2e NVvA Mirror meeting prEN 689
14 April 2016

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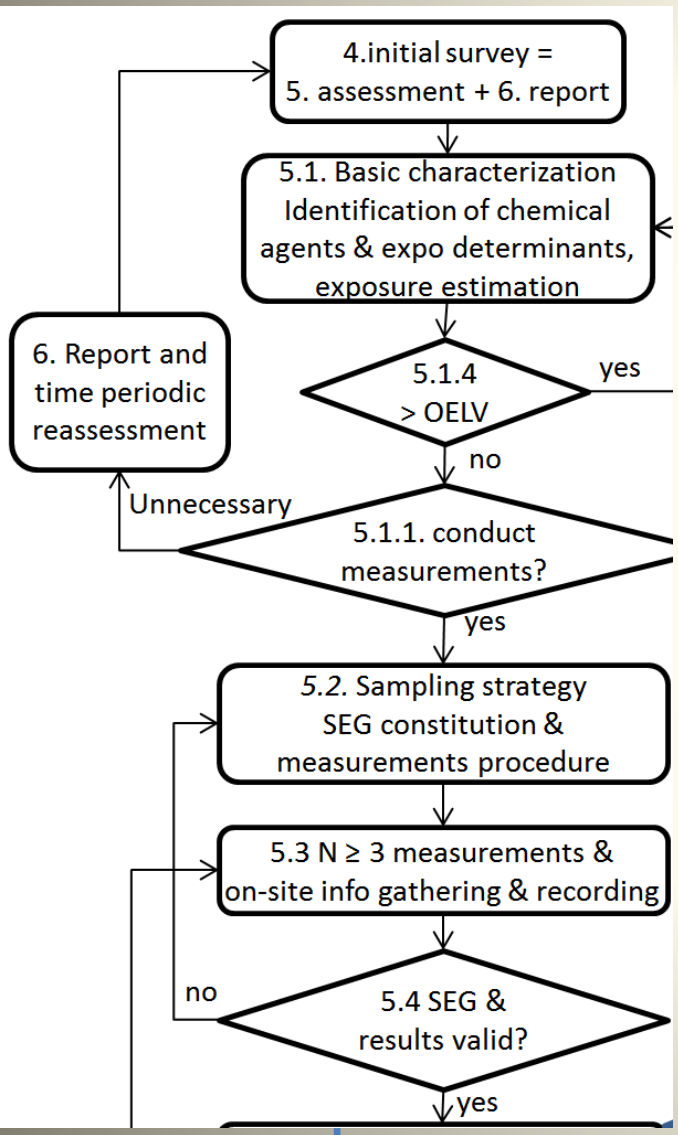
Comparison

Clause	689 (1995)	prEN 689 (2016)	NVvA/BOHS
0->4	Intro/Scope/definitions/General		1
5	Exposure assessment		n.a.
5.1	Basic characterisation		n.a.
5.2	Sampling strategy		n.a
5.3	Measurements		1.2
5.4	Mixtures	Validity (SEG/results)	
5.5	Compliance: Yes, no and in between -> annexes C & D	Screening test 3-5 & Group compliance 6+ Annex F	3.3 Screenings test 3.4 Group compliance 3.6 Individual compliance
quality	Graphical and S-W Annex D.2	Annex E	3.2/5 Validity of SEG, B&W differences
LoQ	-	Annex H 5.5.2	3.7 values <LoQ
7. periodic reassess-ment	Annex E, F	7 + Annex I	

5.5 **Comparison of results with OELVs**

test	689 (1995)	prEN 689 (2016)	NVvA-BOHS (3)
screening	n.a.	3 samples <0,1 OELV 4 samples <0,15 OELV 5 samples <0,2 OELV	3 samples <0,1 OELV
confidence	Annex D Maximum Likelihood (<50%)	6+ samples $C_{95\%,70\%}$<OELV	6+ samples , several workers $C_{95\%,70\%}$<OELV
Between Worker differences	n.a.	(5.4. + Annex E)	ANOVA test on individual outside SEG If, so ↓
Within Worker compliance	n.a.	n.a	Individual compliance (method not really understood)

Screenings test 5.5.2



Decision 5.5.2	Compliance	Non-compliance	No decision
Sample size N	All outcome < f*OELV	k > OEL	Otherwise: additional measurements
3	f=0.1	≥ 1	
4	f=0.15		
5	f=0.2		

Workshop question (1)

What would you decide if:

- Three measurements 0.09; 0.08 and 0.09 mg/m^3
- Filling bags
- CV_t=30%
- OELV: 1 mg/m^3
- 5.5.2. Compliance?
- GSD=1.07 !
- 5.4. Quality. Is this normal for this exposure profile?
- If no, then validate SEG & measurements before compliance testing

Decision 5.5.2	Compliance	Non-compliance	No decision
Sample size N	All outcome < f*OELV	k > OEL	Otherwise: additional measurements
3	f=0.1	≥ 1	
4	f=0.15		
5	f=0.2		

Workshop question (2)

What would you decide if:

- Three solvent measurements 0.01; 0.3 and 10 ppm
- Painting outside
- OELV: 100 ppm

- 5.5.2. Compliance?

Decision 5.5.2	Compliance	Non-compliance	No decision
Sample size N	All outcome < f*OELV	k > OEL	Otherwise: additional measurements
3	f=0.1	≥ 1	
4	f=0.15		
5	f=0.2		

- GSD=31 ! (3 orders of magnitude)
- 5.4. Quality. Normal for this exposure profile?

Screening test 5.5.2. evidence based?

Yes, if exposure variability GSD≤3 !

Only in combination with a sound basic characterization (5.1), sampling strategy (5.2), measurement plan (5.3) and validation (5.4).

Decision 5.5.2	Compliance	Non-compliance	No decision
Sample size N	All outcome < f*OELV	k > OEL	Otherwise: additional measurements
3	f=0.1	≥ 1	
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5	f=0.2		

Workshop question (3)

What would you decide if:

- ≥ 6 measurement in a clean room
- GSD=2
- CV_t=5%
- $C_{95\%,70\%}$<OELV

prEN 689 (2016) 5.5.3

Compliance	Non-compliance
$C_{95,70\%} \leq OELV$	$C_{95,70\%} > OELV$

- 5.5.3. Compliance?
- 5.4. Quality? Is a GSD=2 normal for a clean room?
- If no, then validate SEG & measurements before compliance testing

Workshop question (4)

What would you decide if:

- ≥ 6 measurement outdoor painter, solvent exposure
- GSD=1.4
- CV_t=5%
- $C_{95\%,70\%}$<OELV

prEN 689 (2016) 5.5.3

Compliance	Non-compliance
$C_{95,70\%} \leq$ OELV	$C_{95,70\%} >$ OELV

- 5.5.3. Compliance?
- 5.4. Quality? Is a GSD=1.4 typical for a painter?
- If no, then validate SEG & measurements before compliance testing

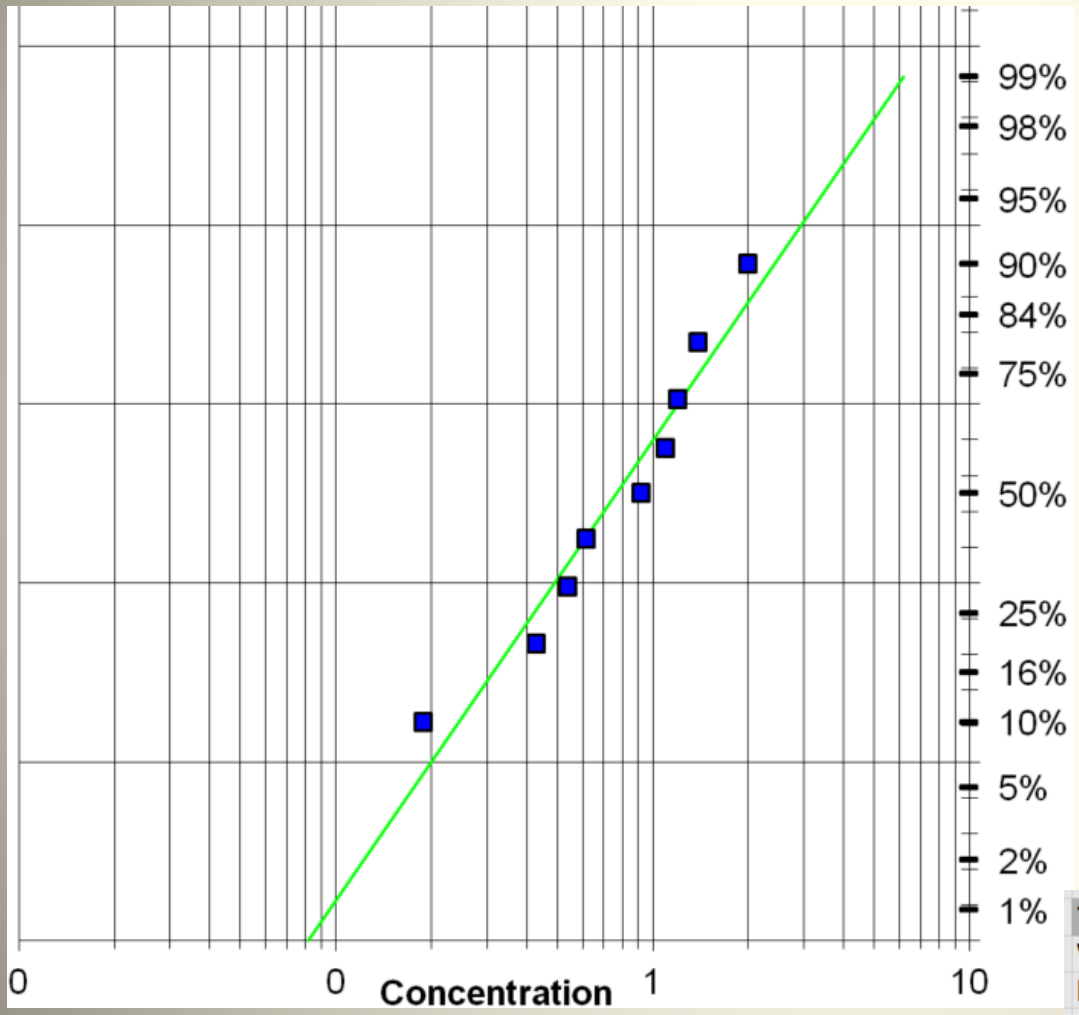
Exposure variability

- Current prEN689 (Annex E) and AIHA IH_Stat condemns GSD>3 as "process out of control or poorly defined SEGs".
- Low GSD's quite often caused by:
  - sampling on one or a few consecutive days within a SEG.
  - small sample size, underestimating the GSD on the average
  - sloppy handling of non-detects
  - autocorrelation (one outcome determines the next)
  - 2-decades analytical detection methods (like gravimetric dust and inorganic acid sampling)
  - EM in stead of PAS
- Use prEN 689 5.4. !

Exposure variability

- ~~Current prEN689 and AIHA IH_Stat condemns GSD>3 as "process out of control or poorly defined SEGs".~~
- Compare your GSD with the typical variability for the exposure profile tested:
  - measurement series performed before
  - GSDs reported in large databases like the German MEGA and the French Colchis
  - Read across with comparable substances and workplaces
  - Modeling
  - Physical-Chemical properties
  - ….

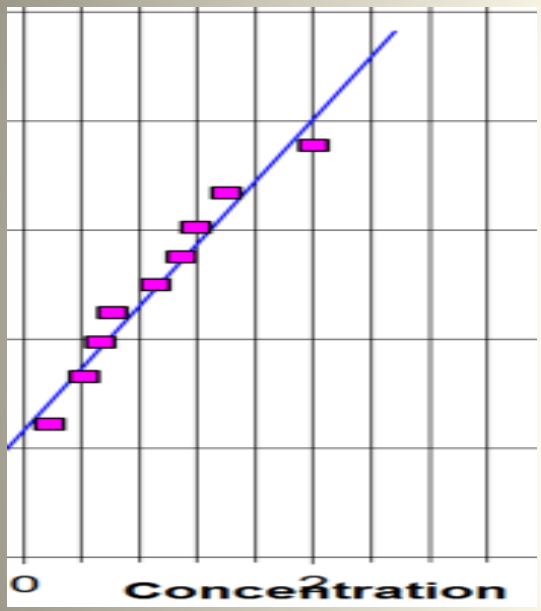
Deviation from lognormal

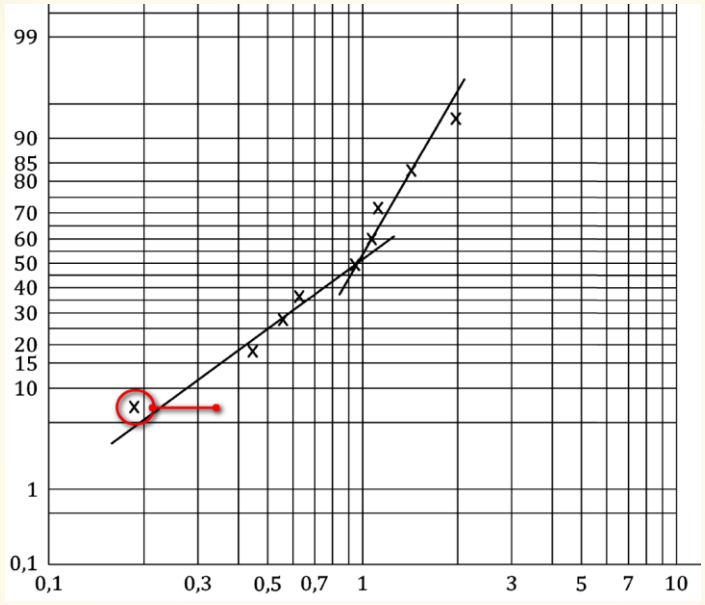


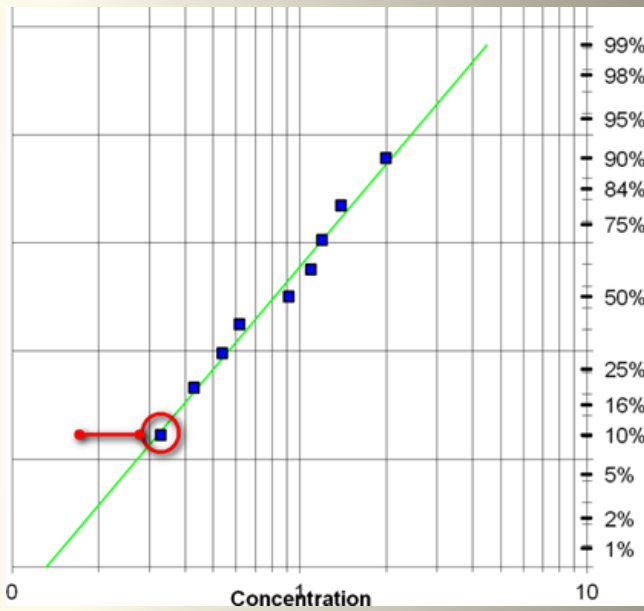
Example
Figure E.2 Annex E of the Standard.
IH-Stat plot
N=9
GSD=2.045

TEST FOR DISTRIBUTION FIT	
W-test of logtransformed data (LN)	0.958
Lognormal (a = 0.05)?	Yes
W-test of data	0.964
Normal (a = 0.05)?	Yes

What to choose?







CVt Normal?

2 lognormal distributions?

Or one inaccurate low value?

Not the statistics, but the exposure determinants (5.1 thru 5.3) will tell!

Some workers deviates

If some workers deviate within a group individual controls may be more effective

Solution

- BOHS-NVvA guidance

prEN 689/NVvA-BOHS testing schemes

Form SEG

Improve technical controls

Take 3,4,5 samples

All < 0.1 x OELV?

Yes

No

Any > OELV?

Yes

No

5.5.2 Screening test

6+ samples→ $C_{95,75\%}$

Complian ce ?

No

5.5.3 Group Compliance

Yes

Apply ANOVA & B&W test

Between-worker dif-ferences?

No

Stage 2 B&W differences

Yes

Apply individual test

Compliance ?

No

3 Individual Compliance

Yes

Routine monitoring (reassessment)

Remarks from NVvA mirror session 150919

Unclear (Introduction):

- **why** using this European Standard
- to **whom** it is addressed
- The **additional value** when used

Definition (clause 3):

- What is **Compliance** ?

No start/ignite

Important issue

Compliance decision

- The screenings test 5.5.2. and the 1995 689 annex D.3 both have a no-decision range (colour orange) where additional (periodic) measurements may confirm if there is compliance or not.
- The 6+ compliance test 5.5.3. is Yes/No only, with periodic resampling in all situations

Decision 5.5.2	Compliance	Non-compliance	No decision
Sample size N	All outcome < f*OELV	k > OEL	Otherwise: additional measurements
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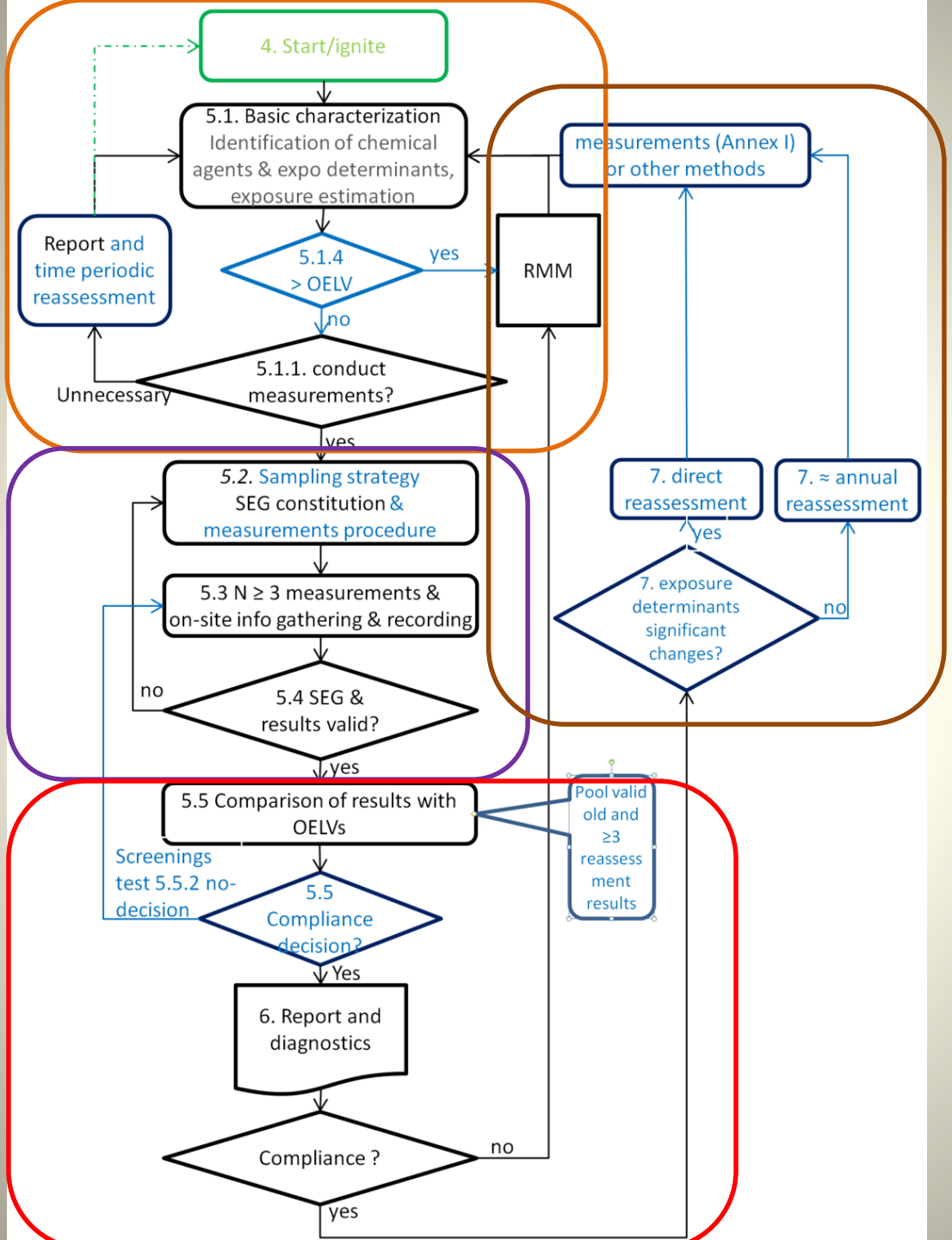
5	f=0.2		

EN 689 (1995) Annex D.3

Compliance	Non-compliance	No decision
P(C>OELV)≤.1%	P(C>OELV)>5%	Otherwise: additional measurements



Green is somehow lacking in the standard

Blue parts in the Figure 1 are in the text but not in the current figure

Next steps 2016

- the CEN enquiry is now scheduled from 2016-06-02 to 2016-09-02 (3 months).
- During this period, each national bodies will organize a national consultation.
- The next WG 1 meeting will be held on 19th and 20th September 2016 in Roma (Italy) and will be dedicated to consider national comments submitted during the CEN-Enquiry.

Who is responsible/accountable for compliance testing quality?

There is no national or EU law demanding compliance testing to be sound science/evidence based, however:

- Causation and control of work-related illness# does!
- As occupational hygiene ethics
- So, we are responsible/accountable for good quality compliance testing
- prEN 689 can be a helpful an protective vehicle, especially if science/evidence does not help in the decisions