Testing compliance with OEL
BOHS/NVvA initiative

ROYAL HASKONING

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NVvA symposium 24 March 2010 session N

Veel NVvA aandacht voor blootstelling

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Nederlandse Vereniging voor Arbeidshygiëne

Nieuws

21.02.10	Nieuw gratis Blootstellingsmodel
19.01.10	Asbest veel gevaarlijker dan gedacht
21.12.09	IOHA Nieuwsbrief
01.12.09	Blootstellingsmodellen
01.12.09	REACH-conference Brussel: Presentaties
01.12.09	Concept nieuwe meetstrategie
30.11.09	NCvB: Beroepsziekten in 2008

NVvA/BOHS initiative

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Draft 26 Sept 09

www.bohs.org: 31 oct 09

Testing Compliance with Occupational Exposure Limits

CONSULTATION

This is draft guidance produced by a joint Working Party of the British Occupational Hygiene Society and Nederlandse Vereniging voor Arbeidshygiëne (the Dutch Occupational Hygiene Society). It is made available for trial and comment, but no liability is accepted by either organisation in connection with its use. Comments should be sent to nvva@arbeidshygiene.nl by 31 December 2009. Comments based on practical workplace trial are particularly welcome.

Agenda

- Introduction
  - Goal of the NVvA BOHS initiative
  - existing exposure assessment documents
  - Content
  - Approach
- Improvements on the current approach:
  - Between and within worker variance
  - Undetectables
  - Unbiased estimators in small sample series

Goal of the NVvA/BOHS document

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Trevor Ogden wrote (100317):

BOHS/NVvA request : “to develop practical guidance for their members and others. The document should focus on measurement strategies for compliance with occupational exposure limits (OELs) for chemical agents with acute and/or chronic health effects. “

- What is the additional value of the new document compared the existing documents/standards?

Why a new NVvA/BOHS document?

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Some existing exposure assessment documents
with a focus on the Netherlands and the EU

Enforcement instruction Labor Inspectorate

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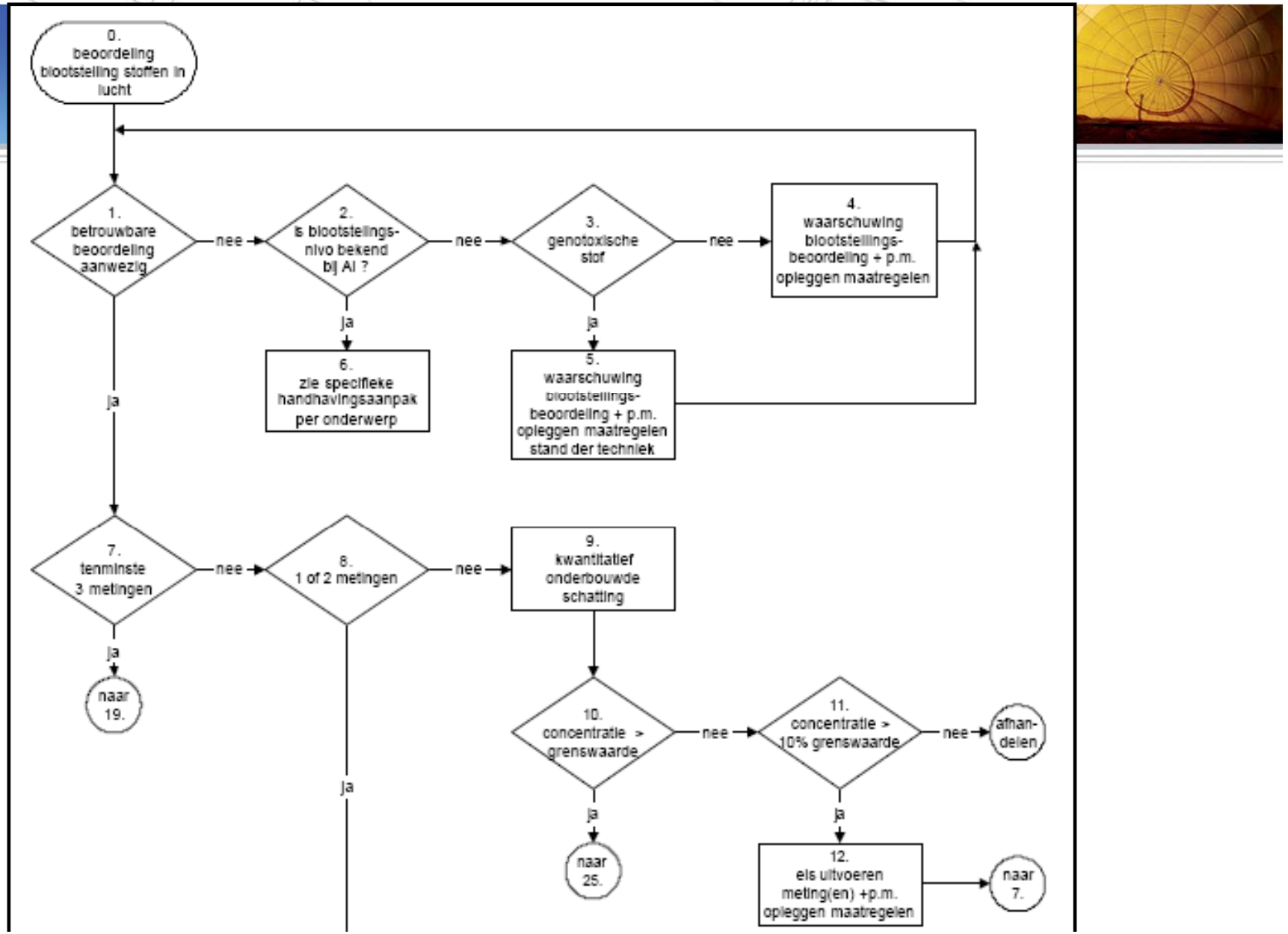
Interne instructie Arbeidsinspectie

Beoordeling van de blootstelling
aan gevaarlijke stoffen
en het
toetsen van de meetresultaten aan
luchtgrensgrenswaarden

INHOUDSOPGAVE

1. INLEIDING

Enforcement instruction Labor Inspectorate



http://www.arbokennisnet.nl/kennisdossier_gevaarlijke_stoffen.html

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Arbodossier (Arboprofessional)	**Dossiers**	**Samenvatting Preventiemedewerkers**
Algemeen stoffenbeleid (arbeidshygiënische strategie)	Dossier	Samenvatting Opslag Samenvatting Etikettering Samenvatting Transport
Kankerverwekkende, mutagene en teratogene stoffen	Dossier	Samenvatting Kankerverwekkende_stoffen Samenvatting Mutagene_stoffen Samenvatting Reprotoxische_stoffen
Irriterende en sensibiliserende stoffen	Dossier	Samenvatting irriterende stoffen Samenvatting Sensibiliserende stoffen
Asbest	Dossier	Samenvatting
Vluchtige organische stoffen	Dossier	Samenvatting
Ontvlambare en ontplofbare stoffen	Dossier	Samenvatting ontvlambare stoffen Samenvatting ontplofbare stoffen

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Dossier Algemeen Stoffenbeleid

Opgesteld door:
Jodokus Diemel
Jaap Maas
Helger Siegert
Peter Wielaard

12 maart 2009

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3.1 Risico-inventarisatie
3.1.1 Inventarisatie in de praktijk
3.1.2 Grenswaarden
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3.1.2.2 MAC-waarden: deels vervallen
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EU/ CEN 689 Sampling Strategy: outdated since 2005

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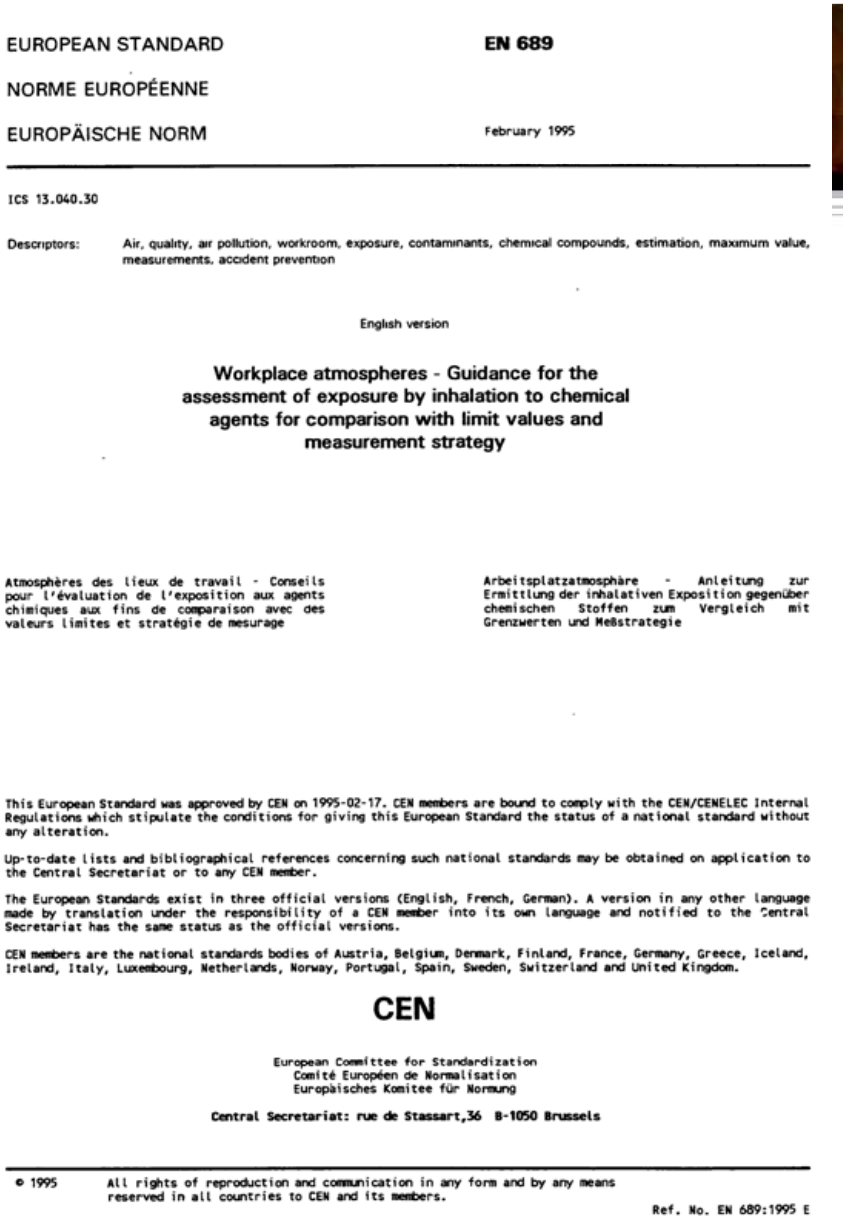
Quantitative assessment

- Chapters 5.2 through 6
- Eight annexes A - G (informative, not part of the standard)



EUROPEAN STANDARD **EN 689**

NORME EUROPÉENNE

EUROPÄISCHE NORM February 1995

ICS 13.040.30

Descriptors: Air, quality, air pollution, workroom, exposure, contaminants, chemical compounds, estimation, maximum value, measurements, accident prevention

English version

Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy

Atmosphères des lieux de travail - Conseils pour l'évaluation de l'exposition aux agents chimiques aux fins de comparaison avec des valeurs limites et stratégie de mesurage

Arbeitsplatzatmosphäre - Anleitung zur Ermittlung der inhalativen Exposition gegenüber chemischen Stoffen zum Vergleich mit Grenzwerten und Meßstrategie

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Ref. No. EN 689:1995 E

EU Chemicals at work directive 98/24

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Dok. 2261-00-00-EN final

INSTITUTO NACIONAL DE SEGURIDAD E HIGIENE EN EL TRABAJO

PRACTICAL GUIDELINES

OF A NON-BINDING NATURE ON THE PROTECTION OF THE HEALTH AND SAFETY OF WORKERS FROM THE RISKS RELATED TO CHEMICAL AGENTS AT WORK

(Articles 3, 4, 5 and 6, and Annex II, section 1, of Directive 98/24/EC)

ANNEX 2: Simplified risk assessment methodologies

ANNEX 3: Application examples of the principles for prevention and specific measures in two industrial processes

ANNEX 4: Quantitative evaluation of exposure to chemical agents

ANNEX 5: Measurement methods for chemical agents in the list of indicative limit values in Directive 2000/39/EC

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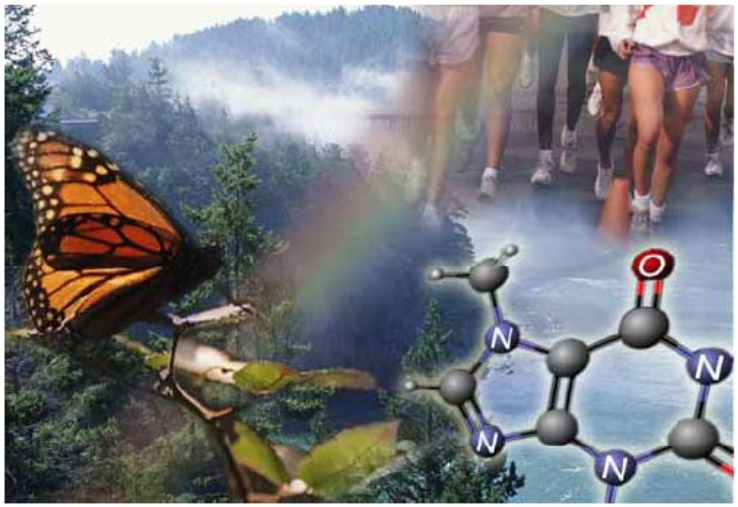
ECHA

Guidance on information requirements and chemical safety assessment

Chapter R.14: Occupational Exposure Estimation



December 2009
(version 2 Rev.:1.1)

Guidance for the implementation of REACH

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ECHA

Guidance on information requirements and chemical safety assessment

Chapter R.13: Risk management measures and operational conditions

May 2008
(version 1.1)

Guidance for the implementation of REACH

Content of the current BOHS/NVvA draft

Testing compliance with OEL

- Chapter 1. Conducting a survey for exposure evaluation
- Chapter 2. The problem of variability
- Chapter 3. Recommended method of measuring compliance
- Chapter 4. Shortcuts and their limitations.
- Appendix 1. Reminder of statistical concepts
- Appendix 2. Calculating between-worker and between-shift variances and group and individual exceedances

Ch. 3 Recommended method of testing compliance

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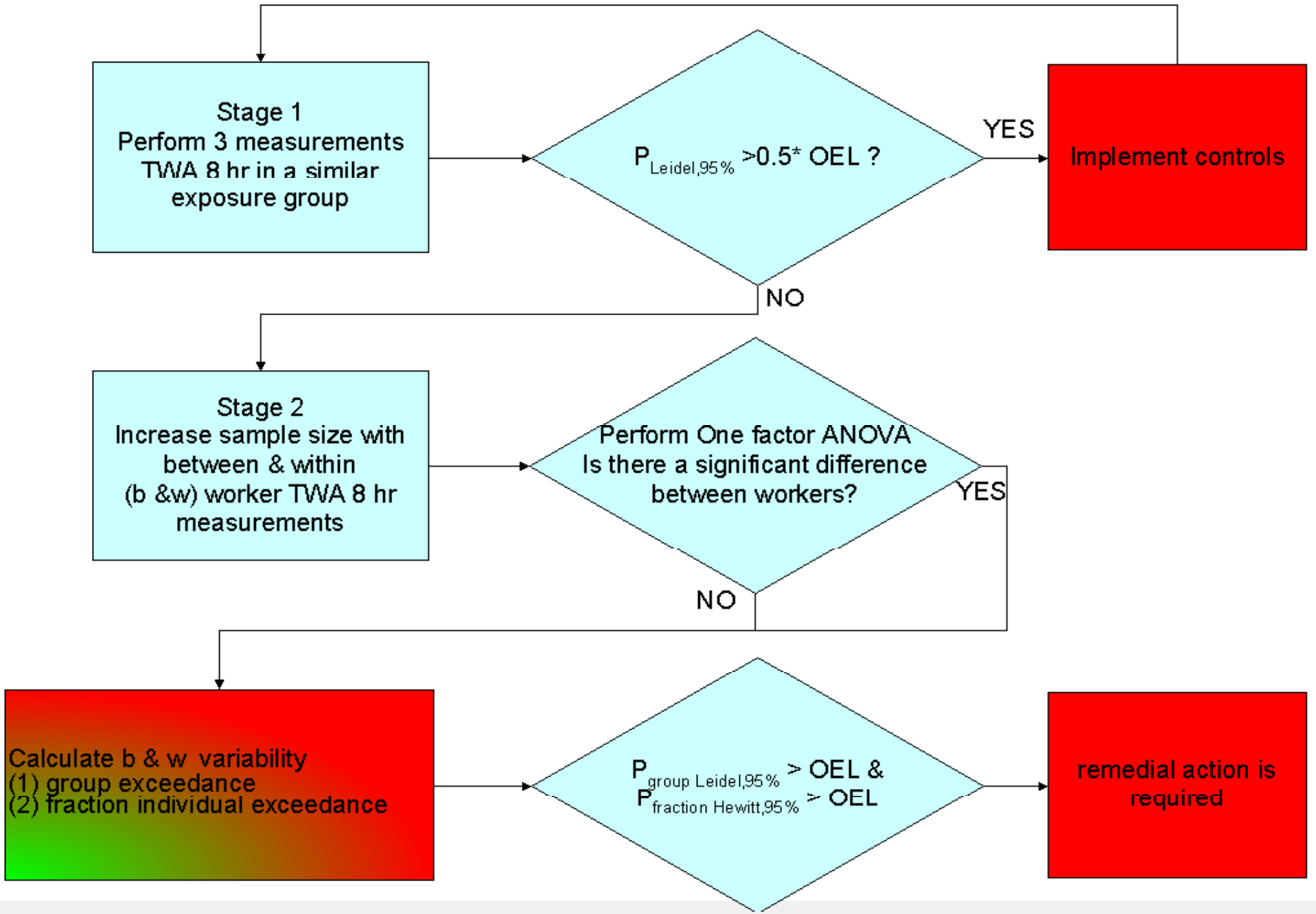
- Stage 1. Three representative samples are taken and their maximum likelihood 95th percentile is compared with half the occupational exposure limit.
- Stage 2. A full monitoring program is used to estimate the within-worker and between-worker variations, and to use these to estimate
  - (1) the percentage of exposures of the whole SEG which would lie above the OEL, and
  - (2) the percentage of the measured workers that would have more than 5% of their exposures above the OEL.

Proposed NVvA BOHS scheme for compliance testing with measurements (Draft Oct 2009)

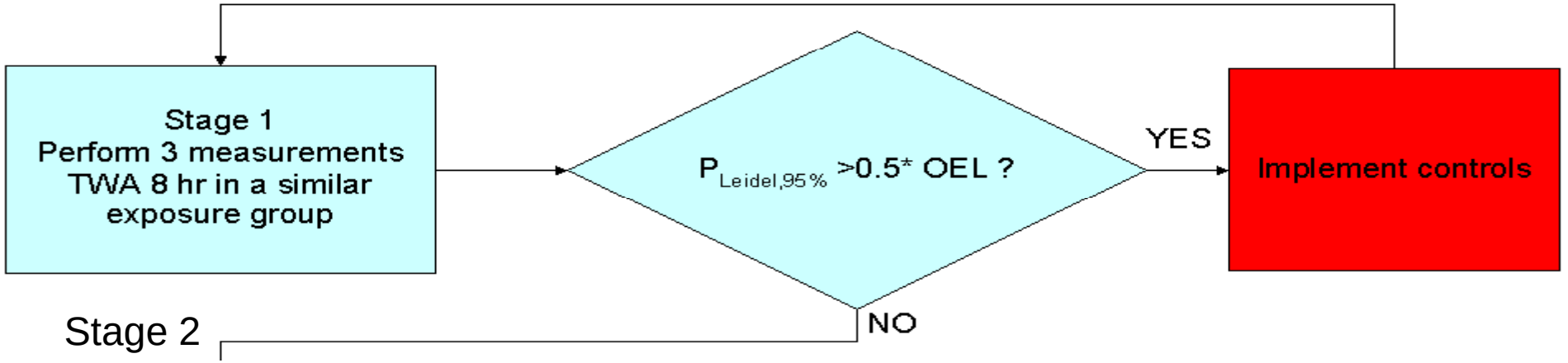


Implicit goals of the NVvA/BOHS document

- To provide enterprises, industrial hygienists and law enforcers in Europe an updated and improved standard in compliance testing now CEN 689 (1995) is more than 10 years old and outdated.
- To gain acceptance for the stage 2 compliance testing of group and individual exceedance, using the within- and between-worker variances.
- A link to REACH ART (mentioned yesterday)

Improvements for stage 1

Proposed NVvA BOHS scheme for compliance testing with measurements (Draft Oct 2009)



- Include qualitative (RMM, OC) and semi quantitative (modeling, surrogate, historical) decision tree (Stage 0) to exclude obvious compliance, to prevent unnecessary measurements and to focus on worst case SEG.
- N=3 measurements is arbitrary/small
- Introduce a stage 1 compliance level (0,1 * OEL?)
- $P_{Leidel,95\%}$ >0.5* OEL: a biased and primitieve statistic.
- $P_{Wilks,95\%}$ > OEL: an unbiased compliance statistic for every N.

Stage 2 exposure assessment

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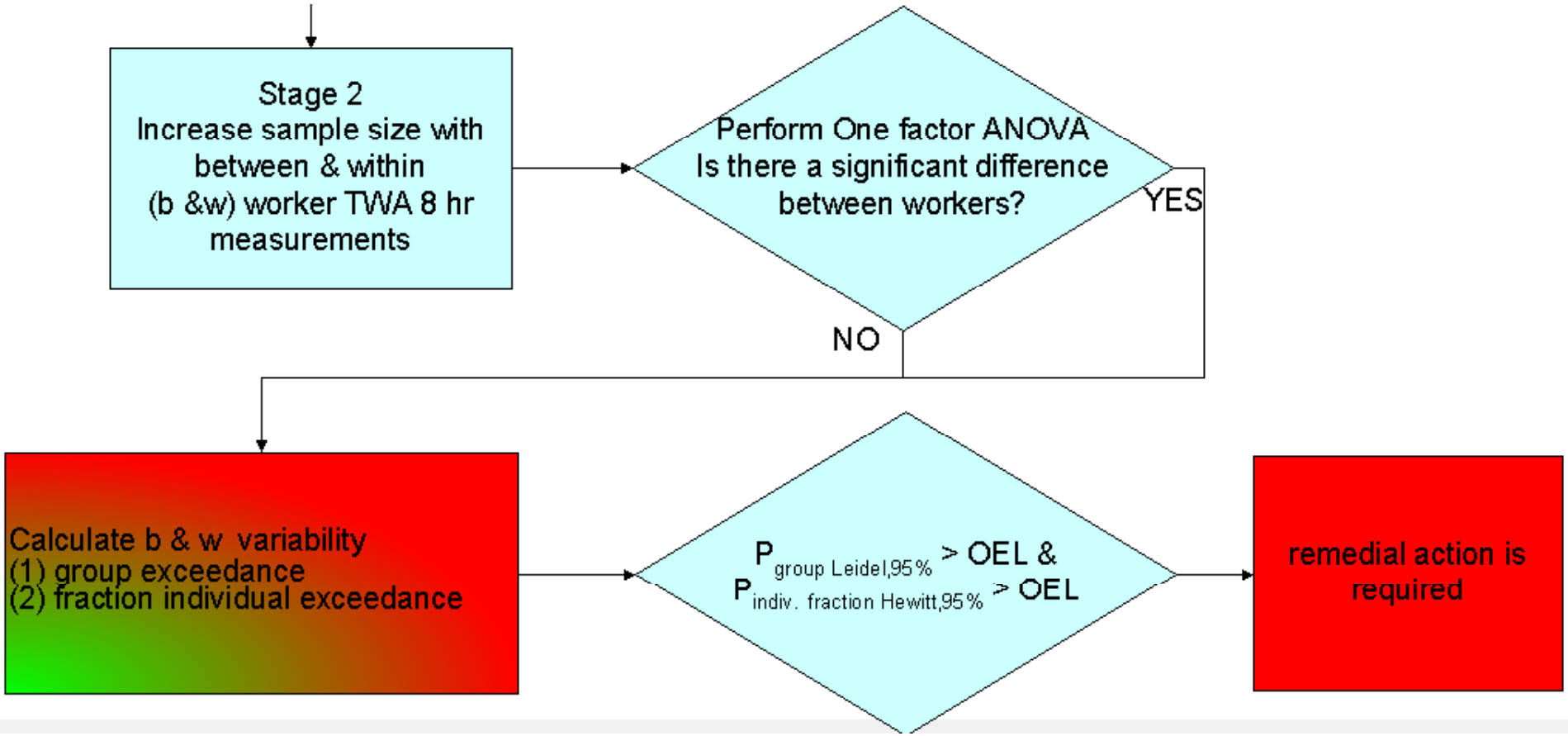

Historical context stage 2 individual testing

- 1981: Every worker is unique! OH-Physician view
- 1985: Introduction HEG/SEG concept in many chemical companies
- 1993: Workers exposure differ in SEGs. (Rappaport/Kromhout).
- Dispute 1995 American Industrial Hygiene Association J.

SEG's with BW ratio>2 and their confidence interval!

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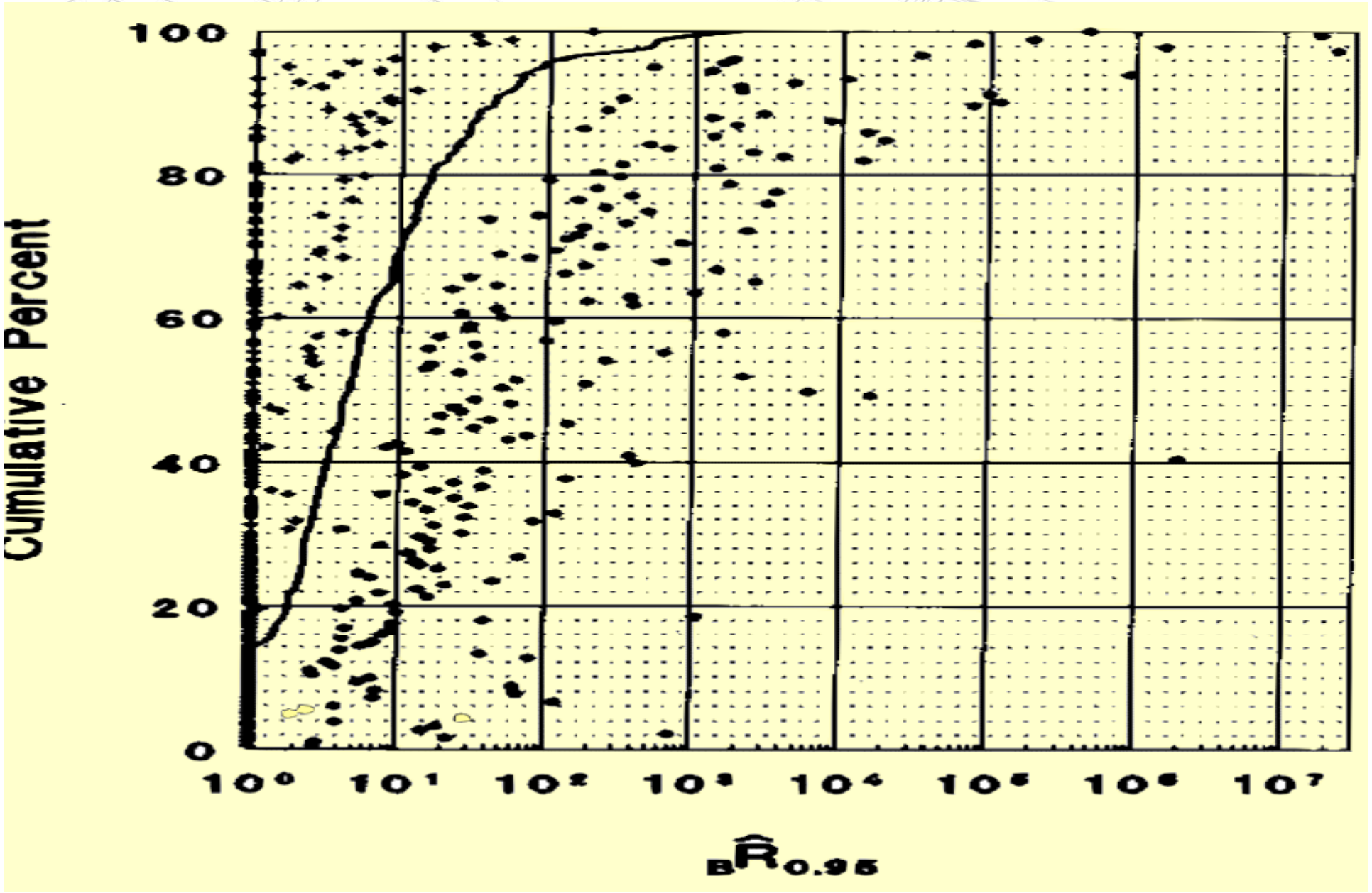

Historical context stage 2 individual testing

- Rappaport/Kromhout: 85% of SEG have BW ratio>2 .
- Scheffers/Rappaport :15-30% significant BW ratio>1
- Scheffers: an additional 5% significant BW due to change.

Conclusion:

Workers exposure within a SEG may or may not origin from the same exposure distribution.

Test if individuals deviate using single factor ANOVA, before running BW models

T8 =(LN(T4)-(T23+1.645*T21))/T17

	L	M	N	O	P	Q	R	S	T
4	Joe	Chloe	Irene	Dean				OEL	0.8
5	-1.34707	-1.714798	-1.96611	-0.69315				parameter 1	1.3113016
6	-0.51083	-0.400478	-0.69315	-0.40048				fraction 1	0.094878
7	-1.05485	-0.813015	-1.12445	-0.79851					
8	-0.36122	-0.436034	-0.88302	-0.91629				parameter 2	-0.9056299
9	-0.27444	-0.083382	-0.46204	-0.18633					
10	-0.5993	-0.743888	-1.19942	-1.17118					

Anova: Single Factor

16						sb2	0.02021
17	SUMMARY					sb	0.142162
18	*Groups*	*Count*	*Sum*	*Average*	*Variance*		
19	Column 1	6	-7.1277	-1.18795	0.2043		
20	Column 2	6	-4.14771	-0.69128	0.17719	sw2	0.2196581
21	Column 3	6	-4.19159	-0.6986	0.31682	sw	0.4686769
22	Column 4	6	-6.32819	-1.0547	0.27359		
23	Column 5	6	-4.16594	-0.69432	0.12638	mean	-0.8653709
24						s2	0.2398681
25						s	0.4897633

ANOVA

	Source of Variat	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
28	Between Gr	1.36367	4	0.34092	1.55204	0.21792	2.7587105
29	Within Gro	5.49145	25	0.21966			
30							
31	Total	6.85512	29				

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22% chance that all indivi-duals have the same exposure distribution

Comments on current stage 2

- Is not included to test if workers exposure origin from the same distributions.
- Crippled handling of undetectables, cause decrease of variability in lower side workers
- No need to test group compliance, because individual fraction is always more conservative.
- Small sample size per worker is calculated using Maximum Likelihood in stead of unbiased techniques, causing underestimation of risk.

Ethical issue in stage 2 testing

Due to chance:

- two workers in one SEG with GSD>2,5 two workers can easily differ in GMs with a factor 2 based on 6 measurements
- Small sample, individual measurements may stigmatize workers as “dirty”

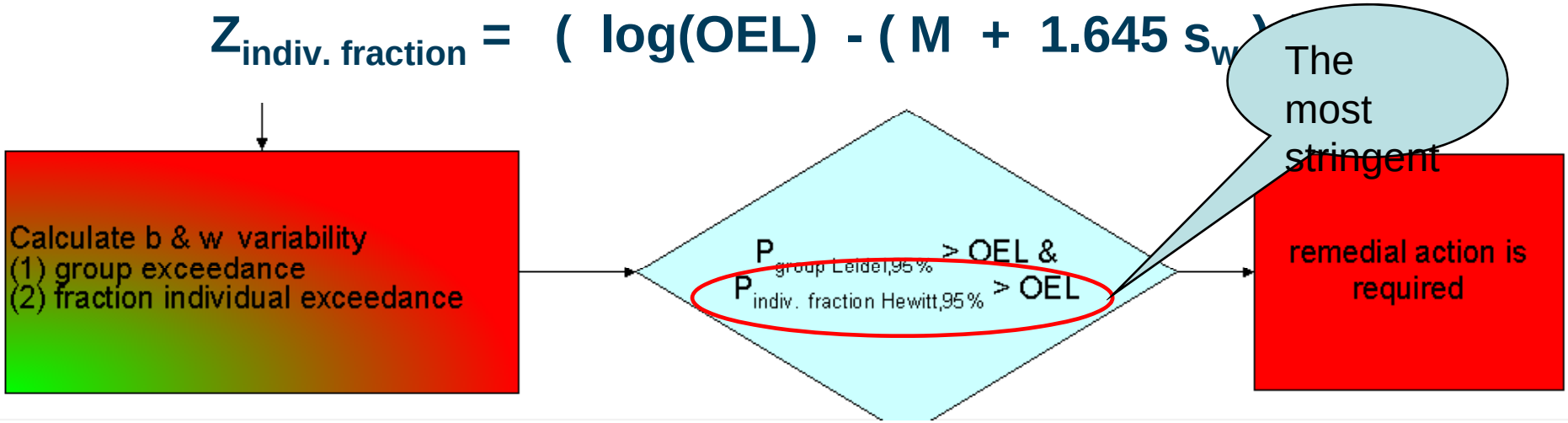
Stage 2 algorithms for group and individual exceedance

- **the group exceedance: the fraction of all exposures of the whole SEG which exceed the OEL:**

$$Z_{group,Leidel} = (\log(OEL) - M) / s$$

the individual exceedance: the fraction of all the workers in the SEG who have 95th percentiles of exposure exceeding the OEL.

$$Z_{indiv.\ fraction} = (\log(OEL) - (M + 1.645\ s_w))$$



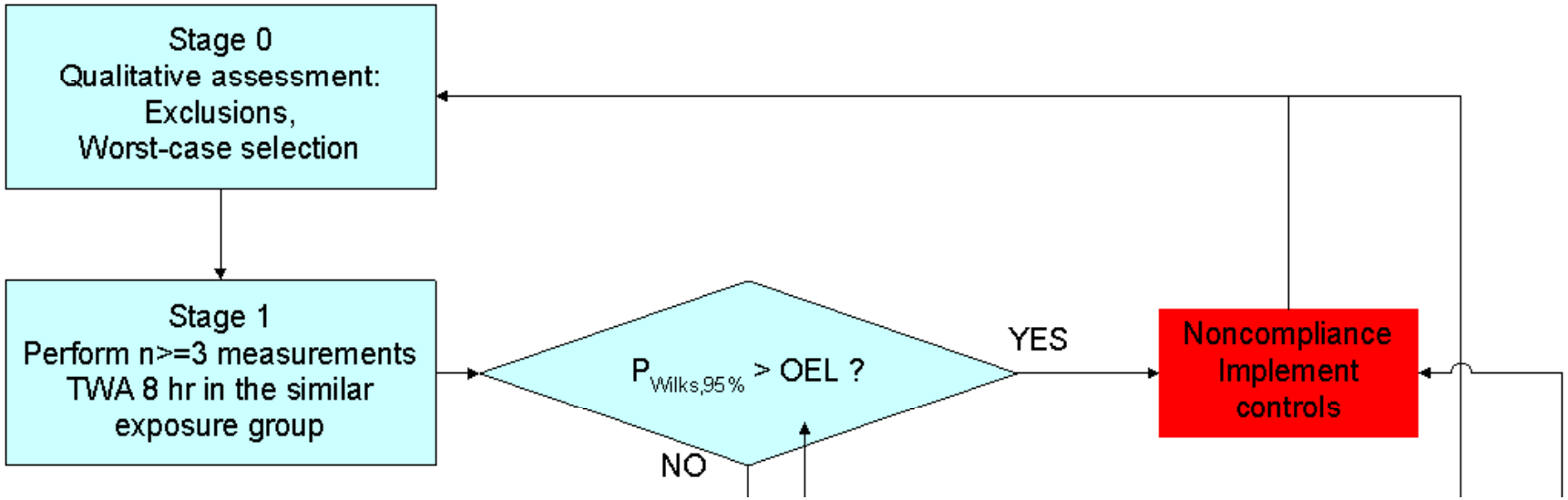
Stage 2 algorithms for group and individual exceedance (2)

Since:

- $Z_1 = (\log(OEL) - M) / s$
- $Z_2 = (\log(OEL) - (M + 1.645\, s_w) / s_b$
- $s > s_b$

- therefore $Z_1 >> Z_2$
- And noncompliance $P(Z_1) << P(Z_2)$
- the individual exceedance is the more stringed test

Alternative NVvA BOHS scheme for compliance testing with measurements (Draft March 2010)



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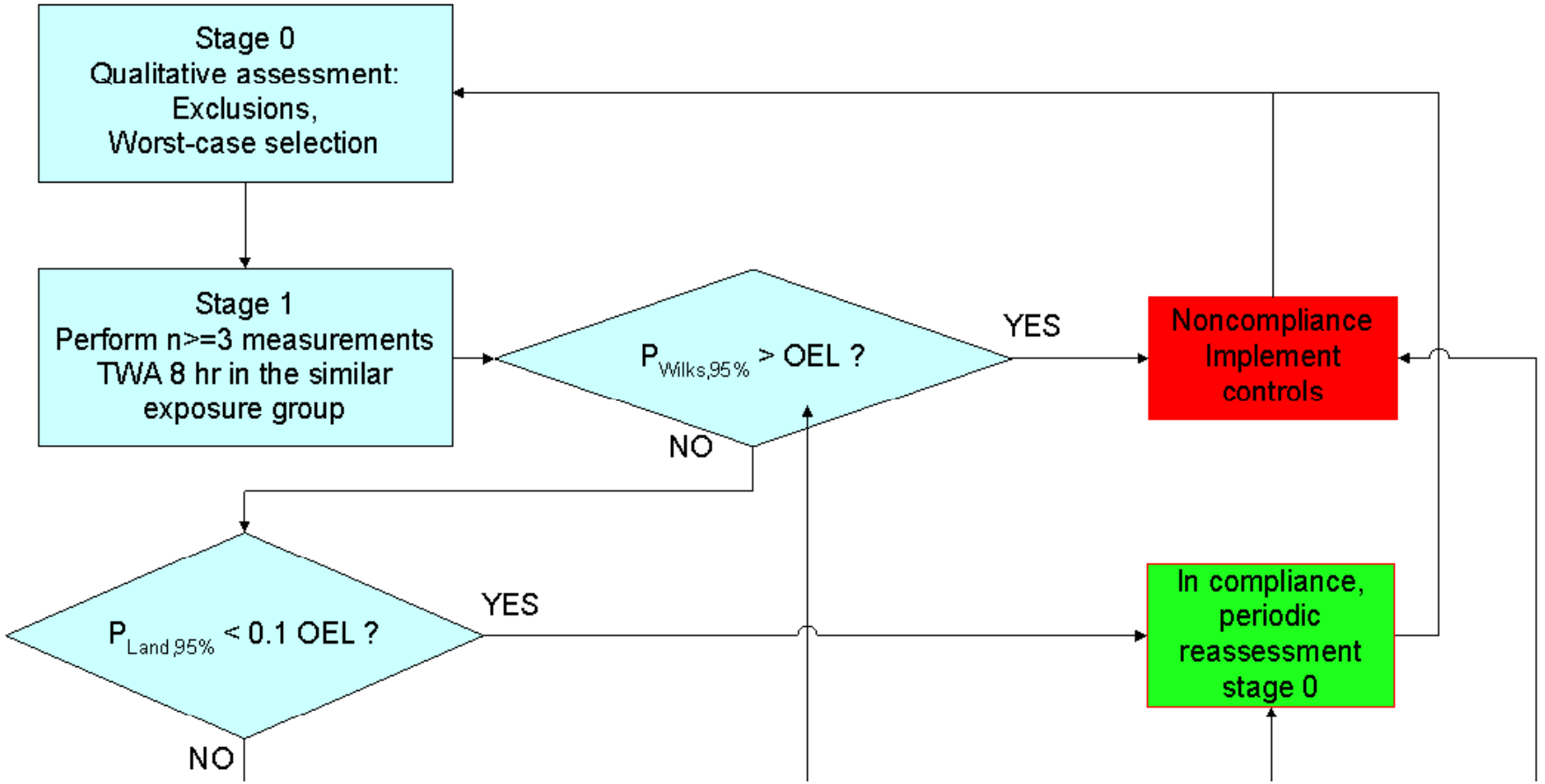

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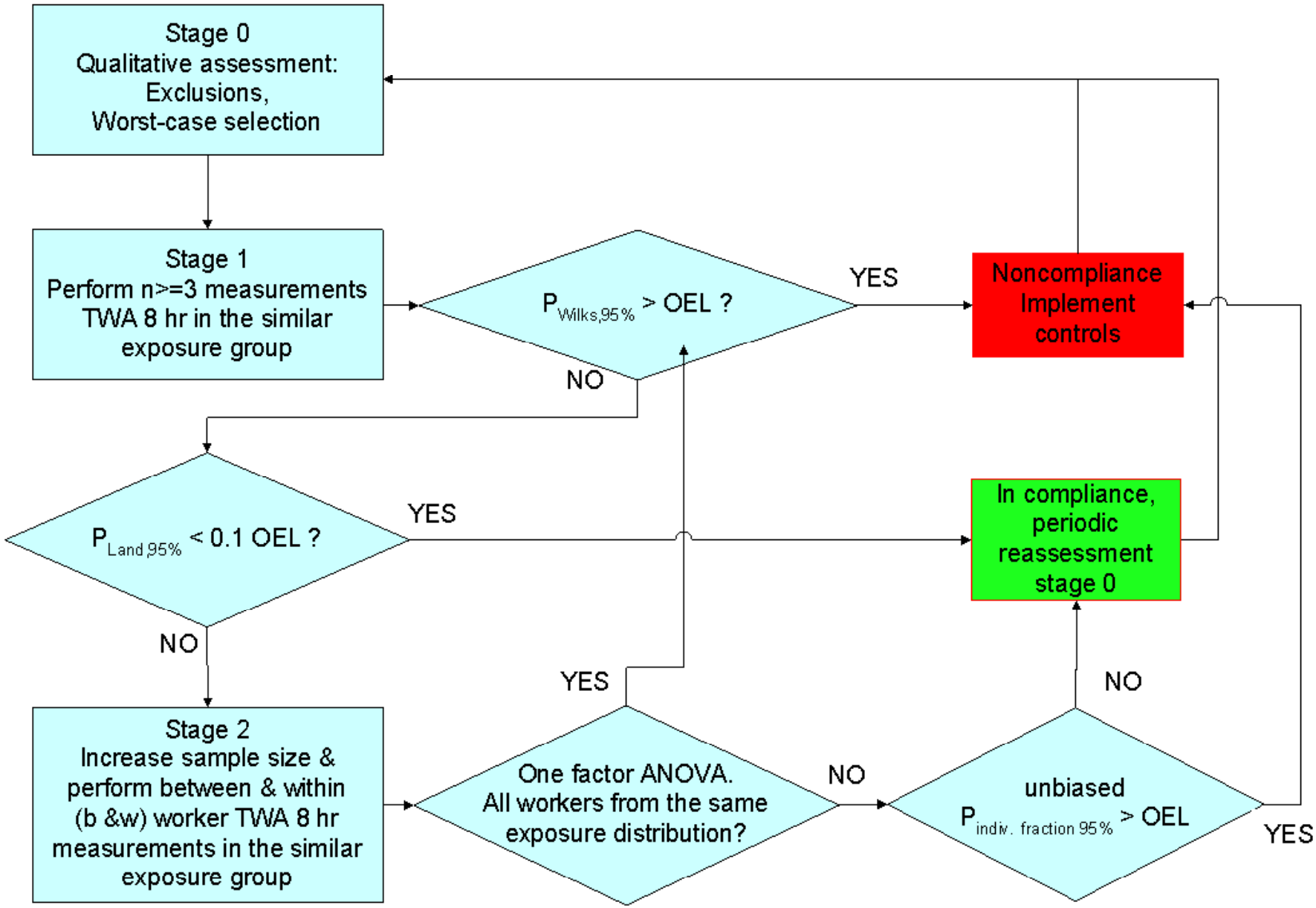

Agenda

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  - Approach
- Improvements on the current approach:
  - Between and within worker variance
  - Undetectables
  - Unbiased estimators in small sample series

How to handle undetectables

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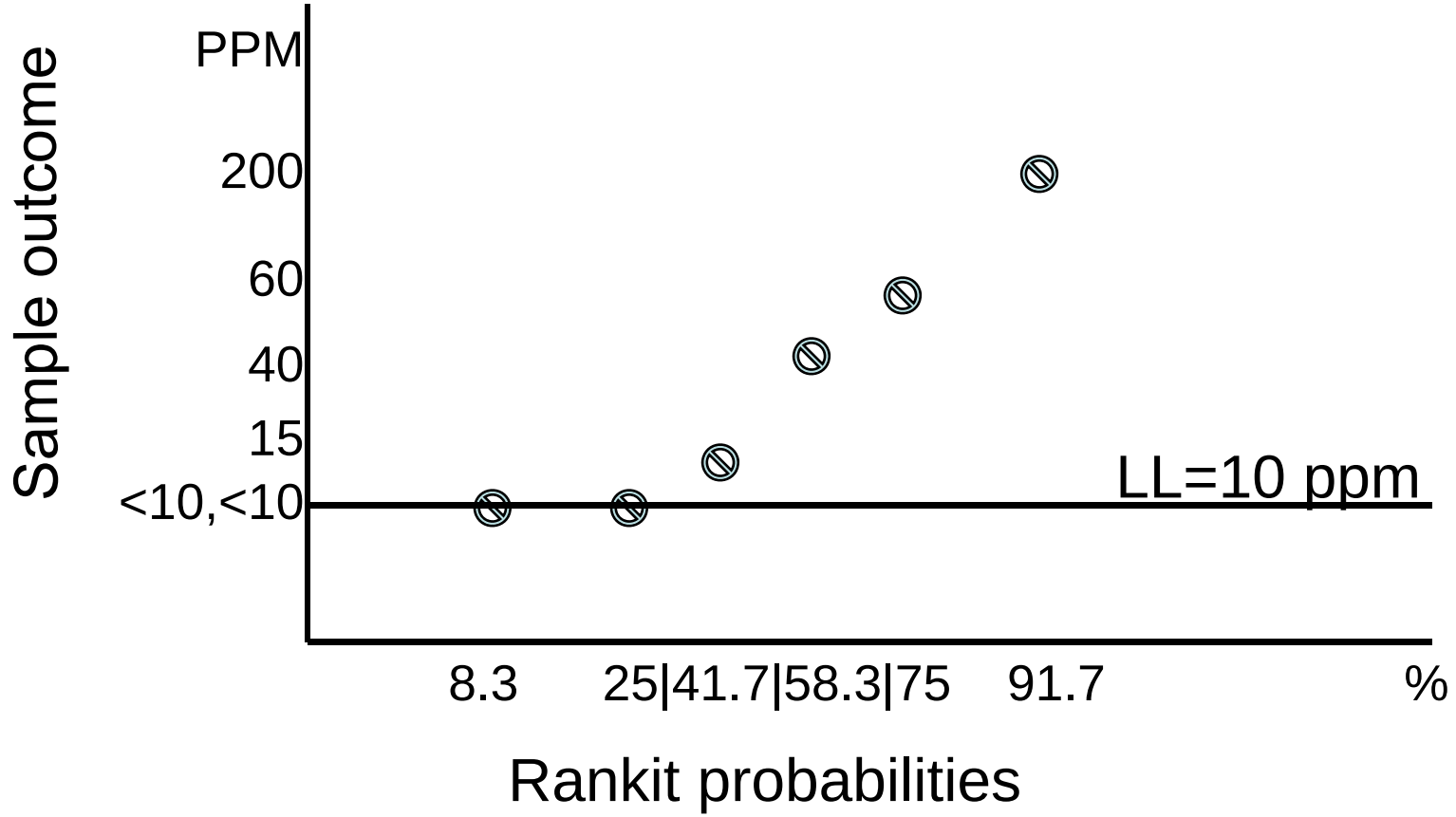
- Ogden.Handling results below the level of detection.ann occ hyg.jan2010 p1-2.pdf
- Helsel.Incorporating Nondetects in Science.Ann Occup Hyg.dec2009.pp.1-6.pdf
- Flynn.Analysis of censored exposure data by the Shapiro-Wilk W statistic.Ann. Occup. Hyg oct2009.pp 1-9.pdf

Lognormal propability plot of exposure distribution with undetectables