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Industrial Hygiene Practice Practice Leader
The World of Occupational Health Risk Evaluation

- Environment factors, air quality, climate change
- Work-life balance, physical activity, diet, age
- Nanoparticles, new chemicals, biohazards
- Traditional IH practice

- Occ. Exposure Assessment w/o OEL and/or S&A methods
- Occ. Exposure Assessment to authoritative OEL
- Occ. Health Protection & Health Promotion
- Environmental Human Health

- Ex: BMW production line retrofit, Obayashi “exoskeleton”
- ADCs, advanced materials, flavorings
# Exposure Guideline Disharmony?

## n-Hexane Exposure Guidelines

<table>
<thead>
<tr>
<th>Type of Limit</th>
<th>Value (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNEL – Derived No Effect Level</td>
<td>4.7</td>
</tr>
<tr>
<td>IOELV - Indicative Occupational Exposure Limit Value</td>
<td>20</td>
</tr>
<tr>
<td>TLV® – Threshold Limit Value</td>
<td>50</td>
</tr>
<tr>
<td>AEGL2 – Acute Exposure Guideline Level (2)</td>
<td>3300</td>
</tr>
<tr>
<td>IDLH – Immediately Dangerous to Life and Health</td>
<td>1100</td>
</tr>
<tr>
<td>RFC – Inhalation Reference Concentration</td>
<td>0.2</td>
</tr>
</tbody>
</table>

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Hierarchy of OELs
As more toxicological and epidemiological data becomes available, we move up the hierarchy of OELs.

Quantitative Health Based OELs
- Regulatory, Authoritative, Traditional (TLVs, MAKs, WELs, MACs, RELs, PELs, WELs)

Health Based OELs
- Moderate Data Requirements (human epidemiology studies)
  > quality, > certainty

Working Provisionals OELs
- Internal company, trade association, vendor limits

Prescriptive Process Based OELs
- (REACH DNELs/DMELs)

Least Data Requirements
- (in vitro and animal studies)

Hazard Banding Strategies
- Pharmaceutical banding
- Occupational exposure banding

Control Banding = Hazard Bands + Exposure Risk Assessment + Exposure Measurement

A Strategy for Assessing and Managing Occupational Exposures

4th Edition

VPSW Section 41st Annual Meeting, January 2016
AIHA Strategic Direction and Content Priorities

► **Vision:** Elimination of Workplace Illnesses

► **Mission:** Creating Knowledge to Protect Worker Health

► **Content Priorities:**

- Exposure Banding/OEL Process
- Sensor Technologies
- Emerging Markets/Global IH/OH Standard of Care
- IH Value Strategy/Business Case Development
- Changing Workforce Demographics/Environment
- Big Data/Data Management and Interpretation
The IH Decision-making Framework and Process

Anticipate and Recognize ➔ Evaluate ➔ Control and Confirm Protection

Risk Assessment

Hazard Assessment
Identify and define dose-response relationships and “Hazard Criteria”
- Occupational Exposure Limits
- Skin Notations, ...
- Hazard Bands

Risk Characterization
Characterize risks associated with “realistic” combinations of hazards and exposures

Exposure Assessment
Collect all “relevant and reliable” exposure information for assessment against and refinement of the “Hazard Criteria”

Risk Management
Use the Hierarchy of Controls to apply “appropriate” controls and programs and confirm protection

Enables Hierarchy of Controls

- **Elimination**
  - Prevention through Design requires the ability to identify chemicals that should be considered for elimination or substitution.

- **Substitution**
  - Facilitate the inclusion of appropriate controls into the design of new molecules, new products and new processes as well as the assessment of the need for controls for existing processes.

- **Engineering Controls**

- **Administrative Controls**
  - Supports the inclusion of appropriate work practice controls.

- **PPE**
  - PPE can be included either to supplement controls or as a redundant control.

Facilitate the inclusion of appropriate controls into the design of new molecules, new products and new processes as well as the assessment of the need for controls for existing processes.

Supports the inclusion of appropriate work practice controls.

PPE can be included either to supplement controls or as a redundant control.
Management Systems Approach

- Establish OSH policy
- Allocate resources
- Identify hazards. OEBs and/or exposure limits
- Assess potential risk from exposure

Plan
Do
Act
Check
Plan

► Establish policy
  - Policy addresses chemical agents without authoritative OELs

  “…to protect laboratory workers from adverse health effect ...regardless of what hazardous substances are used.”

► Allocate resources
  - OEB Tier 1; IH
  - OEB Tiers 2 & 3; IH with specialized expertise, occupational toxicologist
  - Financial resources

► Identify hazards and exposure limits or bands
  - Ex. NIOSH OEB Guidance Document (pending) and AIHA BoK

► Assess potential risk from exposure
Mapping the Differences in OELs

Dose Response Data

Risk Policy

Risk Acceptance (1/1000)

Additional Analysis
- Economics
- Analytical Methods
- Engineering Controls

Description of Uncertainty

Integration of Risk Science & Risk Policy

Developed OEL

Risk Science

Point of Departure

Uncertainty Factors

Weight of Evidence

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Need for a Systematic Process

- Are the exposure guidelines reliable?
  - Yes
  - No

- Are exposure guidelines relevant?
  - Yes
  - No

- Derive new value

- Are modified exposure guidelines applicable?
  - Yes
  - No

Use selected value

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Assessing Potential Exposure Risks

- No Authoritative OEL or OEB Sampling and Analytical Methods Available
- Authoritative OEL Sampling and Analytical Methods to Detect < 0.1 x OEL
- No OEL
- No OEB
- No Sampling Method
- No Analytical Method
- Authoritative OEL or OEB No Analytical Method to Quantify Exposures to < 50% of the OEL
- Semi-quantitative or Surrogate Methods Available

Knowledge of Occupational Health Hazard

Current IH Exposure Assessment Body of Knowledge
Selecting the Appropriate Controls

Physical Form

- milligrams
- kilograms

Task Duration

- 15 minutes
- 8 hours

Occupational Health Hazard

- mild / reversible
- severe / irreversible

Quantity

Engineered local exhaust ventilation

Closed Systems

Exposure Risk

slurry/suspension → agglomerated → highly disperse
Management Systems Approach

- Establish OSH policy
- Allocate resources
- Identify hazards and exposure limits
- Assess potential risk from exposure

- Eliminate and substitute hazards
- Control residual exposures
- Equipment retrofit
- Equipment procurement

Plan  Do  Act  Check
Eliminate and substitute hazards

- Tier 1 provides a rapid and defensible method
- GHS Hazard Categories that prompt “D” and “E” OEBs indicate the potential for irreversible health effects at relatively low doses
Qualitative Example: dimethyl dicarbonate
(CAS 4525-33-1)

Signal word: Danger

Acute toxicity via inhalation (Acute Toxicity 2)

Corrosive to skin (Skin Corr. 1B)

OEB: Band E

No authoritative OEL

No sampling or analytical method

No sensor technology

- Consider substitution
- Closed transfers
- Ventilation known to control exposures to ≤ 0.1 PPM
- Skin and eye protection, RPE
- Access to safety shower and eyewash
- Life cycle assessment; from receipt to ultimate disposal

Well within our IH capabilities!
### Including ALL Chemical Hazards into the Design Process

<table>
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<tr>
<th>Stage</th>
<th>Activities</th>
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<tbody>
<tr>
<td>Conceptual Design</td>
<td>Establish IH goals, identify IH hazards and associated regulations and standards. Identify relevant OELs and/or agents of concern.</td>
</tr>
<tr>
<td>Preliminary Design</td>
<td>Eliminate hazards, if possible. Substitute less hazardous agents / processes, and establish risk minimization targets for remaining hazards (OELs and OEBs). Qualitative exposure assessment; develop control alternatives.</td>
</tr>
<tr>
<td>Procurement</td>
<td>Develop specifications and include in procurements. Develop test protocols for factory acceptance testing and commissioning.</td>
</tr>
<tr>
<td>Construction</td>
<td>Construction site safety and contractor safety.</td>
</tr>
<tr>
<td>Commissioning</td>
<td>Factory acceptance and operational qualification testing. SOPs. Exposure assessments. Mgmt. of residual risks.</td>
</tr>
<tr>
<td>Start Up and Occupancy</td>
<td>Education. Management of change. Modification of SOPs.</td>
</tr>
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Management Systems Approach

Establish OSH policy
Allocate resources
Identify hazards and exposure limits
Assess potential risk from exposure

Eliminate and substitute hazards
Control residual exposures
Equipment retrofit
Equipment procurement

Plan
Do
Act
Check

Exposure control verification
Develop SOPs
Train workers
Health surveillance

Check
Act
Plan
Do
Check

- Exposure control verification
  - Historical data
  - Modeling
  - Surrogates must consider
    - Physical Form
    - Morphology
    - Limit of Detection
    - Particle Size
    - Hygroscopy
    - Flowability

- Exposure control verification using surrogates must replicate the work environment, including work practices and PPE, that the workers will use.
Management Systems Approach

**Plan**
- Establish OSH policy
- Allocate resources
- Identify hazards and exposure limits
- Assess potential risk from exposure

**Do**
- Eliminate and substitute hazards
- Control residual exposures
- Equipment retrofit
- Equipment procurement

**Act**
- Check
- Supplement controls
- Make appropriate changes based on new hazard info

**Check**
- Assess ongoing effectiveness
- Exposure control verification
- Develop SOPs
- Train workers
- Health surveillance
Act

► Make appropriate changes based on new hazard info

► Recent examples
  - Pesticides
  - Fumigants
  - Carbon nanotubes and nanofibers
  - Nano silver
  - Beryllium
  - Silica
  - Flavorings
Business Value of Worker Health

► Estimated costs of $250B*/year

- The medical costs associated with occupational disease and injury: $67B
- Productivity costs $183B, including current and future lost earnings and fringe benefits


► An Integrated Health and Safety Index has been proposed

- Translates the impact of employer health and safety programs into business value for the investment community

Ultimately, the value of a company can be seen as the health of its workforce

Dr. Robert McLellan, co-author of Integrated Health and Safety model
Integrated Health and Safety Index

Economic
- Leadership + Management
- Absence + Disability Management
- Integrated Health + Productivity

Environmental
- Healthy Workers
- Healthy Environment

Social
- Engagement in Prevention + Wellness
- Value-based Benefits
- Corporate Social Responsibility

Dow Jones Sustainability Indices

Source: 2015 American College of Occupational and Environmental Medicine
Occupational Exposure Assessment (ARECC)

- Occupational Risk Assessment
  - OEBs/OELs
  - Total Worker Health
- Occupational Exposure Management
  - Respiratory Protection
  - Engineering Controls
- Direct Reading Instruments
  - Business Case
- IEQ
Move Forward with Confidence