



Theo Scheffers



# OELV compliance decisions & the EN689 preliminary test

NYF Vårkonferanse Oslo 21 April 2022

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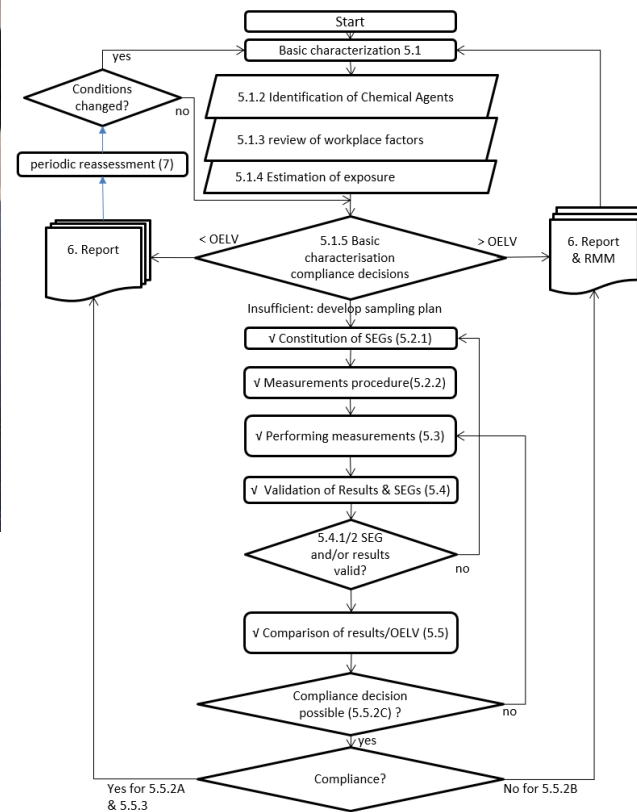
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Ref. No. EN 689:2018+AC:2019 E



The CEN TC 137 / WG1 (2014-2018)



# Aims

## EN689 Introduction

- High degree of confidence  $C \leq OELV$
- Dealing with exposure variability
- use a small number of measurements
- Cost effective

# Compliance testing EN689

1. Basic characterisation §5.1.4
2. Preliminary test § 5.5.2 / Statistiske test §5.5.3

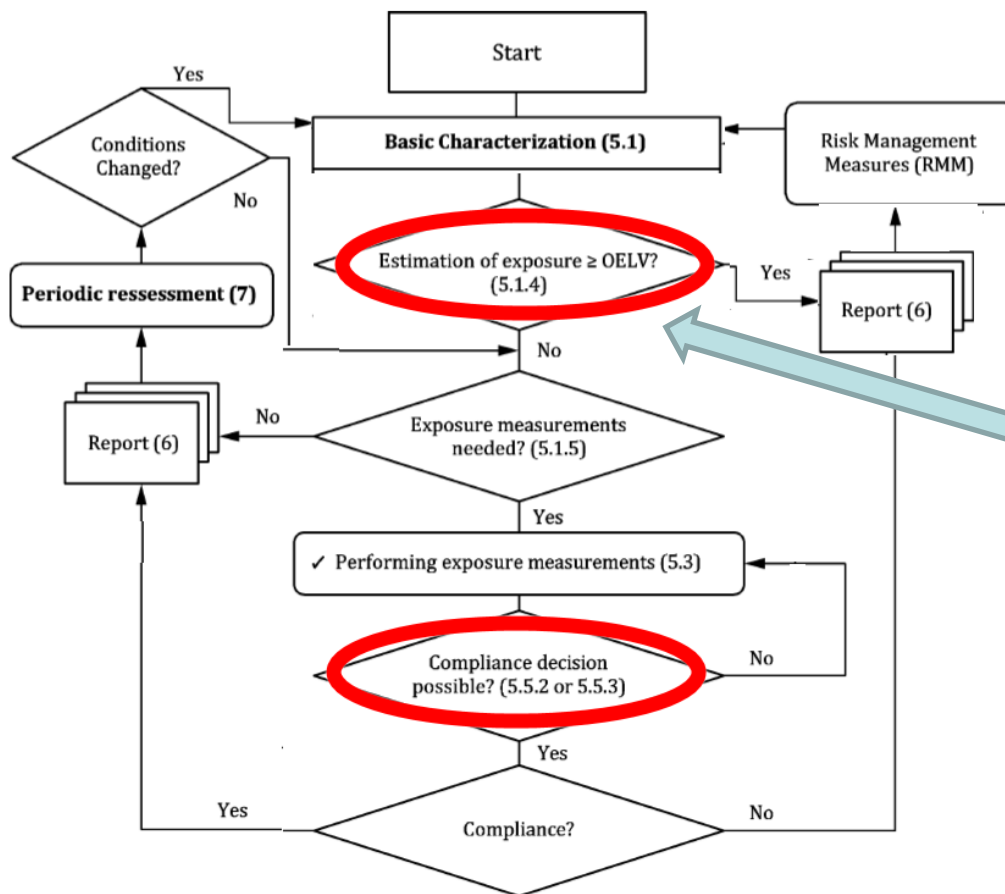
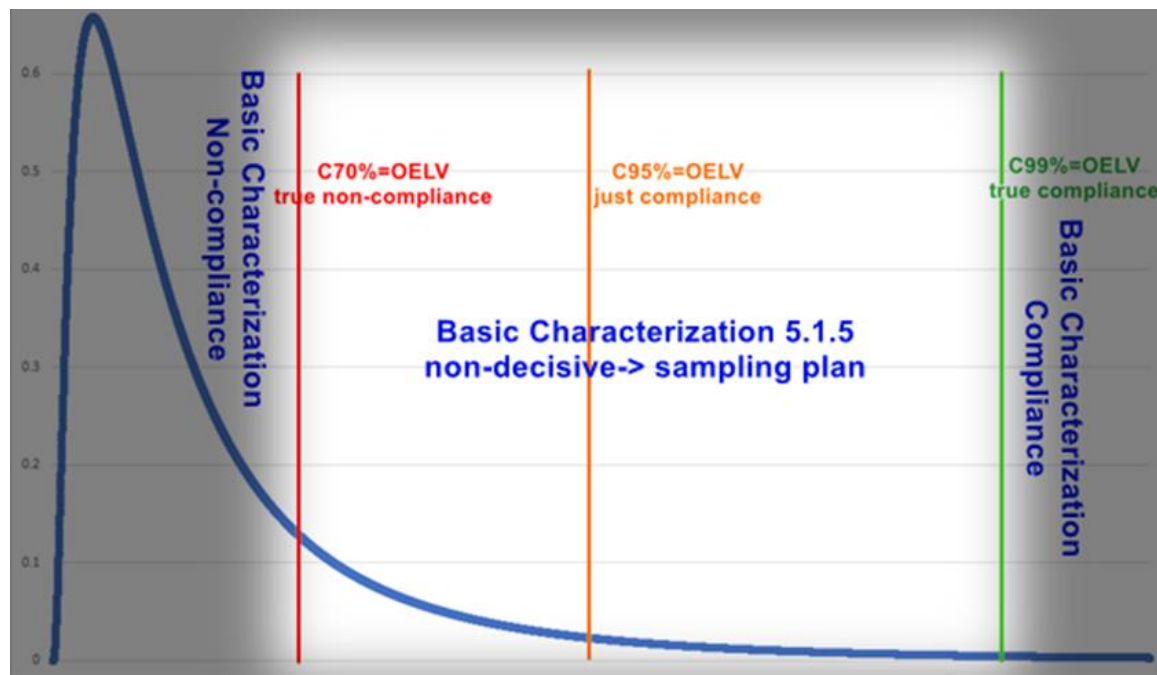


Figure 1 —Schematic overview of the occupational exposure assessment procedures

# When to develop a EN 689 5.2 sampling strategy?

## 5.1.5 basic characterization

Exposure is well below the OELV	Compliance
Exposure is higher than the OELV	Non-compliance
No decision	Sampling plan





# Compliance testing with measurements

## 5.5.2 preliminary test N=3, 4 & 5

$C_{\max} \leq \text{fr}(\text{OELV})$	Compliance
$C_{\max} > \text{OELV}$	Non-compliance
$\text{fr}(\text{OELV}) < C_{\max} \leq \text{OELV}$	No decision $\Rightarrow$ more measurements

## 5.5.3 statistical test N $\geq$ 2

$C_{95,70\%} \leq \text{OELV}$	Compliance
? (Annex F)	Non-compliance

*«It is therefore outside the scope ... to use [5.5.3] to measure non-compliance»*

# Live voting

1. Who performs 3 to 5 measurements within a SEG or exposure profile ?
  1. If YES , next question #2
  2. If NO wait for question #3
2. If YES , which compliance test do you use?
  1. preliminary test (EN689:2018 § 5.5.2)?
  2. statistical test  $C_{95,70\%}$ (EN689:2018 § 5.5.3)?
  3. both
  4. otherwise .....
3. If NO, why not ?
  1. I'm using only the basic characterisation (models, databases, 1 or 2 measurements etc.) § 5.1.5
  2. I always take at least 6 measurements
  3. Otherwise .....

# Live voting (2)

Is preliminary test more reliable than the statistical test for 3 to 5 measurements?

1. Yes, as it is the general line in Europe
2. No, as the variability of exposure is not taken into account
3. otherwise .....
4. No idea!



# Example

1<sup>st</sup> Inhalable dust measurement

OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=
0.76	15.2%						

# Example

2nd consecutive Inhalable dust measurement  
OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=	
0.76	15.2%							
1.52	30.4%		unknown	1.07	1.63	8.49	88.99%	C <sub>95,70%</sub> >OELV

# Example

3<sup>th</sup> consecutive Inhalable dust measurement  
OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=
0.76	15.2%						
1.52	30.4%						
0.81	16.2%	no decision	Normal	0.98	1.47	2.87	99.42% compliance

## 5.5.2 Preliminary test a) 1)

Compliance if all results are below 0,1 OELV for a set of three exposure measurements

# Example

4<sup>th</sup> consecutive Inhalable dust measurement  
OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=
0.76	15.2%						
1.52	30.4%						
0.81	16.2%						
0.6	12%	no decision	logNormal	0.87	1.49	2.29	99.87% compliance

## 5.5.2 Preliminary test a) 2)

Compliance if all results are below 0,15 OELV for a set of three exposure measurements

# Example

5<sup>th</sup> consecutive Inhalable dust measurements  
OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=
0.76	15.2%						
1.52	30.4%						
0.81	16.2%						
0.6	12%						
0.28	5.6%	no decision	logNormal	0.69	1.84	2.70	99.10% compliance

## 5.5.2 Preliminary test a) 3)

Compliance if all results are below 0,2 OELV for a set of three exposure measurements

# Example

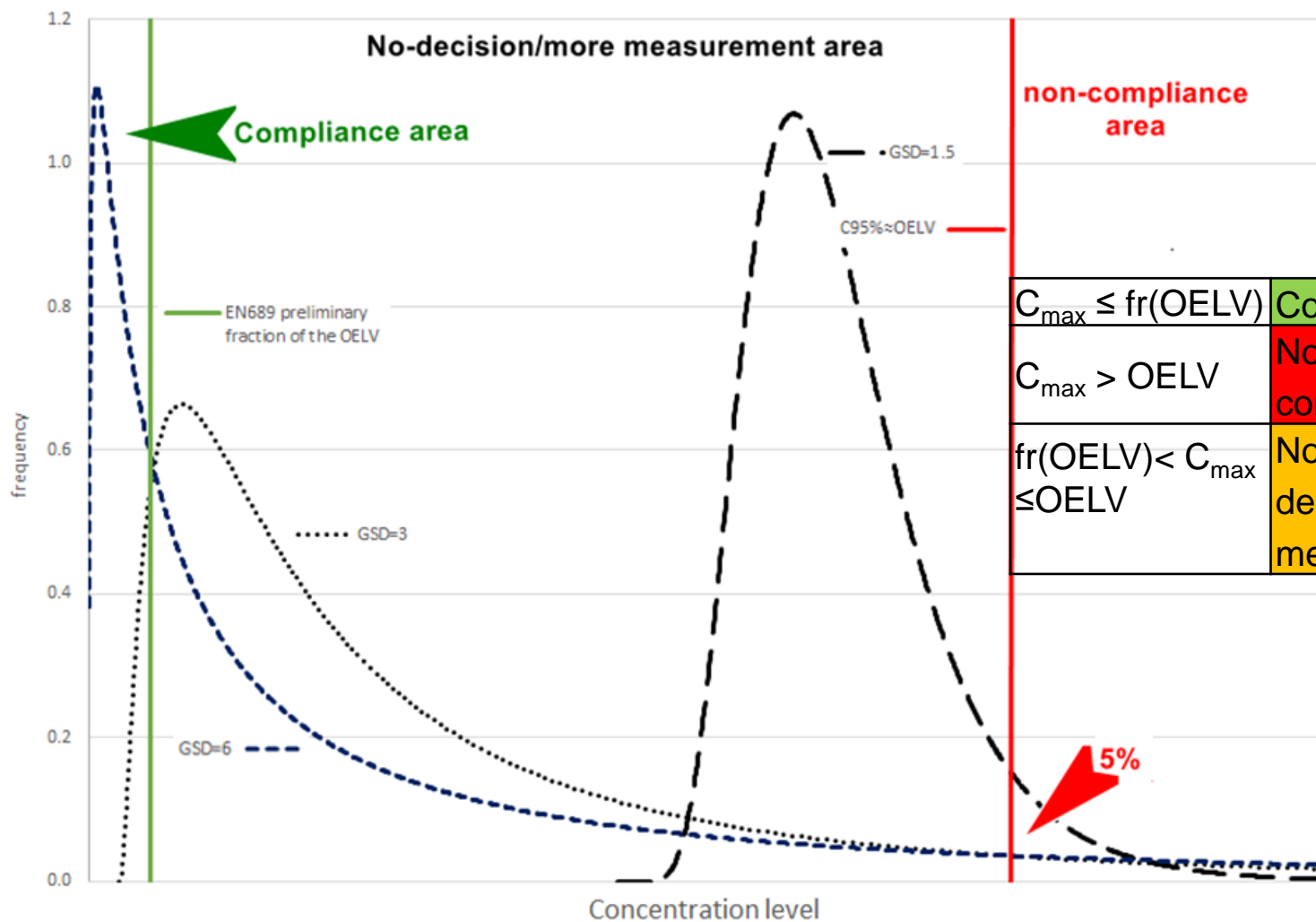
6<sup>th</sup> consecutive Inhalable dust measurement  
OELV 5 mg/m<sup>3</sup>/8 hours

result (mg/m <sup>3</sup> /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C <sub>95,70%</sub>	Statistical test 5.5.3 Compliance if C <sub>X≥95,70%</sub> =OELV X=
0.76	15.2%						
1.52	30.4%		unknown	1.07	1.63	8.49	88.99% <b>C<sub>95,70%</sub>&gt;OELV</b>
0.81	16.2%	no decission	Normal	0.98	1.47	2.87	99.42% <b>compliance</b>
0.6	12%	no decission	logNormal	0.87	1.49	2.29	99.87% <b>compliance</b>
0.28	5.6%	no decission	logNormal	0.69	1.84	2.79	99.10% <b>compliance</b>
0.54	10.8%	-	logNormal	0.66	1.74	2.23	99.70% <b>compliance</b>

**5.5.3 Statistical test ...** shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OELV (*or at least 95% equal to the OELV*)


# Does the preliminary test performs less?

EN689 preliminary OELV fraction cutoff in 3 lognormal distribution with  $C_{95\%} = \text{OELV}$  (just compliance) and different GSD's



# Is the PM test validated?

- No peer review publication
- INRS publication (2005) ND2231, not specific for the fr(OELV) and  $C_{95,70\%}$  used in EN689

HST	ND 2231 - 200 - 05	
<b>ASPECTS STATISTIQUES ET RÔLE DE L'INCERTITUDE DE MESURAGE DANS L'ÉVALUATION DE L'EXPOSITION PROFESSIONNELLE AUX AGENTS CHIMIQUES</b>		<input type="checkbox"/> Exposition professionnelle <input type="checkbox"/> Mesure <input type="checkbox"/> Produit chimique <input type="checkbox"/> Incertitude <input type="checkbox"/> Statistiques  ► Michel GRZEBYK, Jean-Paul SANDINO INRS, Département Métrologie des polluants  STATISTICAL ASPECTS AND INFLUENCE OF MEASUREMENT UNCERTAINTY ON EVALUATION OF OCCUPATIONAL EXPOSURE TO CHEMICAL AGENTS

INRS - Hygiène et sécurité du travail - Cahiers de notes documentaires - 3<sup>e</sup> trimestre 2005 - 200 / 9



# Validation

## 1. Statistical:

- $P(C \leq \text{fr}(\text{OELV}))^{N=3,4,5}$

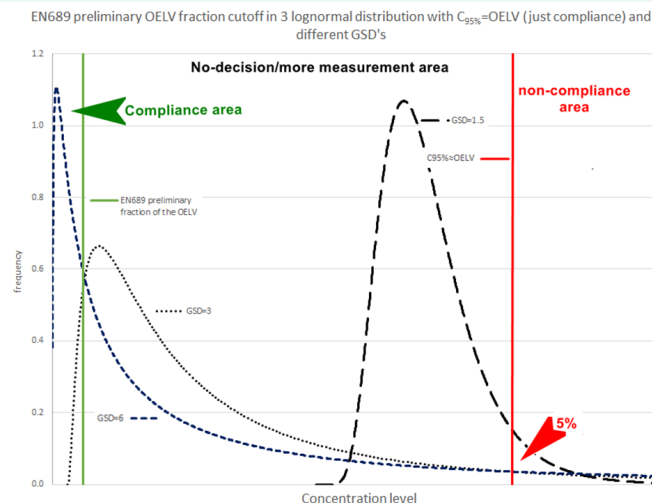
## 2. Monte-Carlo:

10000 samples

from a lognormal population distribution

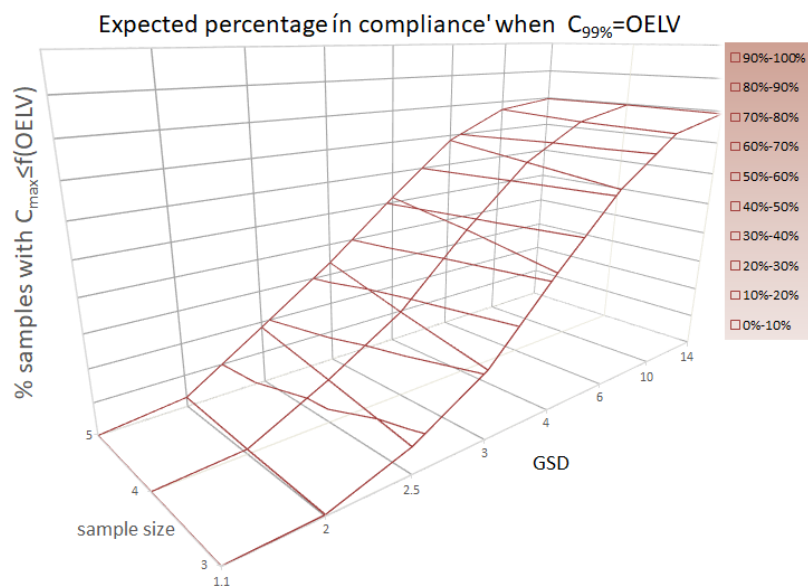
- $N=3, 4 \text{ \& } 5$
- $\text{GSD}=1.1, 1.5, 2, 2.5, 4, 5, 6, 10 \text{ \& } 14$
- $C_{99\%}$ ,  $C_{95\%}$  &  $C_{70\%}$

## 3. Cumulative Binomial for OELV exceedance

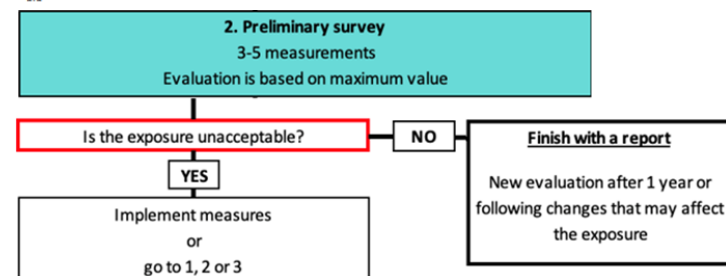
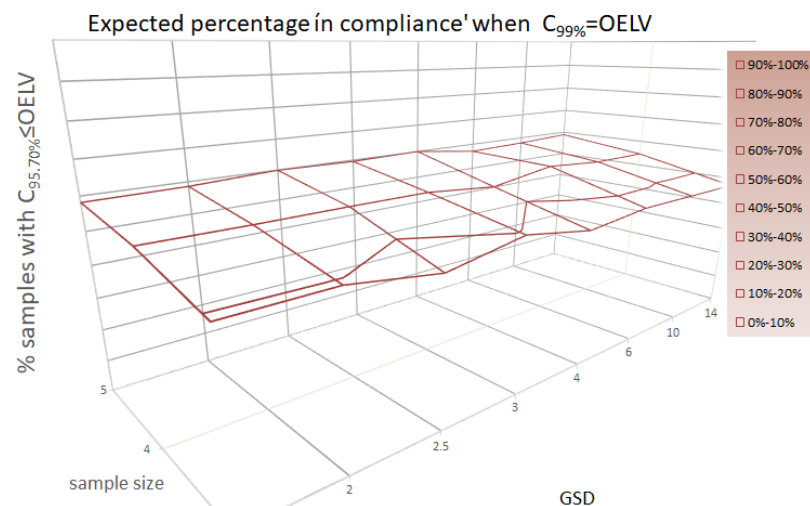


# Compliance performance if $C_{99\%} = OELV$

## 5.5.2 preliminary test

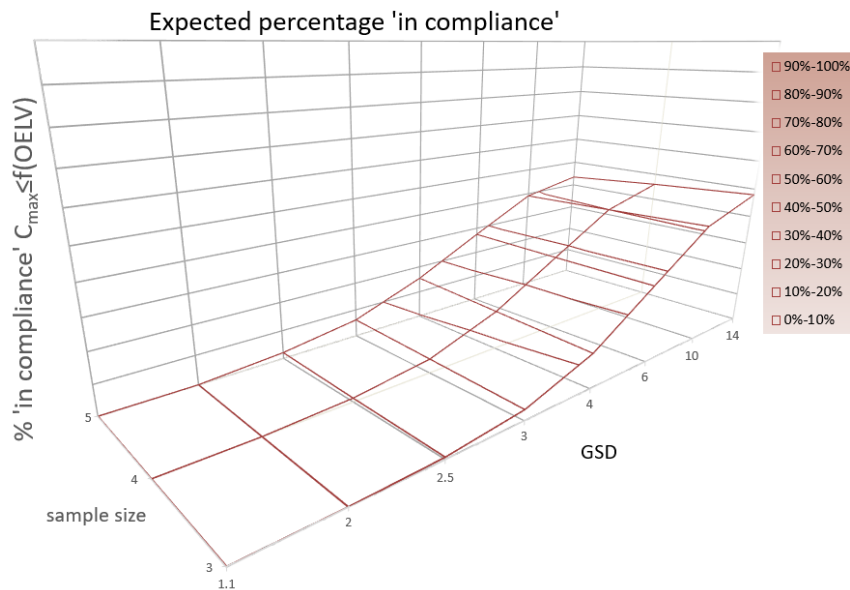


## 5.5.3 statistical test

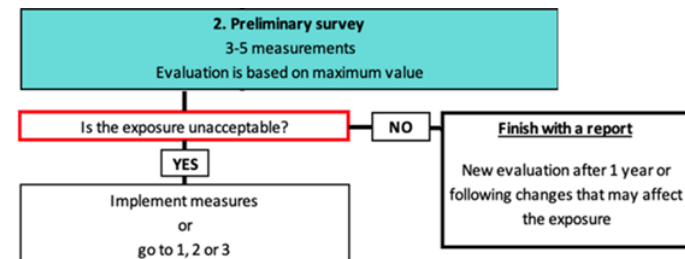
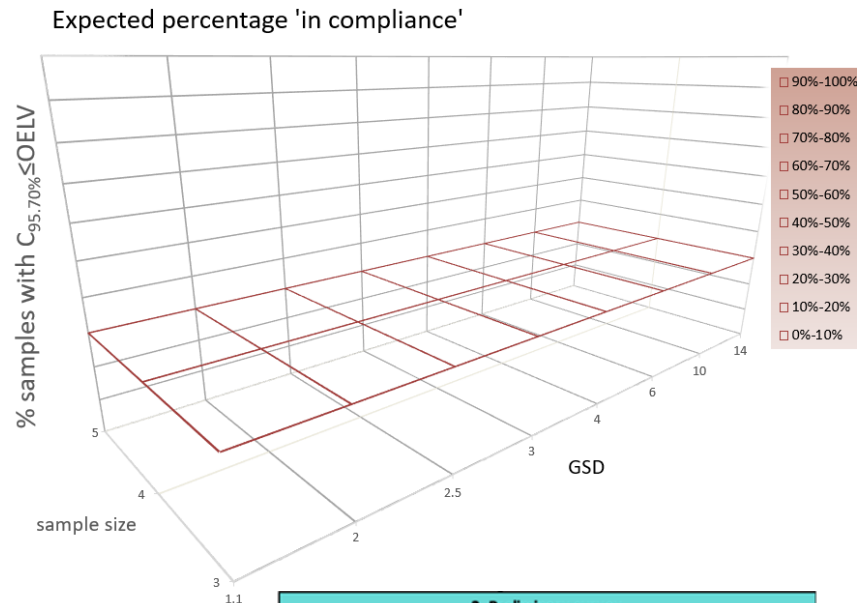


# Compliance performance for $C_{95\%} = OELV$

## 5.5.2 preliminary test



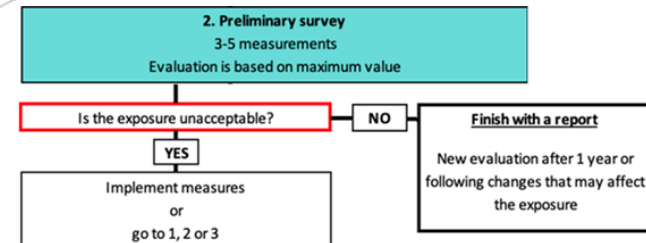
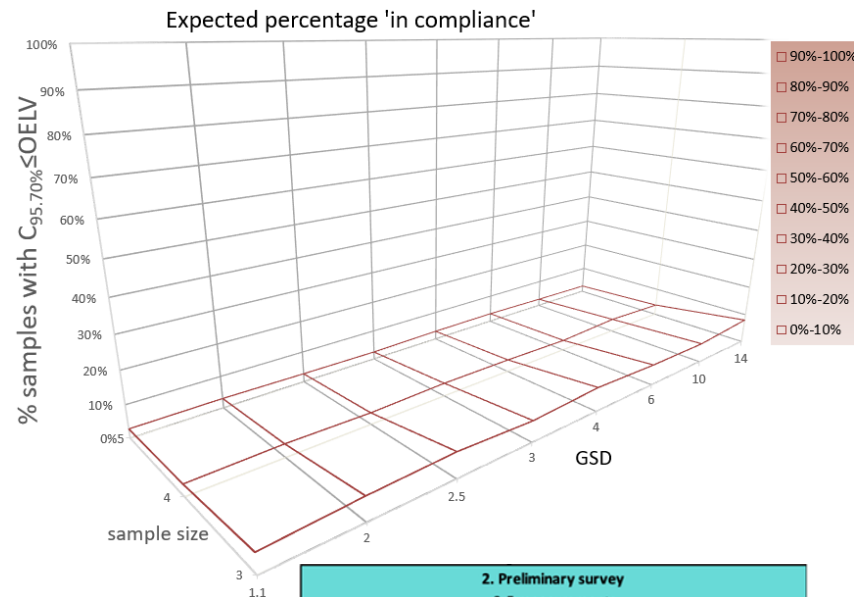
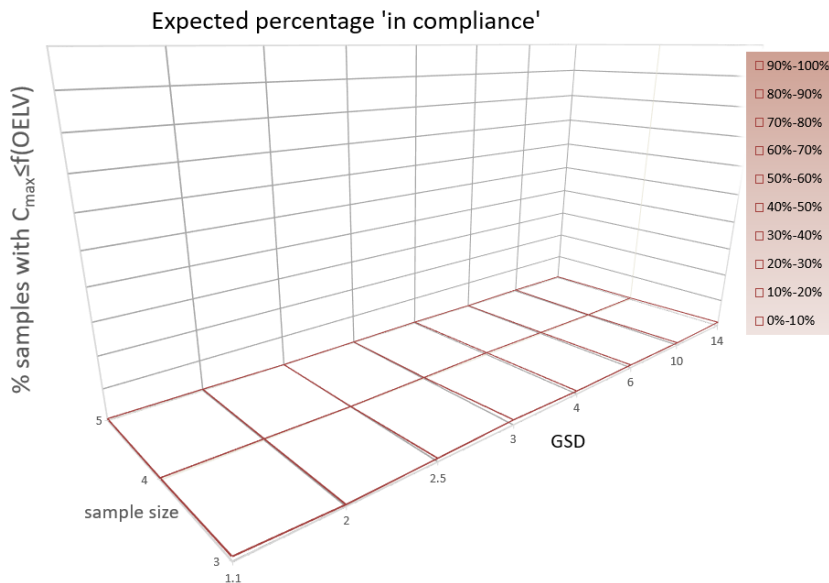
## 5.5.3 statistical test



# compliance performance if $C_{70\%} = OELV$

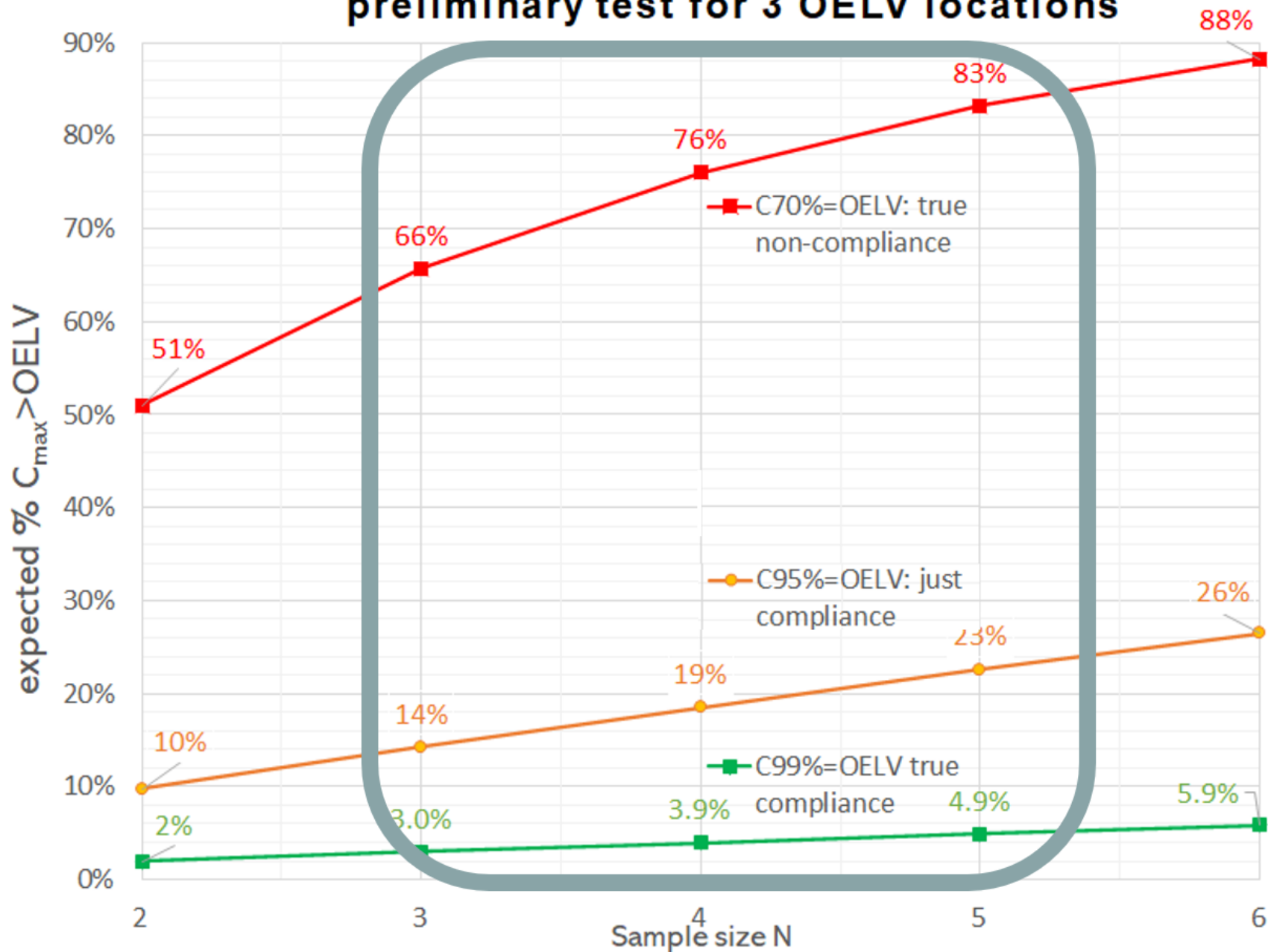
## preliminary test (5.5.2 a)

## statistical test (5.5.3)

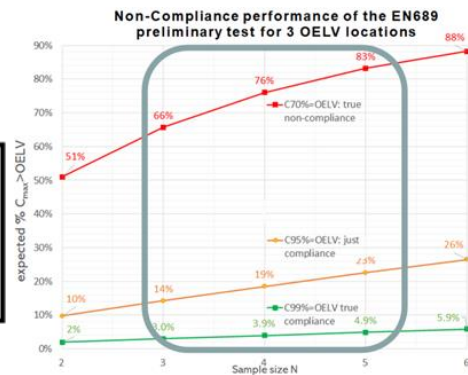
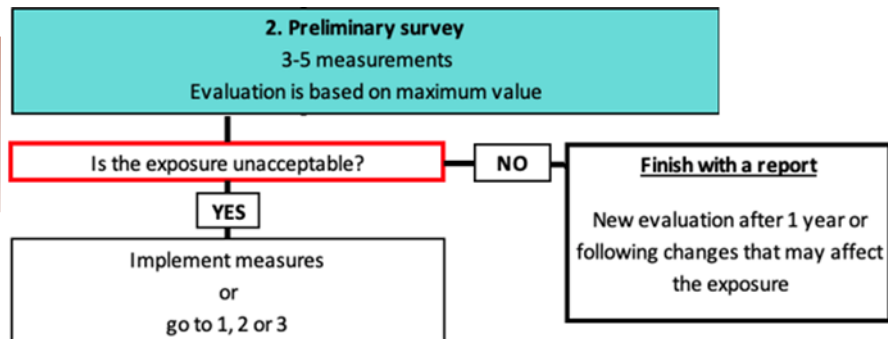
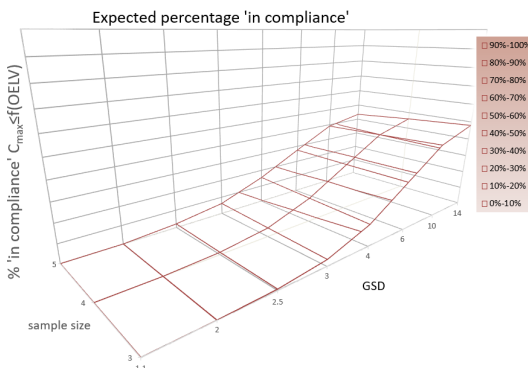




# Non-Compliance performance of the EN689 preliminary test for 3 OELV locations



# preliminary test performance



Conceptually ignores exposure variability

Non-compliance: not or delayed detected

Compliance: almost never found for  $GSD < 3$

In daily practice it's a 'No decision/more measurements' test



# Origin preliminary test

- Code travail (2009)
- BOHS-NVvA (2011)

Both use 0.1 OELV for  
3,4 & 5 measurements

17 décembre 2009

JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE

Texte 35 sur 156

## Décrets, arrêtés, circulaires

MINISTÈRE DU TRAVAIL, DES RELATIONS SOCIALES,  
DE LA FAMILLE, DE LA SOLIDARITÉ ET DE LA VILLE

Arrêté du 15 décembre 2009 relatif aux contrôles techniques des valeurs limites d'exposition professionnelle sur les lieux de travail et aux conditions d'accréditation des organismes chargés des contrôles

NOR : MTST0924705A

### *Testing Compliance with Occupational Exposure Limits for Airborne Substances*



British Occupational Hygiene Society  
Pride Park Derby  
DE24 8LZ, UK  
[www.bohs.org](http://www.bohs.org)

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Nederlandse Vereniging voor  
Arbeidshygiëne  
Postbus 1762,  
5602 BT Eindhoven  
The Netherlands  
[www.arbeidshygiene.nl/](http://www.arbeidshygiene.nl/)

# Why using a decision scheme?

- Obstructions to use statistics in legislation (?)
- Appraisers are insufficient skilled

Inclusion in a EU standard increases its credibility, despite lack of scientific ground





nyf

# Performance Compliance tests

## EN689

	Preliminary	Statistical $C_{95\%} < OELV$
degree of confidence	Varying (N, GSD)	Always 70%
Dealing with exposure variability	No	Yes
Cost effective	No	Yes
Validated	Limited	Yes
Simple	Yes	for appraisers
Worldwide accepted	No	Yes

# Consequences

- Professionals may be held responsible for unnecessary costs and unsafe working conditions when prescribing the test
- Bad reputation EU Industrial Hygiene community

# Other omissions in EN689:2018

Non compliance :

Included in the Basic characterisation decision and Preliminary test

1. Exposure index §5.5: not defined
2. Statistical §5.5.3 not defined

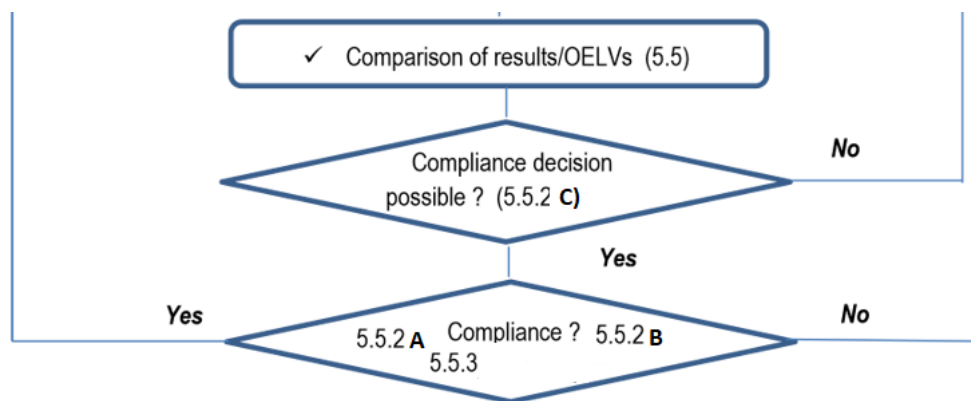


Figure 1 Schematic overview of the occupational exposure assessment procedures<sup>1</sup>.

# Proposed OELV test improvement

## 5.1.5 basic characterization

Exposure is well below the OELV	Compliance
Exposure is higher than the OELV	Non-compliance
No decision	Sampling plan

## 5.5 Exposure Index $I = \sum_{i=1}^n \frac{Ei}{OELVi}$

Threat $I$ as a concentration and apply 5.5.3	Compliance
	Non-compliance
	No decision $\Rightarrow$ more measurements

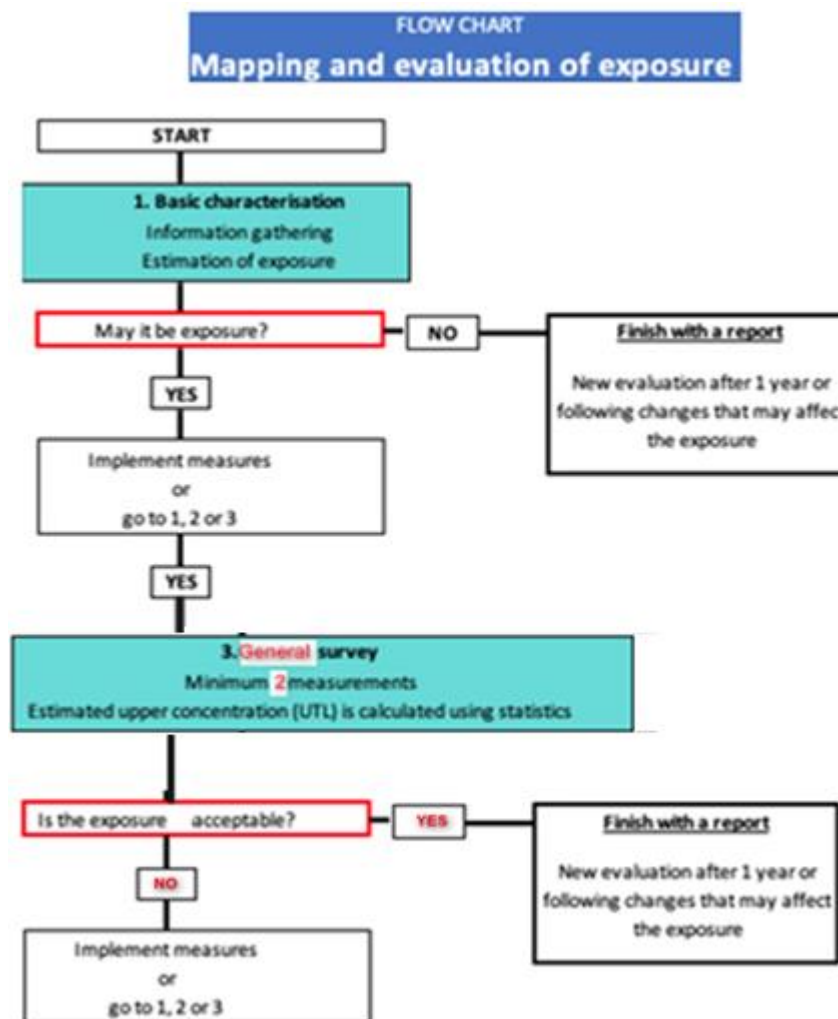
## 5.5.2 preliminary test N=3, 4 & 5

$C_{\max} \leq fr(OELV)$	Compliance
$C_{\max} > OELV$	Non-compliance
$fr(OELV) < C_{\max} \leq OELV$	No decision $\Rightarrow$ more measurements

## 5.5.3 statistical test N $\geq$ 2

$C_{95,70\%} \leq OELV$	Compliance
$C_{95, (ML, 30\% \text{ or } 5\%)} > OELV$	Non-compliance
$C_{95,70\%} > OELV \leq C_{95, X}$	No decision $\Rightarrow$ more measurements

- Simplify the NYF low chart as proposed to the right
- Offer it to the EU IH platform
- Make the preliminary test a self-test for employers (if the variability is not too large)



# Other EN689 improvements

*“I have tried to find textbooks articles etc. that in a IH relevant manner discuss the use and limitations of the “Noncentral-Student distribution with 70% confidence”, but without any success.”*

- Improve concept and priors for Normal test in Annex F (5.4.3 & EN482 table 1)
- Align  $U_T$  test in Annex F with the more universal  $GM \cdot GSD^{UT} \leq OELV$
- Align the exposure pattern in Annex D with the standard and with Annex G (prolonged exposure)  $E_d = C_i \times \frac{t}{8}$
- Expand the subgroup analysis (5.4.3) as described in an BOSH-NVvA 2011/[BWStat](#) (ANOVA/homoscedasticity)
- Include an annual reassessment using  $C_{95,70\%} \leq OELV$  to establish the number of measurements

Finish with a report

New evaluation after 1 year or following changes that may affect the exposure