Risk Assessment in Control Banding

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ERAM – Exposure Risk Assessment and Management

A new name for a proven process? Why Control Banding now?

- IH's losing the preferential status for exposure assessment
- IH's perceived as 'pump hangers' because we don't characterize the 'risk' associated with exposure control
- We need to re-invent ourselves to our clients as "Exposure Risk Assessors and Risk Managers"

We need to 'speak the language' of the decision-makers ($$$$$)

- We need to talk about risk management controls in terms of "risk"
  - Risk relative to non-compliance with OELs
  - Risk relative to known toxicology without OELs
  - Risk of compliance with OELs
- How do we do that today?
  - We rarely speak in terms of relevant risks (maybe only 'compliance')
- We are not making ourselves RELEVANT

Question!

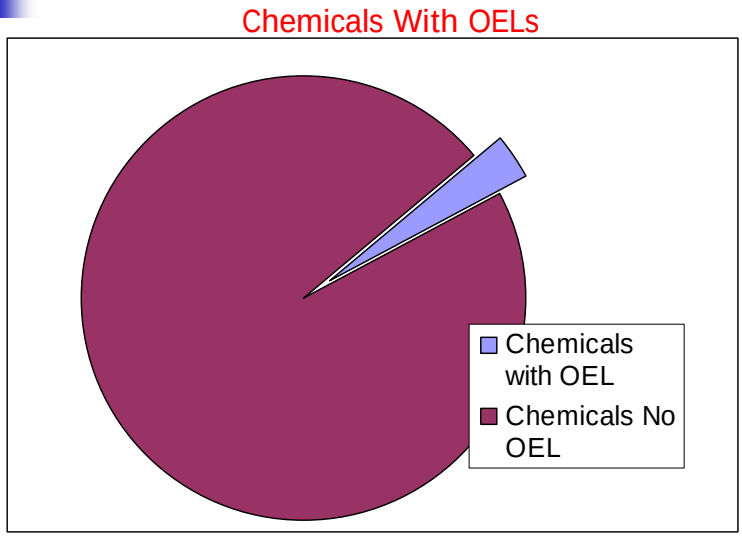
- Just how irrelevant are Industrial Hygienists in ERAM ?

The landscape seems bare!

- ~21,000,000 commercially available chemicals
- 107,067 REACH* registrations (1-3-11) for >1000 tons production volume or those of high concern
- But…only ~ 500 PELs, ~ 650 RELs, ~ 125 WEELs, ~ 650 TLVs

**REACH – Registration, Evaluation, Authorization, and Restriction of Chemicals*

But, without OELs, how do we improve our position?



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"You can't always get what you want, but if you try some times you might find, you'll get what you need" – Mick Jaeger

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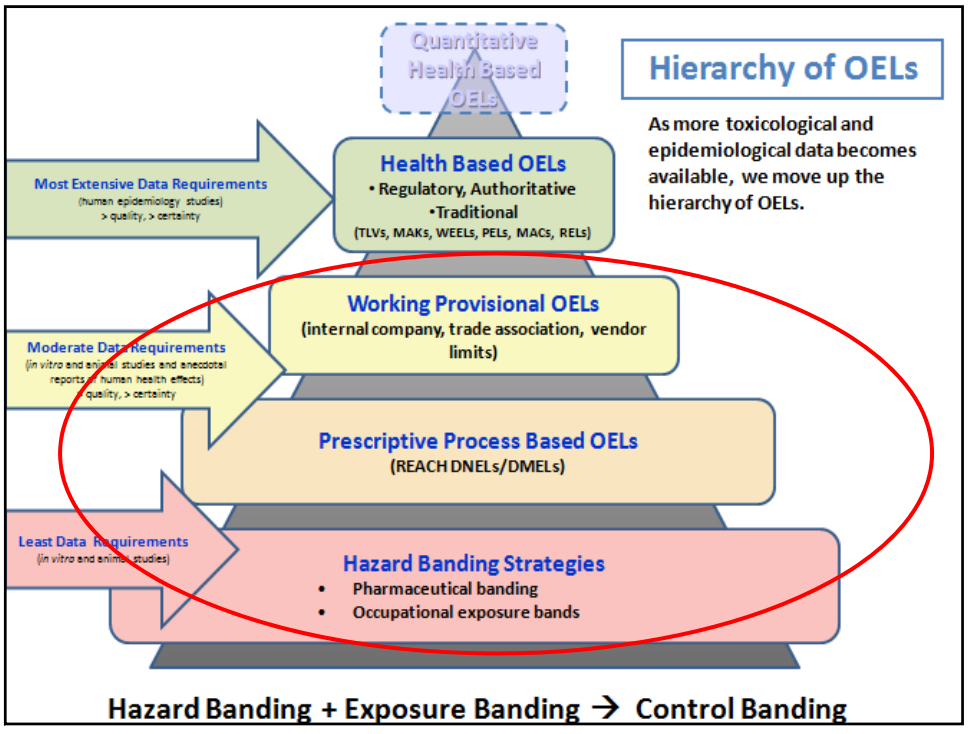
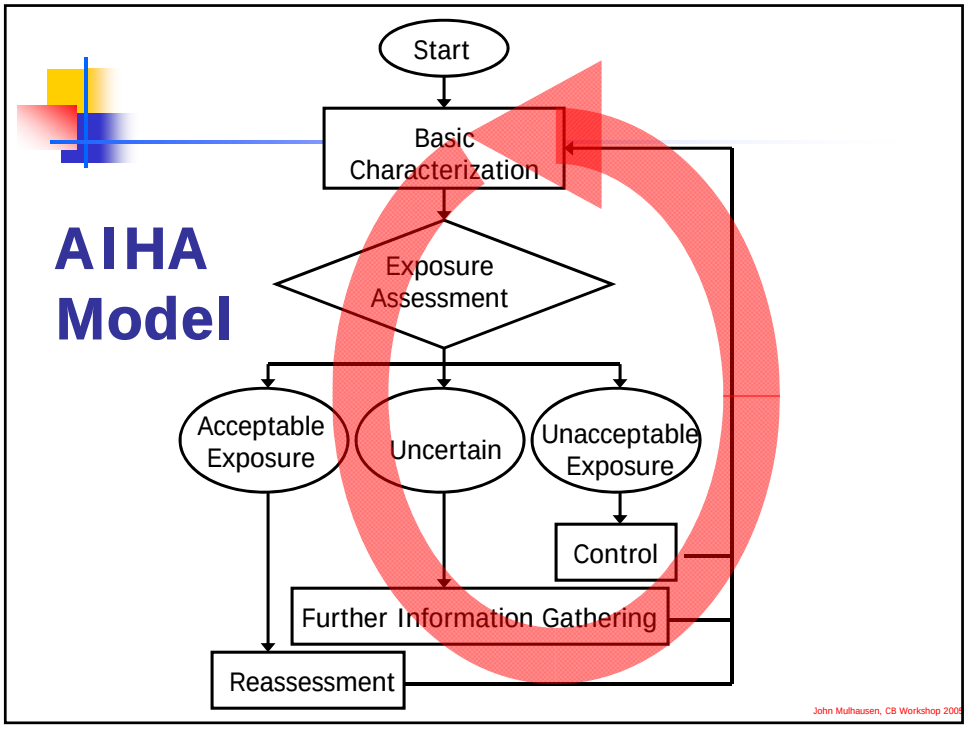


. . . . . .Working OELs

- **Occupational Exposure Banding** provides a mechanism for the evaluation of hazard and risk to offset the misconceptions by employers and workers that a substance must be non-toxic if there is not an OEL!

Integration of Control Banding Concepts into Exposure Risk Management System



Control Banding Useful?

Control banding concepts offer a significant opportunity to improve exposure assessment efficiency and effectiveness **if . . .**

integrated into a tiered, continuous improvement approach to exposure risk assessment and management.

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COSHH Essentials

HEALTH HAZARD	+	EXPOSURE POTENTIAL	→	GENERIC RISK ASSESSMENT	→	CONTROL APPROACH
Substance allocated to a hazard group, using R phrases		Substance allocated a dustiness or volatility band and a band for the scale of use		Combination of health hazard and exposure potential factors determine desired level of control		Type of approach needed to achieve adequate control

substance allocated to a hazard group or hazard band + substance/ operation allocated to an exposure predictor band → risk assessment: compare hazard band to exposure predictor band → determine control needed

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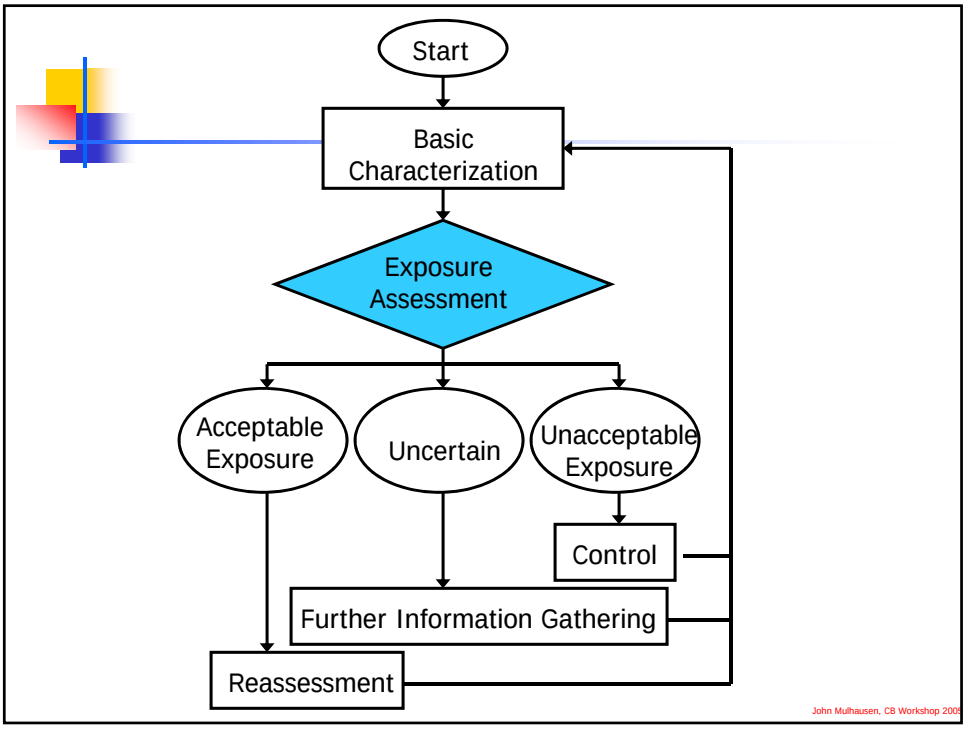

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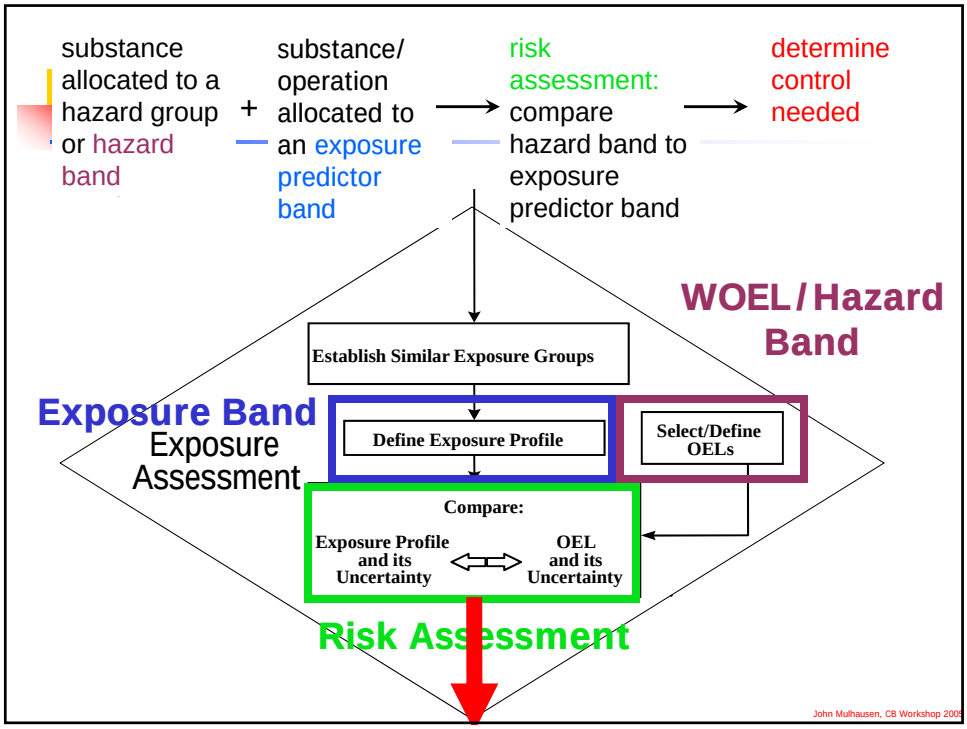
substance allocated to a hazard group or hazard band
+
substance/ operation allocated to an exposure predictor band
risk assessment: compare hazard band to exposure predictor band
determine control needed
WOEL / Hazard Band
Establish Similar Exposure Groups
Exposure Band
Exposure Assessment
Define Exposure Profile
Select/Define OELs
Compare:
Exposure Profile and its Uncertainty
OEL and its Uncertainty
Risk Assessment
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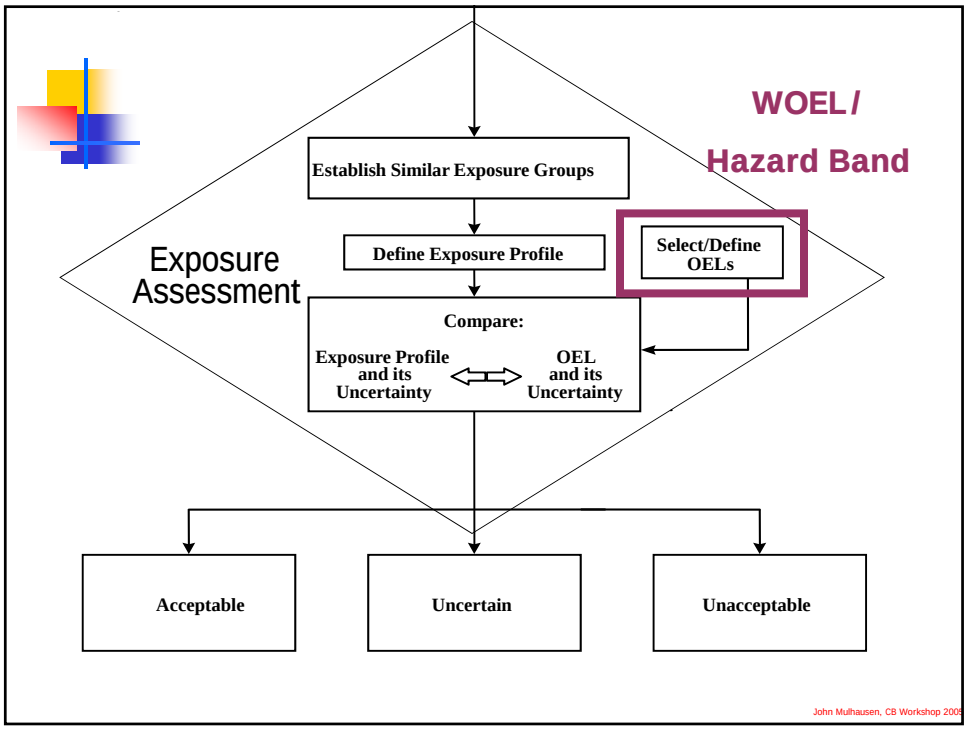
WOEL / Hazard Band
Establish Similar Exposure Groups
Exposure Assessment
Define Exposure Profile
Select/Define OELs
Compare:
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Acceptable
Uncertain
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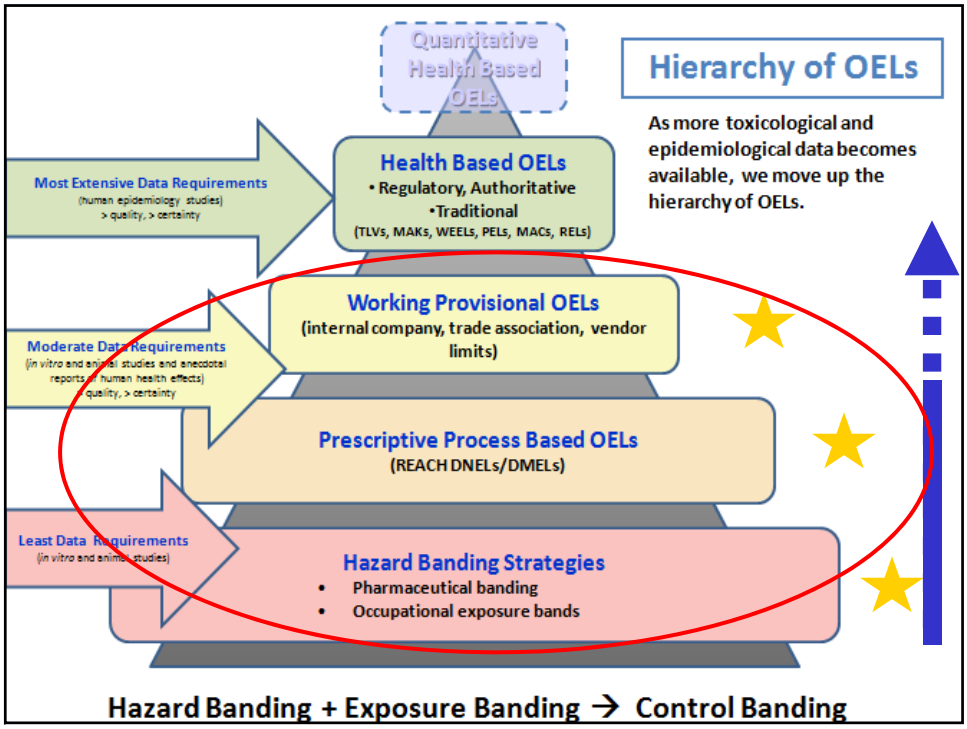

Example: COSSH Essentials

Hazard Group vs. Target Exposure Range

Hazard group	Target airborne concentration range	R phrases
A -Skin and eye irritants	>1-10 mg/m3 dust >50-500 ppm vapor	R36, R38 All substances that do not have R phrases in groups B - E
B - Harmful on single exposure	>01-1 mg/m3 dust >5-50 ppm vapor	R20/21/22, R40/20/21/22
C -Severely irritating & corrosive, skin sensitizers	>0.01-0.1 mg/m3 dust >0.5-5 ppm vapor	R48/20/21/22, R23/24/25, R34, R35, R36/37, R37/38, R36/37/38, R37, R39/23/24/25, R41, R43
D -Very toxic on single exposure, reproductive hazard	< 0.01 mg/m3 dust < 0.5 ppm vapor	R48/23/24/25, R28/27/28, R39/26/27/28, Carc Cat 3 R40, R60, R61, R62, R63
E - Carcinogen, occupational asthma	*Seek Specialist Advice*	Muta Cat 3 R40, R42, R42/43, R45, R46, R49
S: Skin and eye contact	*Prevention or reduction of skin and/or eye exposure*	R21, R24, R27, R34, R35, R36, R38, R41, R43, R48/21, R48/24, plus R -phrase combinations containing these. Skin

WEEL Banding Matrix

Criterion	ND	Virtually Non-Toxic A	Low Toxicity B	Moderate Toxicity C	Toxic D	High Toxicity E	Comments/Rationale
Acute toxicity (Rat oral LD50)		>2,000 mg/kg Rats: 2820 to 4400 mg/kg Mice: 5520 mg/kg Dogs: >5000 mg/kg dog emesis at 250 mg/kg	300-2,000 mg/kg	50-300 mg/kg	5-50 mg/kg	<5 mg/kg	
Acute toxicity (Rat inhalation LC50)- Not Available		>10,000 ppm	>10,000 ppm	1000-10,000 ppm	100-1000 ppm	1-100 ppm	Extrapolated from comments only
Sensory irritation (RD50)- Not Available		>3,000 ppm	>3,000 ppm	300-3000 ppm	30-300 ppm	1-30 ppm	Corrosive to respiratory tract
Skin or eye irritation		mild to moderate	moderate to severe	severe to corrosive	corrosive	corrosive	Corrosive to eyes, skin and respiratory tract; Inhalation of high concentrations can cause pulmonary edema
Irritation threshold (ppm)- Not Available		>1000	100-1000	10-100	1-10	<1	
Target organ toxicity NOEL Neurotoxicity		>1000 ppm >100 mg/kg/d	>1000 ppm 10-100 mg/kg/d	100-1000 ppm 1-10 mg/kg/d Moser: 16 mg/kg/d LOAEL Neurotox	10-100 ppm 0.1-1 mg/kg/d	1-10 ppm <0.1 mg/kg/d	
Severity of target organ toxicity		severity of the toxicity can push the above NOEL into a higher cell					
Repro/dev tox NOEL		>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d LOAEL 12.5 mg/kg/d (90d study in dogs)	<0.3 mg/kg/d	LOAEL 12.5 mg/kg/day (sodium salt) in dogs 90 day study showed degeneration of testicular germinal cell epithelium and syncytial giant cell formation
Reproductive toxicity		severity of the toxicity can push the above NOEL into a higher cell					
Developmental toxicity		severity of the toxicity can push the above NOEL into a higher cell					14 mg/kg/day was identified as a NOAEL for dev. Tox
Genetox		negative	equivocal	likely / limited or based on *in vitro*	positive WOE including *in vivo*	positive WOE and potent	
Cancer dose-NOEL/NOAELs		>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d	<0.3 mg/kg/d	
Carcinogenicity potential		severity of the toxicity can push the above NOEL into a higher cell					
Warning properties / odor		good: 0.04 ppm	good	fair to none	poor to none	poor to none	
OEL range (mcg/m3 and ppm)		≥1000	≥100, <1000	≥10, <100	≥1, <10	<1	
Skin notation		No	Yes LD50=510 mg/kg				greater than 200 mg/kd
Sensitization notation		No	Yes				

WOEL Example:

Hazard Bands → Working OELs

Type	Airborne Concentration Range	Units	WOEL Code
Particulate	>1 – 10	mg/m3	A-P
Particulate	>0.1 – 1	mg/m3	B-P
Particulate	>0.01 – 0.1	mg/m3	C-P
Particulate	>0.001 – 0.01	mg/m3	D-P
Particulate	≤ 0.001	mg/m3	E-P
Vapor	>50 – 500	ppm	A-V
Vapor	>5 – 50	ppm	B-V
Vapor	>0.5 – 5	ppm	C-V
Vapor	> 0.05 – 0.5	ppm	D-V
Vapor	≤ 0.05	ppm	E-V

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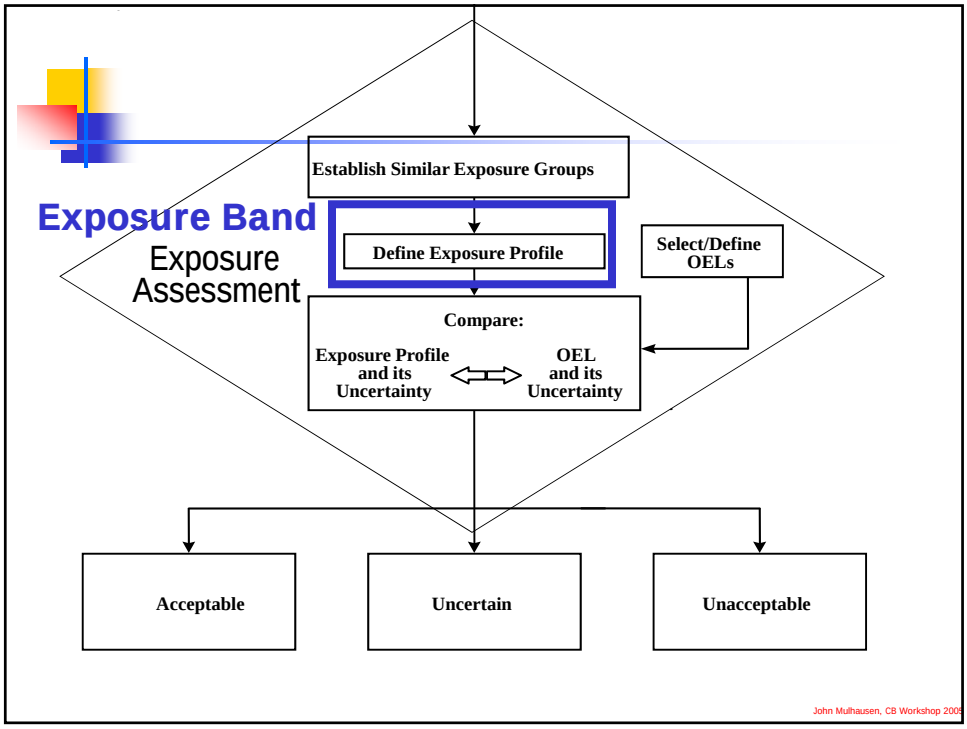
Exposure Band
Exposure Assessment
Establish Similar Exposure Groups
Define Exposure Profile
Select/Define OELs
Compare:
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OEL and its Uncertainty
Acceptable
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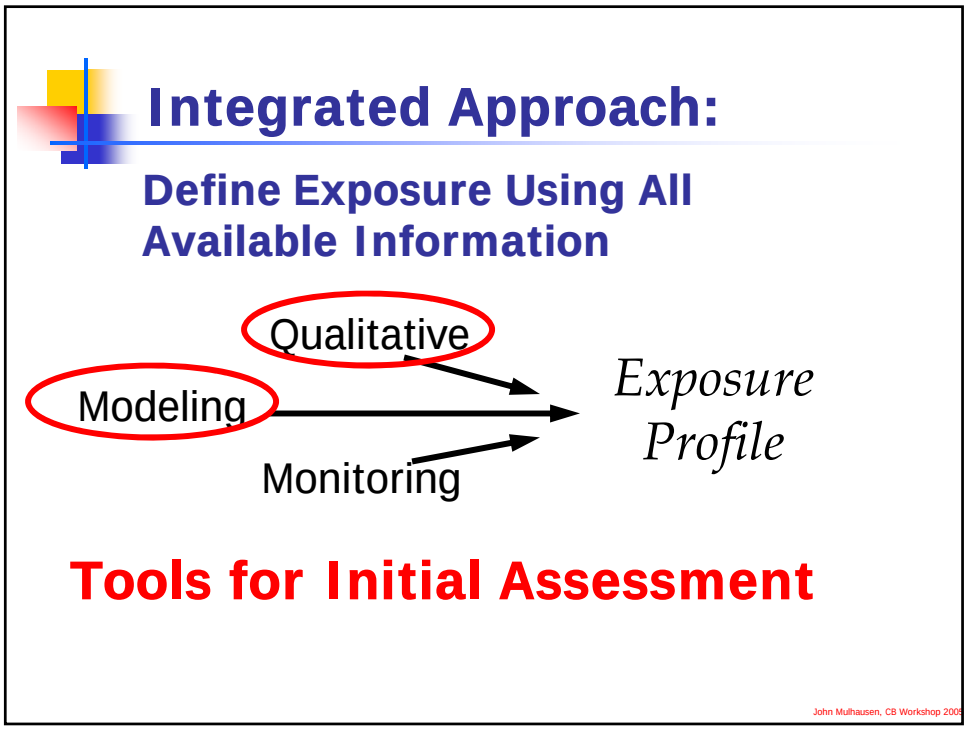
Integrated Approach:
Define Exposure Using All Available Information
Qualitative
Modeling
Monitoring
Exposure Profile
Tools for Initial Assessment
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Example: Exposure Estimate

Agent "X"
G= steady generation rate (mg/hour)
35 to 65 mg/hour
Q= steady ventilation rate (m^3/hour)
3.6 to 540 m^3/hour

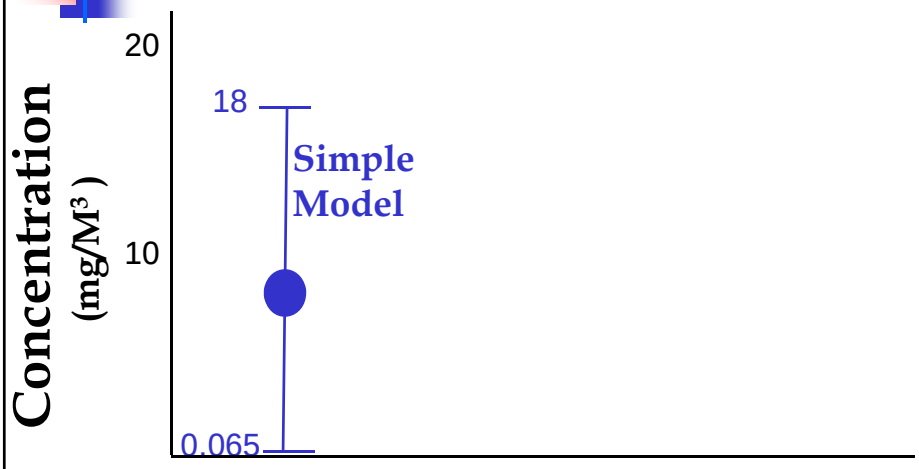
Simple Model:

$$C = \frac{G}{Q}$$

Worst Case $\quad C = \dfrac{65 \text{ mg/hour}}{3.6 \text{ m}^3\text{/hour}} = 18 \text{ mg/m}^3$

Best Case $\quad C = \dfrac{35 \text{ mg/hour}}{540 \text{ m}^3\text{/hour}} = 0.065 \text{ mg/m}^3$

Uncertainty and Acceptability



Example: Exposure Estimate

Agent "X"
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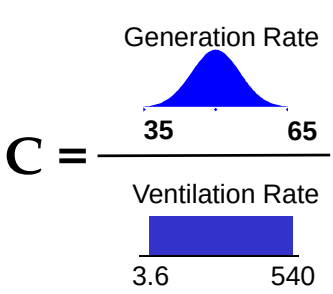
Statistical Modeling:
Monte Carlo
Uncertainty Analysis



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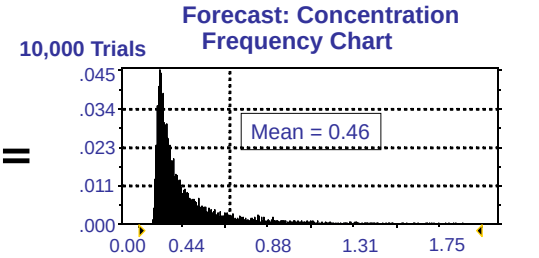
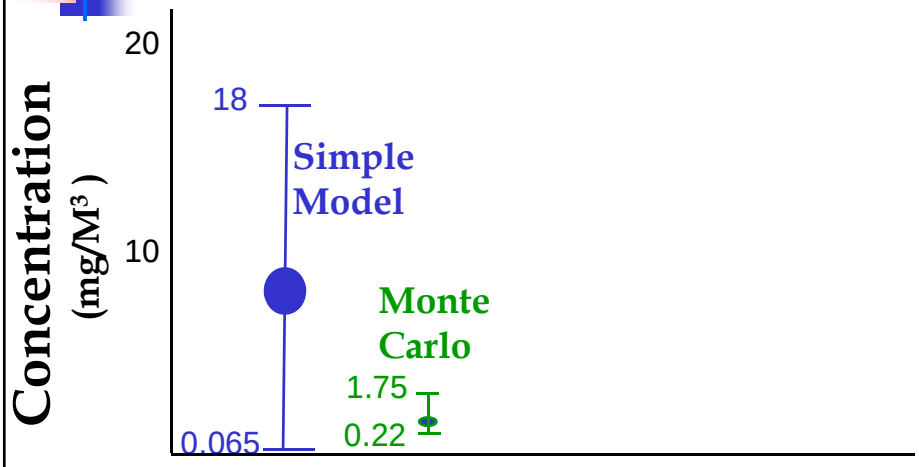


Certainty is 95.30% from 0.00 to 1.75 mg/m3

Uncertainty and Acceptability



COSHH Essentials

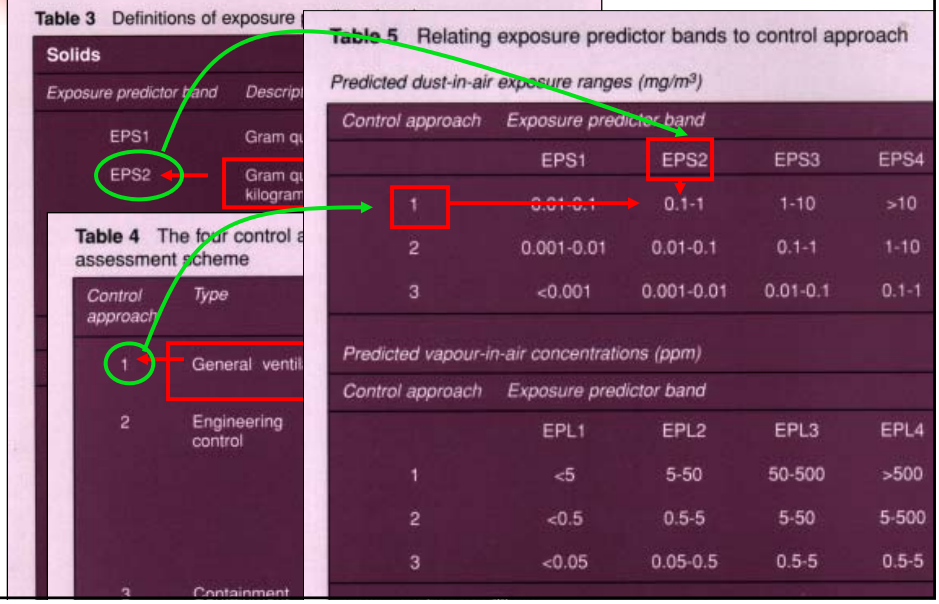


Table 3 Definitions of exposure

Solids

Exposure predictor band	Descrip
EPS1	Gram q
EPS2	Gram q kilogram

Table 4 The four control a assessment scheme

Control approach	Type
1	General venti
2	Engineering control
3	Containment

Table 5 Relating exposure predictor bands to control approach

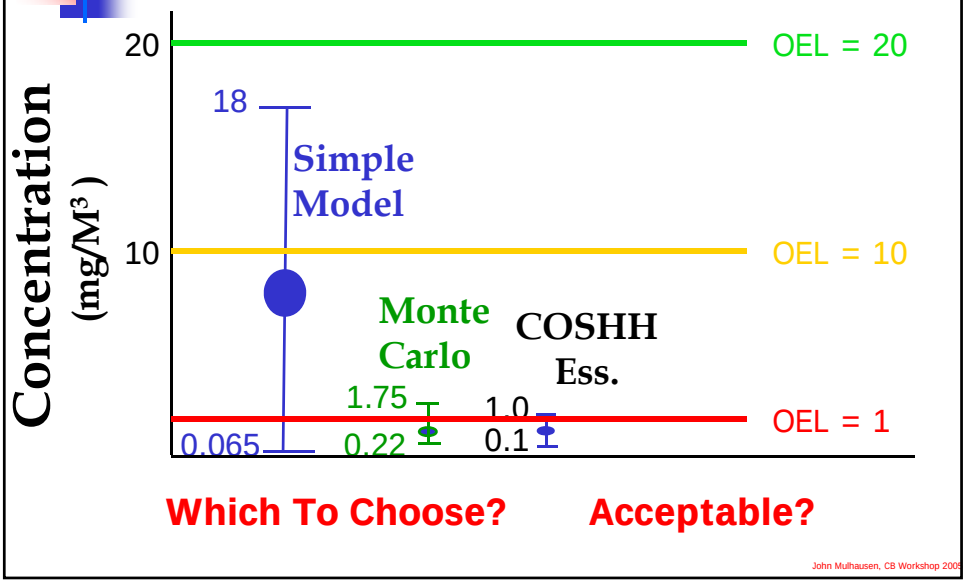
Predicted dust-in-air exposure ranges (mg/m³)

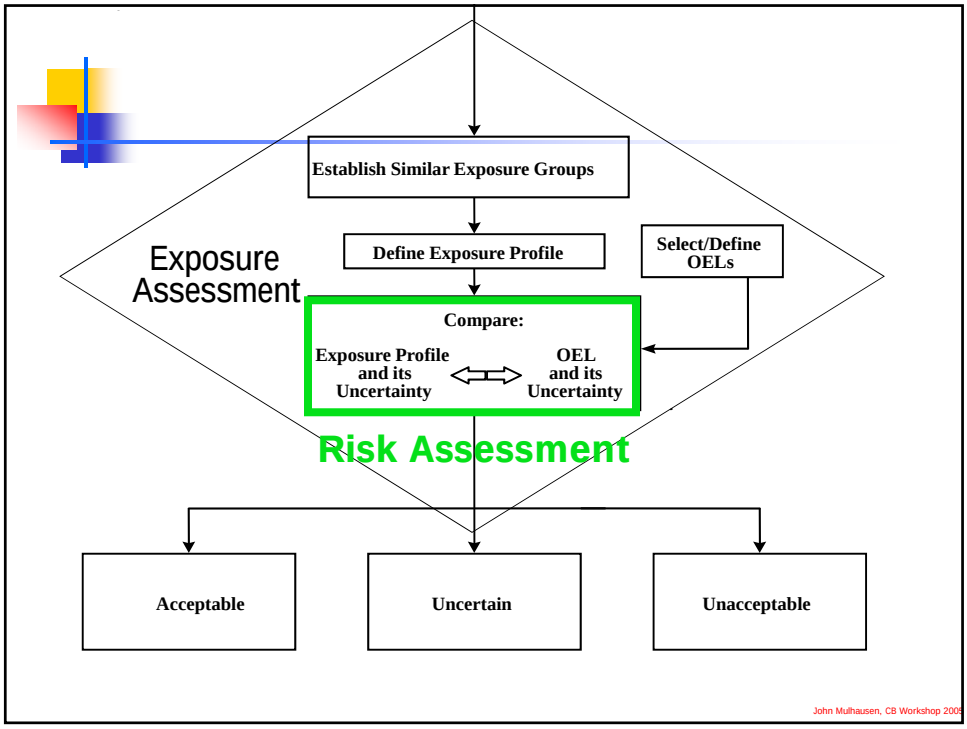
Control approach	Exposure predictor band			
	EPS1	EPS2	EPS3	EPS4
1	0.01-0.1	0.1-1	1-10	>10
2	0.001-0.01	0.01-0.1	0.1-1	1-10
3	<0.001	0.001-0.01	0.01-0.1	0.1-1

Predicted vapour-in-air concentrations (ppm)

Control approach	Exposure predictor band			
	EPL1	EPL2	EPL3	EPL4
1	<5	5-50	50-500	>500
2	<0.5	0.5-5	5-50	5-500
3	<0.05	0.05-0.5	0.5-5	0.5-5

Uncertainty and Acceptability

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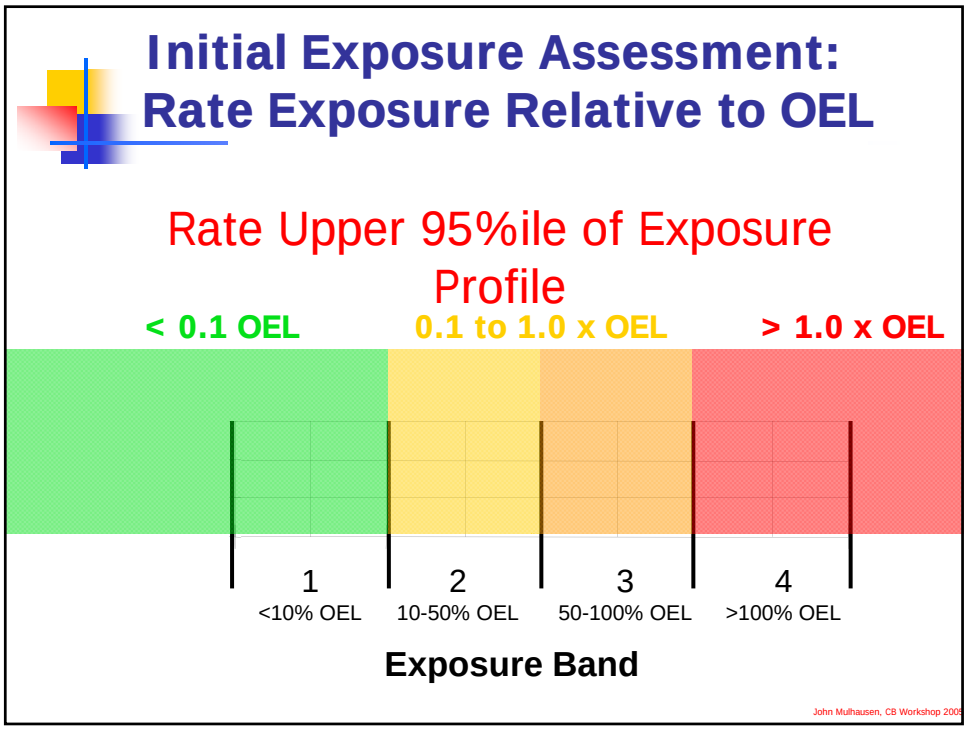
Initial Exposure Assessment:
Rate Exposure Relative to OEL
Rate Upper 95%ile of Exposure Profile
< 0.1 OEL
0.1 to 1.0 x OEL
> 1.0 x OEL
1
<10% OEL
2
10-50% OEL
3
50-100% OEL
4
>100% OEL
Exposure Band
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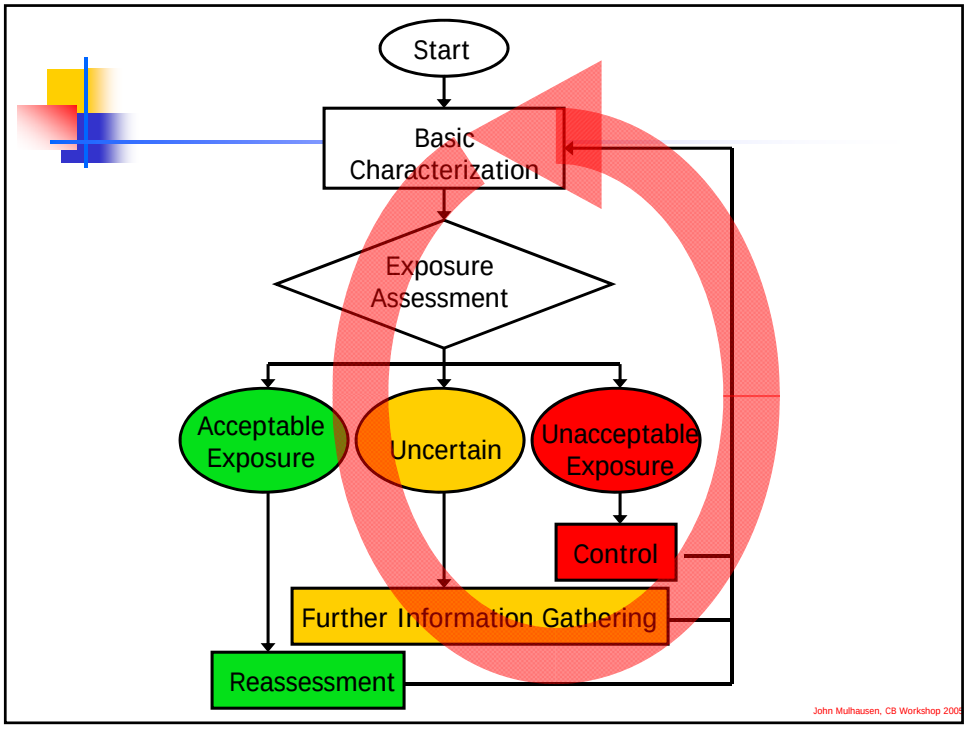
Start
Basic Characterization
Exposure Assessment
Acceptable Exposure
Uncertain
Unacceptable Exposure
Control
Further Information Gathering
Reassessment
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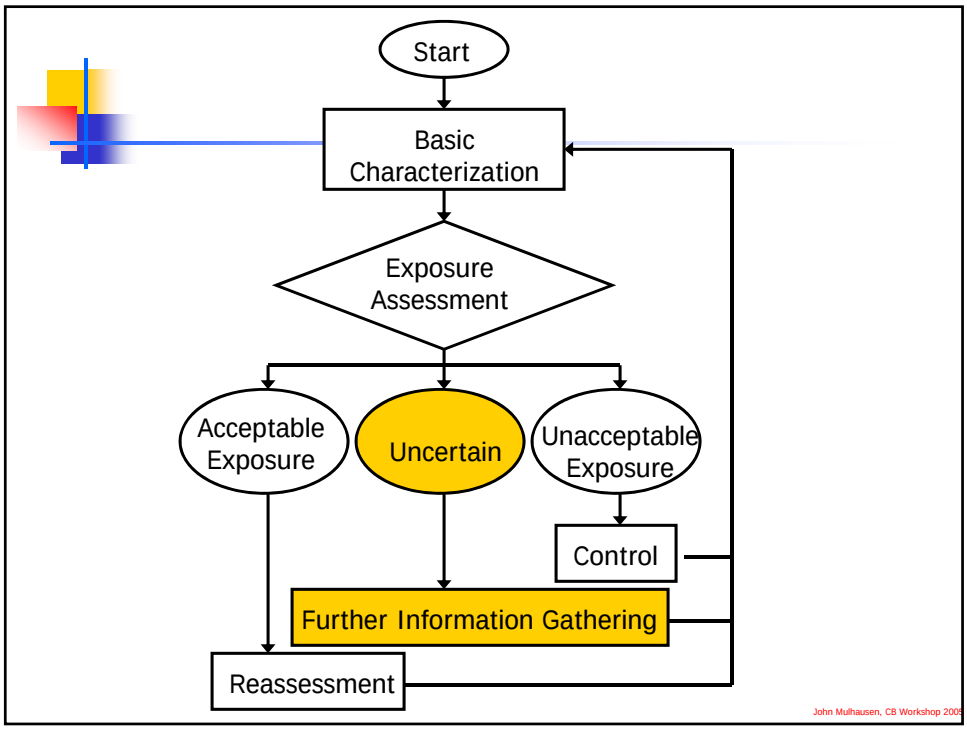
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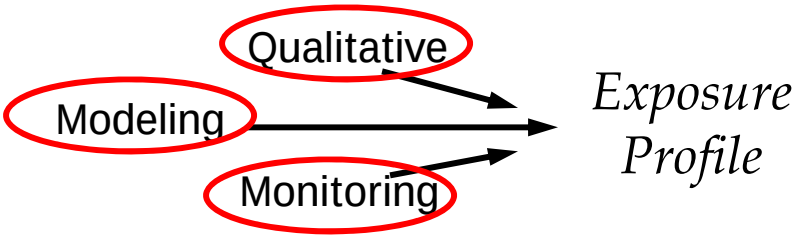
Integrated Approach:

Define Exposure Using All Available Information



Add Monitoring Data . . .
Validate Initial Judgments

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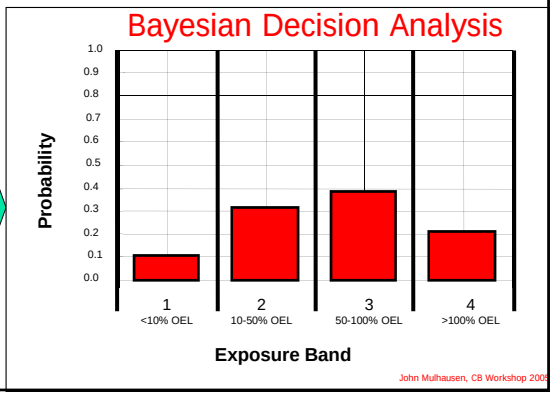
Example: Exposure Estimate

Agent "X"
G= steady generation rate (mg/hour)
35 to 65 mg/hour
Q= steady ventilation rate (m^3/hour)
3.6 to 540 m^3/hour

Monitoring Results:

0.05 mg/M^3
0.14 mg/M^3
0.21 mg/M^3
0.37 mg/M^3
0.78 mg/M^3



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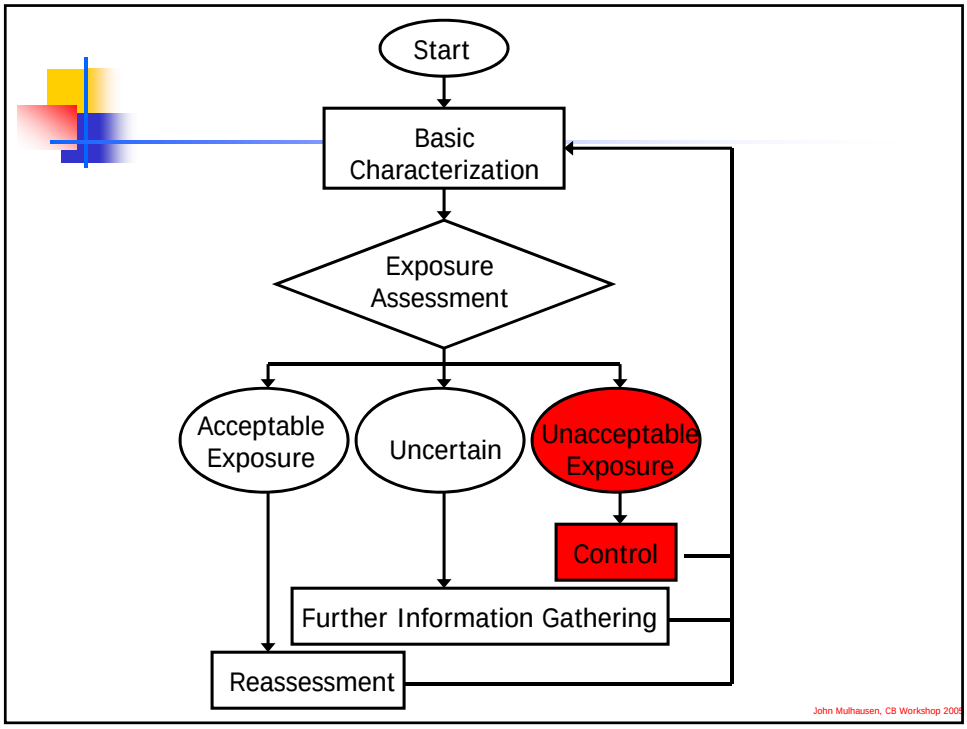
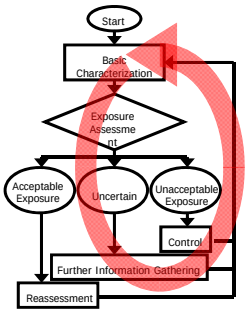


Future use of Control Banding concepts

Integrate Control Banding concepts into a tiered, continuous improvement exposure risk assessment and management system.

- Working OELs are starting point for prioritized health-based OEL improvement
- Initial assessments characterized as Exposure Bands
- Validation of initial assessments based on Exposure Predictor Models and other assessment tools
- Verification of Control effectiveness in specific applications – leverage information to similar operations and to improve and validate models
- Continuous improvement and prioritization approach can focus down to specific operations, tasks, and individual work practices when needed



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