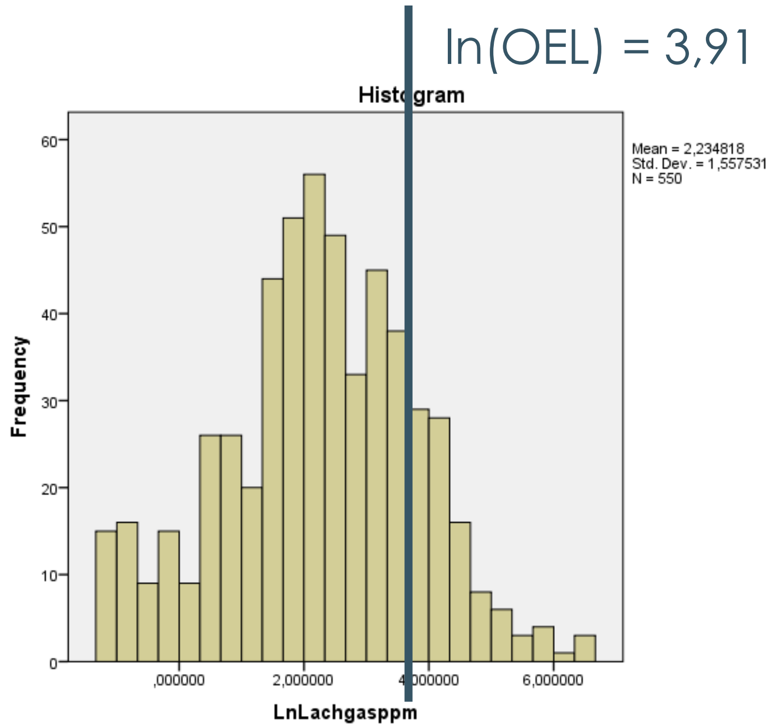


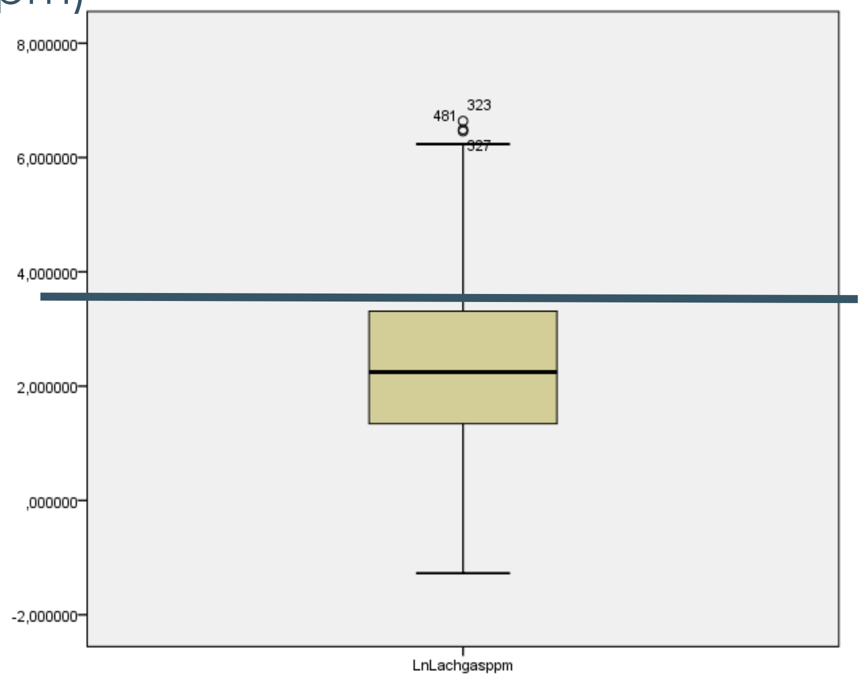


Use knowledge from other workplaces

Example 2: with a huge nitrous oxide exposure dataset

ln(OEL) = 3,91 ln(ppm)





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Use knowledge from other workplaces

Example 2: with a huge nitrous oxide exposure dataset

- Database nitrous oxide
  - More than 500 records
  - Over more than 10 years measured on over 40 sites
  - Arithmetic mean: 29 ppm, geometric mean: 9 ppm
  - Chance to exceed 50 ppm: 14%
    - oel<-log(50)
    - m<-2.234818
    - s<-1.557531
    - 1-pnorm(oel,m,s)

    [1] 0.1407768
- Conclusion: exceedance is plausible, detailed survey needed

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After the basic characterization follows a detailed one...

using an effective approach with efficient use of resources

- "Effective" is missing from the text

  5.2.1 Constitution of Similar Exposure Groups (SEGs)

  In practice it is usually not possible to measure the exposure of each worker during each working day. In order to obtain quantitative data on exposure measurement, an approach shall be taken that allows the most efficient use of resources.

- More background information on performance based (effective and efficient) exposure assessment strategies:
  - e.g. material Paul Hewett: the key message is that the stategy should be effective (reliable) and efficient (few samples and thus cheap)
  - presentation "A tale of two strategies" (www.bohs.org)
  - document "PBEAS design" (www.oesh.com)

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Validity of each individual result and the SEG as a whole

Two necessary quality checks to be performed!

- The validity check has to be performed for each sample separately as well as for the SEG as a whole

5.4 Validity of SEGs and results

5.4.1 General

Before testing the compliance with the OELV (or other numerical value), it is necessary to evaluate the representativeness of each measure and a posteriori confirm the constitution of SEGs. Therefore, the evaluation of measurement results serves two objectives:

a) The representativeness of each sample is evaluated.

b) Each SEG is confirmed as being suitable for compliance testing as explained in 5.5.

- For further guidance, the text refers to annex E for both parts
- You "shall" analyse log probability plots (boxplots not mentioned)

To check whether all individuals belong to the same SEG, and whether the distribution of measurements is log-normal, the log probability plot of the data shall be analysed. Guidance is given in Annex E.

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Validity of each individual result

The use of the term outlier in the first part is inappropriate

- Each (individual) sample has to be evaluated. The representativity of the sample deals with the working conditions during the sampling process: did something go wrong with the equipment? Has there been any form of manipulation, sabotage, etc? In this stage each sample is "unique" i.e. does not belong to a certain distribution. It is inappropriate to use the word outlier here since this implies a comparison to an underlying distribution. The reference to Annex E here is in our opinion wrong
- However, indications for problems with the validaty of the SEG (e.g. using boxplots or q.q. plots = log probability plots) may be a trigger to investigate those individual samples in more detail
- Modified boxplots incorporate criteria for outliers and extreme values

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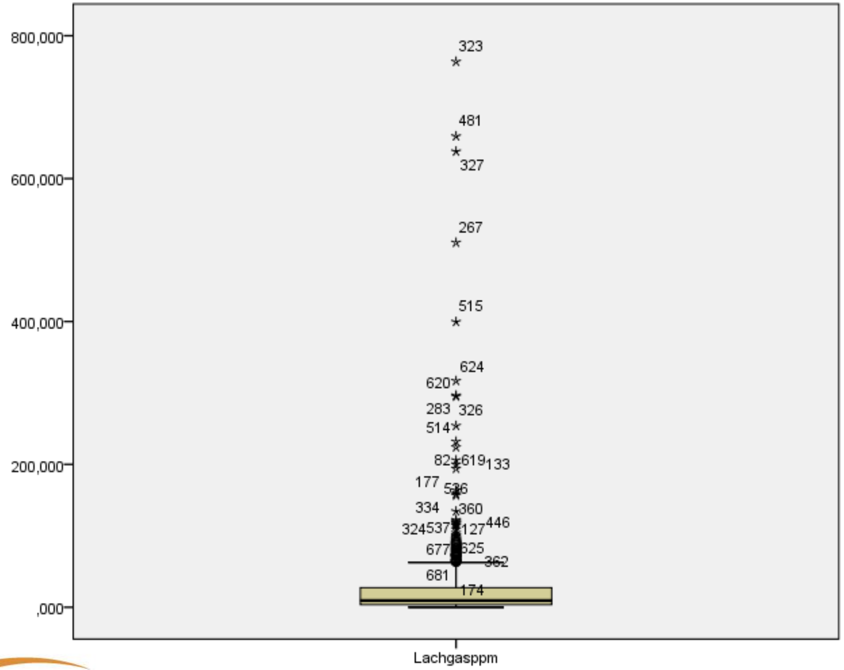
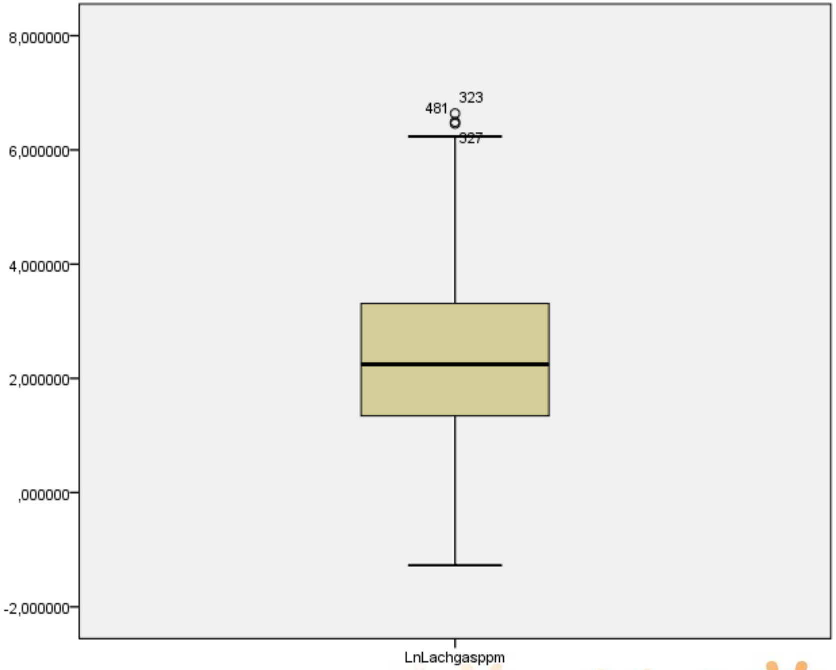
Validity of each individual result

We retake the N_2O example to illustrate the context dependancy

- an identified outlier (o) or extreme (*) in a normal model is not the same as in a lognormal model (more on boxplots here and here)





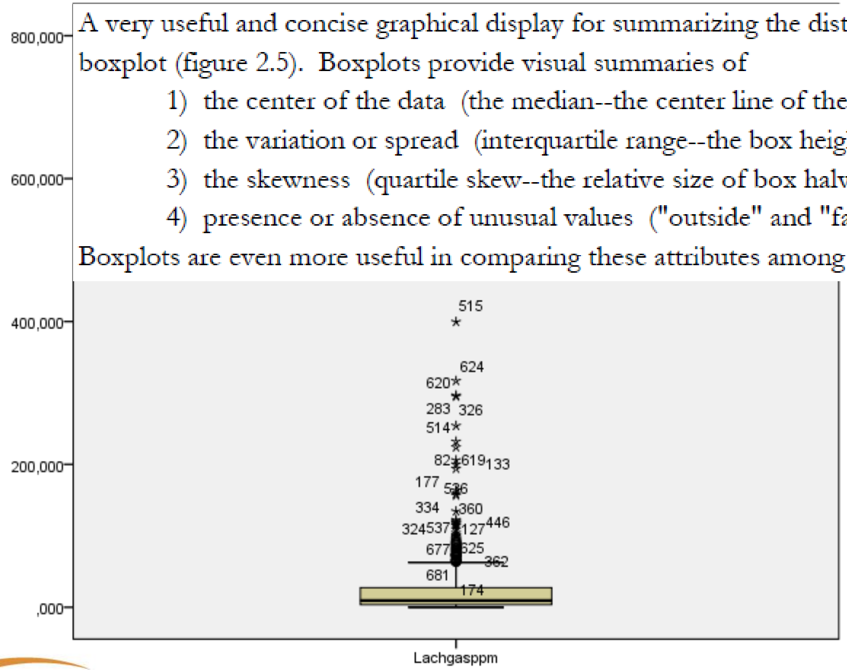
Validity of of the SEG as a whole: visual check with boxplots

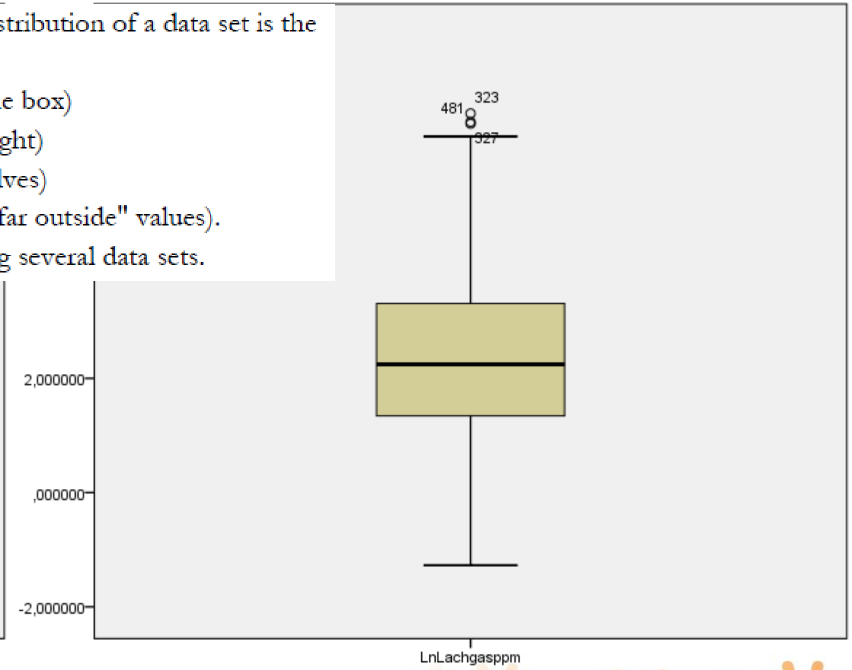
Measurement results need to follow the same distribution as assumed in the (statistical) compliance test (5.4.3) + appraisers assume lognormality (5.5.3)

A very useful and concise graphical display for summarizing the distribution of a data set is the boxplot (figure 2.5). Boxplots provide visual summaries of

1) the center of the data (the median--the center line of the box)
2) the variation or spread (interquartile range--the box height)
3) the skewness (quartile skew--the relative size of box halves)
4) presence or absence of unusual values ("outside" and "far outside" values).

Boxplots are even more useful in comparing these attributes among several data sets.

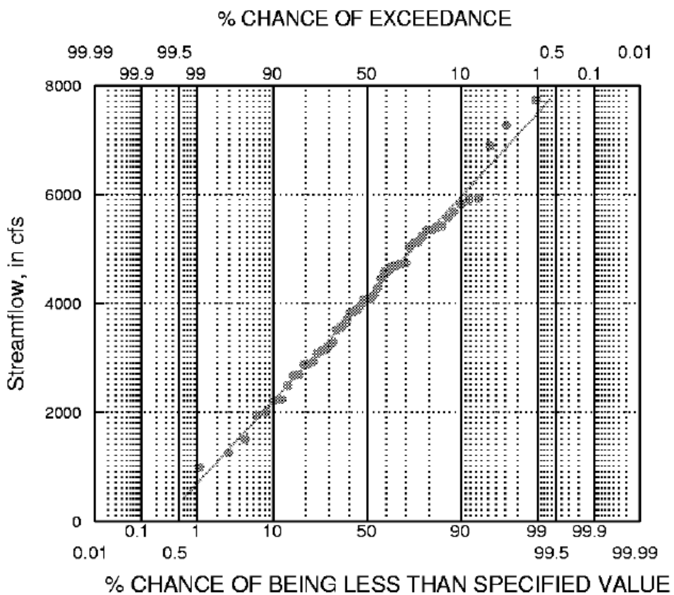


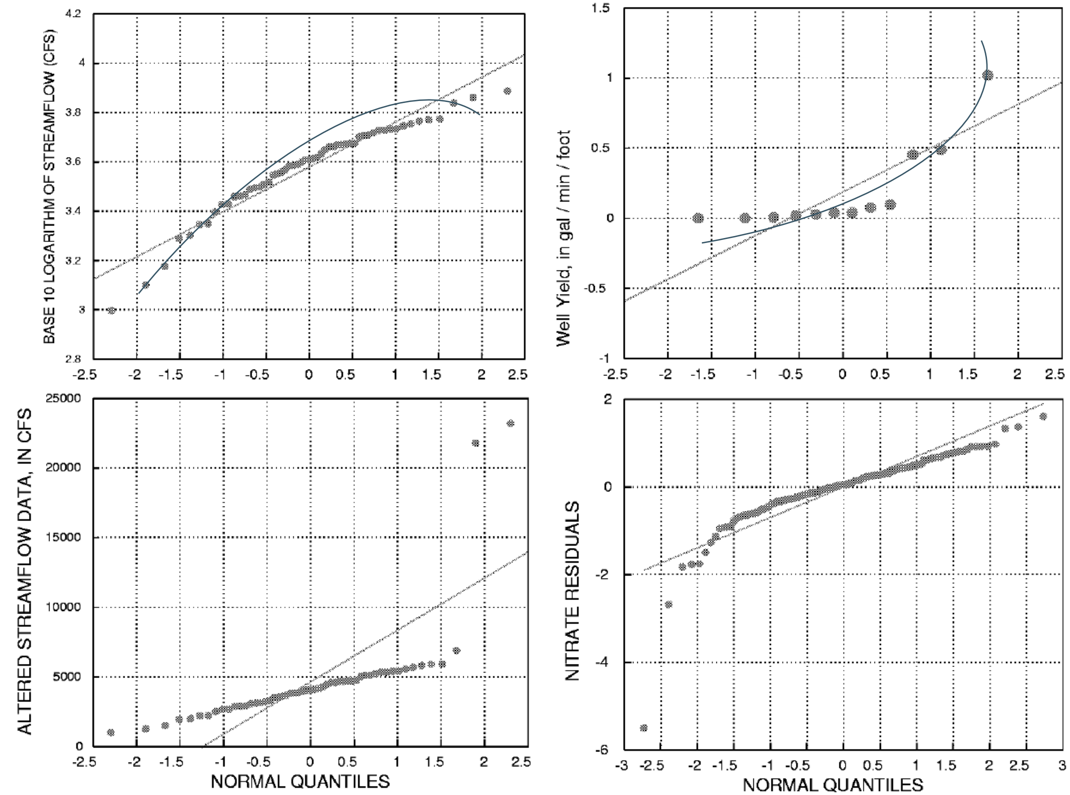


Validity of of the SEG as a whole: visual check with qqplots

Examples from Statistical Methods in Water Resources (Helsel and Hirsch)

- flying banana’s and S-curves are indications for deviation of normality
- patterns deviating from a lines indicate problems





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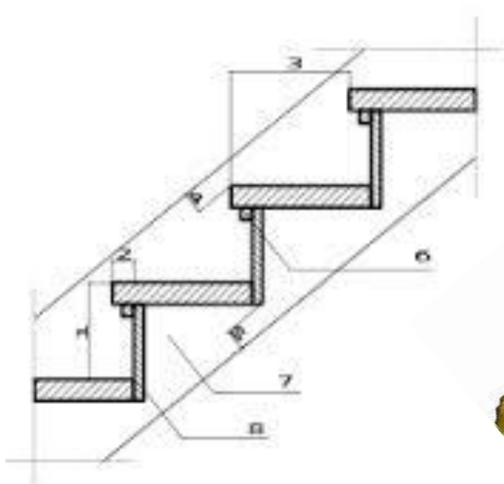
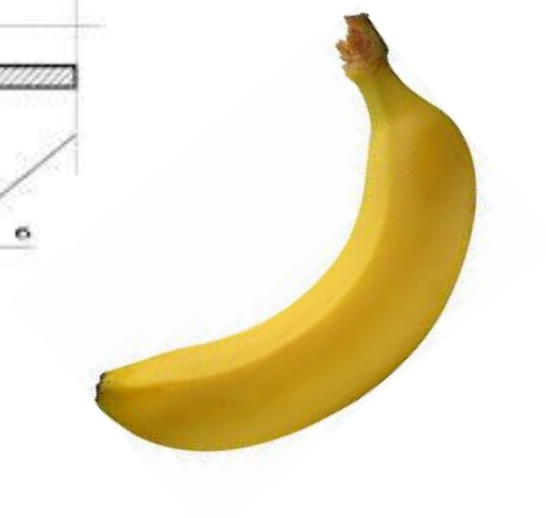
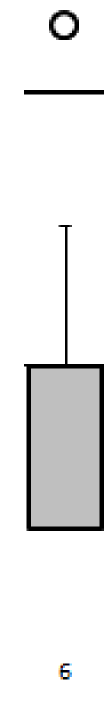
Validity of of the SEG as a whole: visual check with qqplots

a picture is worth a thousand words…

- Boxplots: extremes (*), outliers (o), assymmetry, large difference between upper and lower part of the IQR (box), squeezed parts?
- QQ-plots: staircases, banana’s, S-curves
  or other apparent deviations from straight lines?







How can you do this in excel?

Or on real log probabilty paper if you'd like…

- Enter the concentrations "x_k" and calculate the plotting positions "P_k" ("concentration"-3/8)/("tot number of concentration"+1/4)

Table E.1 — Example of nine exposure measurements with the associated probability values for plotting on log-probability paper.

Exposure x_k mg m^{-3}	k	P_k	P_k as percentage
0,32	1	0,068	6,8
0,60	2	0,176	17,6
0,62	3	0,284	28,4
0,90	4	0,392	39,2
0,93	5	0,500	50,0
1,1	6	0,608	60,8
1,2	7	0,716	71,6
1,35	8	0,824	82,4
2,4	9	0,932	93,2

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How can you do this in excel?

Or on real log probabilty paper if you'd like…

- calculate the "z-scores" (a linear scale) for the %s (=NORM.S.INV("P_k"))
- insert a scatterplot with h-axis = exposure (log-scale) and v-axis = z-score

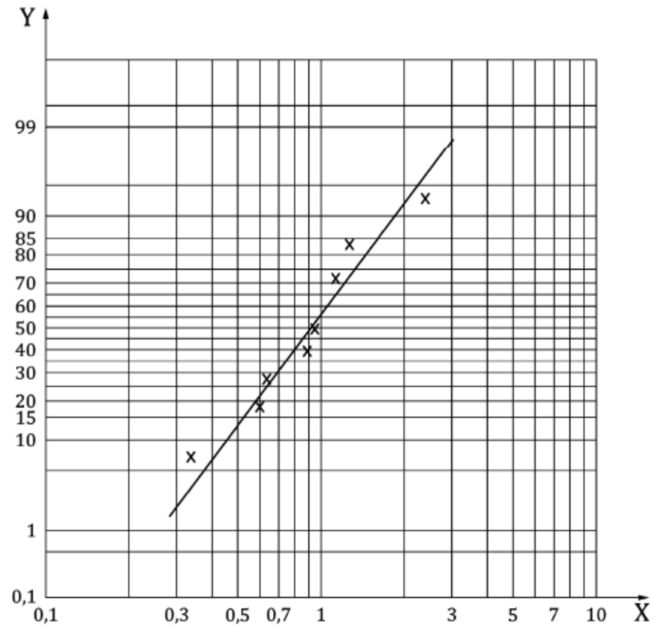
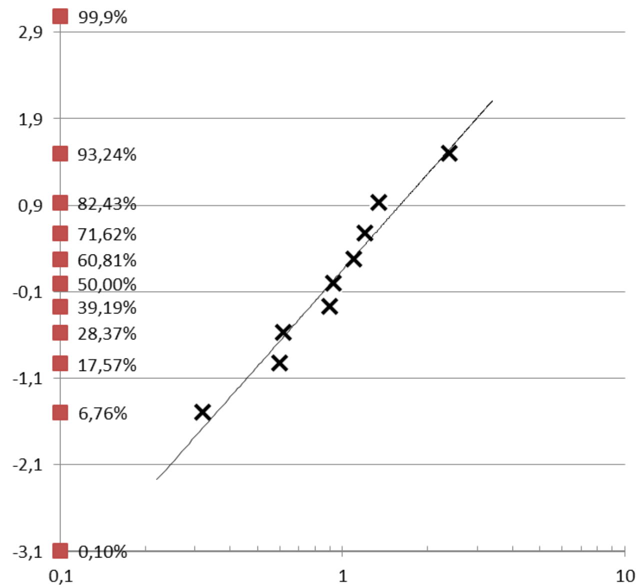


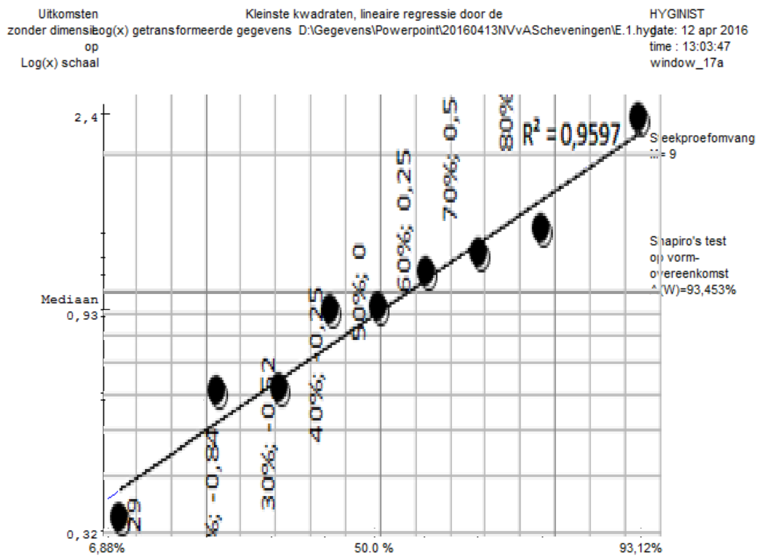
Figure E.1 — Nine exposure measurements and their probability values plotted on log-probability paper.

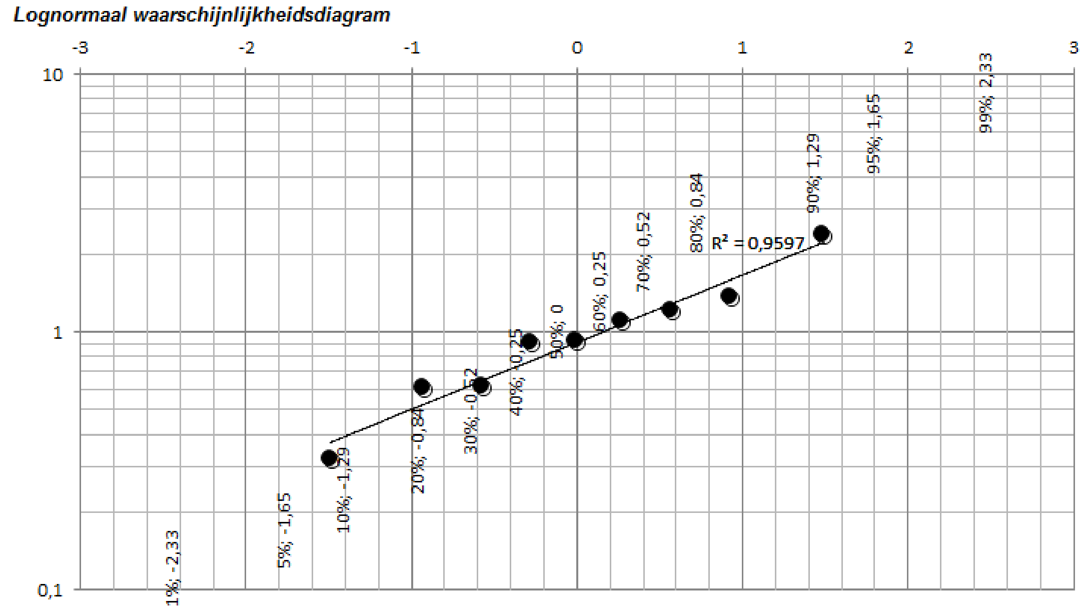


Much easier: use Hyginist or BWStat

Or on real log probabilty paper if you'd like…

- Hyginist E.1
- BWStat E.1





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Much easier: use Hyginist or BWStat

Or on real log probabilty paper if you'd like…

- Hyginist E.1
- BWStat E.1

Start | Ruwe gegevens | Grenzen | Kengetallen | Waarschijnlijkheidspapier | Vergelijk

Omschrijving van de blootstellinggegevens

Naam: D:\Gegevens\Powerpoint\20160413NVvAScheveningen\E.1.hyg

Steekproef Omvang M= 9

Schatters van de log-Normale kengetallen

GM maximale waarschijnlijkheid = 0,91

GM zuivere schatter= 0,895

GSD= 1,773

Vier schatters van het rekenkundige gemiddelde

AM maximale waarschijnlijkheid = 1,072

AM zuivere schatter = 1,05

Kleinste kwadraten AM = 0,995

XM lineair= 1,047

Twee schatters van de rekenkundige standaard afwijking

SD zuivere schatter = 0,614

SD lineair= 0,602

Individuele statistieken

	Calculated parameters									Regression estimators					Summary					
	AM	AStdev	GM	GStdev	Shapiro-Wilk	Shapiro-WilkCrit	U	UCrit95%,70%	UTL95%,70%	GMGraph (intercept)	GStdevGraph (slope)	UGraph	UCritGraph95%,70%	UTLGraph95%,70%	aantal > OEL	Lognormal	Compliant95%,70%	df (aantal -1)	CompliantGraph95%,70%	df (aantal > LoQ -1)
Groep	1,05	0,60	0,91	1,77	0,98	0,83	2,98	2,04	2,92	0,91	1,82	2,84	2,04	3,08	0	1	1	8	1	8

Much easier: use Hyginist or BWStat

Also to illustrate the relative importance of eyeballing vs statistical testing

- Hyginist E.1
- BWStat E.1

BWStat

E.3 Statistical methods for the validation of SEGs

More rigorous statistical tests of the fit of the lognormal and other distributions to exposure results are included in data-handling software (for example Altrex-Chimie, ~~IHDataAnalyst~~, ~~HISTAT~~, etc.), but the power of such tests to identify non-lognormality is limited for the small sample numbers considered here. For example, of the cases presented in E.2, only the data in Figure E.5 is identified by the Shapiro and Wilk test [3] as inconsistent with a lognormal distribution.

Individual statistics

	AM	AStdev	GM	GStdev	Shapiro-Wilk	Shapiro-WilkCrit	U	UCrit95%,70%	UTL95%,70%	GMGraph (intercept)	GStdevGraph (slope)	UGraph	UCritGraph95%,70%	UTLGraph95%,70%	number > OEL	Lognormal	Compliant95%,70%	df (number -1)	CompliantGraph95%,70%	df (number > LoQ -1)
	Calculated parameters									Regression estimators					Summary					
Group	**1,26**	**1,25**	**0,92**	**2,16**	**0,97**	**0,95**	**2,19**	**1,77**	**3,61**	**0,92**	**2,16**	**2,19**	**1,77**	**3,62**	**1**	**1**	**1**	**54**	**1**	**54**
E.3a (lowest GM)	0,54	0,27	0,48	1,80	0,94	0,76	4,00	2,29	1,83	0,48	1,86	3,76	2,29	1,99	0	1	1	4	1	4
E.3b (highest GM)	1,34	0,42	1,30	1,35	0,97	0,76	4,50	2,29	2,57	1,30	1,39	4,14	2,29	2,73	0	1	1	4	1	4
Individuals																				
E.1	1,05	0,60	0,91	1,77	0,98	0,83	2,98	2,04	2,92	0,91	1,82	2,84	2,04	3,08	0	1	1	8	1	8
E.2	0,94	0,57	0,77	2,06	0,96	0,83	2,58	2,04	3,37	0,77	2,13	2,47	2,04	3,60	0	1	1	8	1	8
E.3a	0,54	0,27	0,48	1,80	0,94	0,76	4,00	2,29	1,83	0,48	1,86	3,76	2,29	1,99	0	1	1	4	1	4
E.3b	1,34	0,42	1,30	1,35	0,97	0,76	4,50	2,29	2,57	1,30	1,39	4,14	2,29	2,73	0	1	1	4	1	4
E.4	1,37	1,15	1,06	2,08	0,94	0,83	2,12	2,04	4,70	1,06	2,13	2,05	2,04	4,95	0	1	1	8	1	8
E.5	0,95	0,40	0,84	1,81	0,82	0,83	3,00	2,04	2,81	0,84	1,78	3,11	2,04	2,70	0	0	1	8	1	8
E.6	2,32	2,51	1,28	3,43	0,97	0,83	1,10	2,04	15,76	1,28	3,69	1,04	2,04	18,27	1	1	0	8	0	8

Validity of of the SEG as a whole: the BW complication

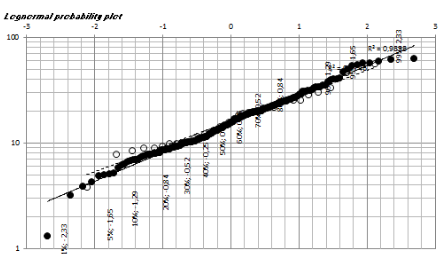
An important complication is the phenomenon between-worker variability

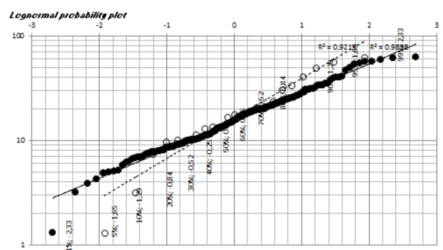
- This issue is dealt with in detail in the BOHS-NVvA sampling strategy…

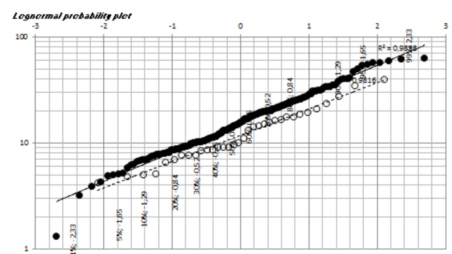
An important complication is that two workers doing the same job need not to have the same exposure. This phenomenon, known as between-worker variability, means that measurements of one worker's exposure cannot simply be assumed to apply to others doing nominally the same job. Furthermore, exposure varies from shift to shift, giving rise to within-worker variability.

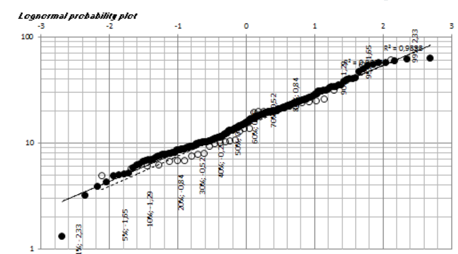
If the measurements show that one or more workers have exceptional exposure, which seems inconsistent with the distribution of results from the rest of the SEG, the reasons shall be investigated and these workers may be treated separately, for example forming a new SEG and taking more measurements as necessary. Guidance is given in Annex E.

- … and BWStat remains usefull for the visual checks required in prEN689 (in which graph the line through the open circles has the worst fit???)









The screening test …

Requires 3 – 5 measurements on workers belonging to a SEG

5.5.2 Screening test

The test requires three to five exposure measurements on workers belonging to a SEG.

a) If all results are below :

1) 0,1 OELV for a set of three exposure measurements or,

2) 0,15 OELV for a set of four exposure measurements or,

3) 0,2 OELV for a set of five exposure measurements

then it is considered that the OELV is respected: **Compliance.**

b) If one of the results is greater than the OELV, it is considered that the OELV is not respected: **Non-compliance.** In case that the first measurement result is above the OELV, it is not necessary to perform any additional measurements.

c) If all the results are below the OELV and a result above 0,1 OELV (set of three results) or 0,15 OELV (set of four results) or 0,2 OELV (set of five results) it is not possible to conclude on compliance with the OELV. **No-decision.**

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… seems to be on the safe side

Requires 3 – 5 measurements on workers belonging to a SEG

- OEL Thresholds proposed in the screening test are based on table VII in ND2231, the calculation method is detailed in the annex of the ND 2231.
- http://www.inrs.fr/media.html?refINRS=ND%202231

TABLEAU VII

Fraction de VL, en fonction de l'écart-type géométrique et du nombre de mesures, que le maximum d'une série ne doit pas dépasser, correspondant à une probabilité de dépassement inférieure ou égale à 0,01.
LV fraction, with respect to geometric standard deviation and number of measurements, which the series maximum must not exceed, corresponding to a probability of exceeding less than or equal to 0.01.

Nombre de mesures	Écart-type géométrique					
	1,1	1,5	2	2,5	3	4
1	0,80	0,39	0,20	0,12	0,08	0,04
2	0,84	0,48	0,28	0,19	0,14	0,08
3	0,86	0,53	0,34	0,24	0,18	0,11
4	0,88	0,57	0,38	0,28	0,22	0,15
5	0,89	0,60	0,42	0,31	0,25	0,17
6	0,89	0,62	0,45	0,34	0,28	0,20
7	0,90	0,64	0,47	0,37	0,30	0,22
8	0,91	0,66	0,49	0,39	0,33	0,24
9	0,91	0,68	0,51	0,42	0,35	0,27
10	0,92	0,69	0,53	0,44	0,37	0,28

~0,10
~0,15
~0,20

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The compliance test …

Requires 6 or more measurements on workers belonging to a SEG

5.5.3 Test of compliance with the OELV

The appraiser shall select a statistical test of whether the exposures of the SEG comply with the OELV. The test shall measure, with at least 70% confidence, whether less than 5 % of exposures in the SEG exceed the OELV.

A suitable test is given in Annex F. Other tests may be used provided that they have been shown to meet the above confidence specification.

… finds a good balance for decision errors

Requires 6 or more measurements on workers belonging to a SEG

- http://fhvmetodik.se/wp-content/uploads/2014/08/OgdenT_2012.pdf
- You can reuse measurements from the screening test; the prEN689 does not impose a time limit, but you should be confident the work situation remained unchanged since then
- Annex F using BWStat

EXAMPLE

A series of six exposure measurements is used to test compliance with an OELV of 10 ppm.

Result in ppm	ln (result)
0,8	-0,223143551
0,9	-0,105360516
1,1	0,09531018
1,4	0,336472237
4,5	1,504077397
6	1,791759469
ln(GM)	0,566519203
ln(GSD)	0,863733553

GM = 1,76 ppm ; GSD = 2,37; Arithmetic mean = 2,45 ppm.

Calculation of UR

$$U_R = \frac{\ln(10) - 0{,}566519203}{0{,}863733553} = 2{,}009$$

The U_R value is lower than the U_T value (2,187) corresponding to six exposure measurements, concluding the OELV is likely to be exceeded: **Non compliance.**

	Calculated parameters									Regression estimators					Summary					
	AM	AStdev	GM	GStdev	Shapiro-Wilk	Shapiro-WilkCrit	U	UCrit95%,70%	UTL95%,70%	GMGraph (intercept)	GStdevGraph (slope)	UGraph	UCritGraph95%,70%	UTLGraph95%,70%	number > OEL	Lognormal	Compliant95%,70%	df (number -1)	CompliantGraph95%,70%	df (number > LoQ -1)
Group	2,45	2,23	1,76	2,37	0,84	0,79	2,01	2,19	11,65	1,76	2,40	1,99	2,19	11,92	0	1	0	5	0	5

$U_R < U_T$

E: OK F: NOT

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The compliance test …

Requires an approach for handling <LOQ

If one or more of the exposure measurements are below the limit of quantification (LOQ), and the statistical test selected involves use of geometric standard deviation (GSD) and/or geometric mean (GM), then the values below the LOQ shall be treated in a way which produces a reliable result. A suitable method is described in Annex H.

Applying such tests to the exposure measurements assumes that the measurements are log-normally distributed (see Annex E). This is usually true at least approximately, and it is unusual to have enough measurements to show statistically that it is not true. The appraiser shall assume that it is true unless there is good reason to believe that it is not true.

Annex H gives a procedure to handle measurements that are below the limit of quantification (LOQ) when the statistical test given in 5.5.3 is used.

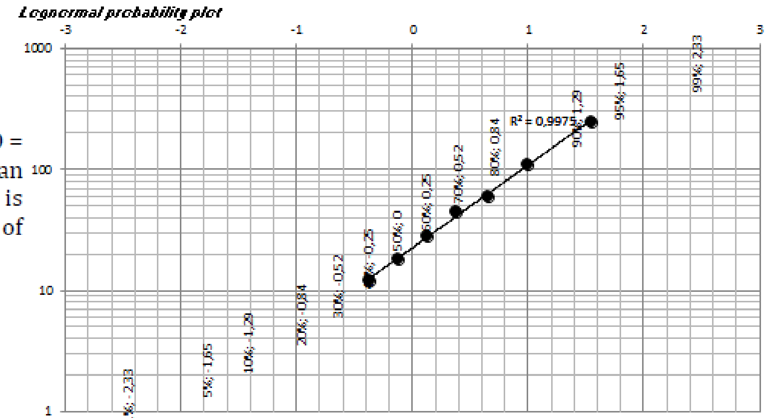
Results below LOQ should be taken into consideration since they are valid (see 5.4), and they should not be replaced with a fixed value such as LOQ/2, as these methods are likely to overestimate GM and underestimate GSD, which can lead to a wrong compliance decision.

Free of charge software that automates the procedure in this Annex is listed in H.5. It works quicker and with a higher precision, reproducibility, and reliability than the manual method, and its use is recommended. However, this Annex presents a graphical procedure which illustrates the method and which only requires the use of widely-available statistical tables.

… with <LOQ results can be done automated or manually

Requires an approach for handling <LOQ

- You can automate this (eg in a spreadsheet), but it's implemented already in Hyginist, Altrex, NDExpo and of course BWStat



The regression coefficient (in this case 1,5739) is the natural log of the GSD of the distribution, so GSD = exp(1,5739) = 4,8 approximately, and the intercept 3,1129 is the natural log of the geometric mean exposure: GM = exp(3,1129) = 22,5 ppm. This can be checked against Figure H.1, because the GM is equal to the median for a lognormal distribution, and the geometric standard deviation is the ratio of the concentrations at the 0,841 and 0,50 fraction points.

ROS+ SUB

H

	Calculated parameters									Regression estimators					Summary					
	AM	AStdev	GM	GStdev	Shapiro-Wilk	Shapiro-WilkCrit	U	UCrit95%,70%	UTL95%,70%	GMGraph (intercept)	GStdevGraph (slope)	UGraph	UCritGraph95%,70%	UTLGraph95%,70%	number > OEL	Lognormal	Compliant95%,70%	df (number -1)	CompliantGraph95%,70%	df (number > LoQ-1)
Group	53,64	76,57	22,42	4,32	0,98	0,84	2,59	2,01	421,98	22,49	4,83	2,41	2,01	527,66	0	1	1	9	1	6

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