"Which Chemical Exposure Limits should I use now?"

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Why are we talking about this?

- **Dr. David Michaels, Assistant Secretary of Labor** in October of 2013: *"'"There is no question that many of OSHA's chemical standards are not adequately protective…I advise employers, who want to ensure that their workplaces are safe, to utilize the occupational exposure limits on these* ***annotated tables****, since simply complying with OSHA's antiquated PELs will not guarantee that workers will be safe."*

Today's Presentation

- Introduction / Definitions
- Some history
- Some technical discussion
- Some practical strategies
- Some thoughts about the future of OELs
- Today's presentation is NOT:
  - a review of the types of limits (TWA, STEL, etc.)
  - An in-depth discussion of REACh exposure limits

Introduction - Definitions

- What *is* an Occupational Exposure Limit (OEL)?
- An OEL is a representation by an OEL-setting agency or organization that no current scientific evidence exists to suggest exposure to a toxic agent will be injurious to workers if they are exposed to the agent at levels below the OEL for their working life.
- ***It is really a risk management and/or regulatory compliance tool at its core….***

Introduction - Setting Health-Based OELs

- Typically done by a committee consisting of toxicologists, IHs, Epidemiologists, Occupational Health Physicians, that:
  - Acquire and review all available health hazard data
  - Select a critical health endpoint and associated dose descriptor (NOAEL, LOAEL, etc.)
  - Modify the dose descriptor, as necessary
  - Account for uncertainties using an appropriate safety/uncertainty factor

Introduction - Definitions

- **Consensus OELs**
  - ANSI, ISO
  - Canvas opinions and positions of all interested parties and then develop a position that is acceptable to all the parties – generally considers economic or technical feasibility
- **Non-consensus OELs (most common ones)**
  - ACGIH TLVs, NIOSH RELs
  - ACGIH - No attempt made to balance competing interests on OEL-setting committees
  - NIOSH - weight of evidence standard based on health effects and technical feasibility – *may* invite public comments

Introduction - Definitions

- **Regulatory OELs** (legal compliance)
  - OSHA PELs – Federal and State
  - OUS (outside U.S.) Country-specific OELs; includes EU REACh (e.g. DNELs)
- **Health-based OELs** (generally do not consider costs, feasibility, etc.)
  - ACGIH TLVs
  - AIHA WEELs
  - NIOSH RELs
  - Manufacturer OELs
  - Association Guidelines
- The Annotated PELs have muddied these…

Which limits are enforceable??

- In November of 2013, OSHA levied a fine against Fiberdome, Inc., a Wisconsin company for overexposing workers to styrene under the OSHA General Duty Clause
- The company was maintaining exposures below the current PEL of 100 ppm. The annotated tables lists a 50 ppm NIOSH REL and 20 ppm ACGIH TLV
- Two workers were taken to the hospital with symptoms attributed to styrene exposure by physician
- Case has since been settled with abatement *(Note: Trade association limit of 50 ppm was chosen as the abatement limit because it represents 'best practice')*

Some Historical Perspective…

- **1883:** Max Gruber at the Hygienic Institute in Munich, Germany published carbon monoxide limits
- **1921**: U.S. Bureau of Mines published a technical paper with tables of hazardous air concentrations for 33 compounds (based on Kobert's work in Germany)
- **1930**: Russia published MAC list of 30 chemicals
- **1938** Germany published a list of 100 OELs
- **1946**: ACGIH published its first list of 148 MACs (Maximum Allowable Concentrations) - in 1950 was changed to the "Threshold Limit Values"
- Earliest limits were fairly accurate for acute toxicants but much too high for many chronic ones

More Historical Perspective…

- 1971: OSHA adopted the safety and health standards derived from the 1969 Walsh-Healy Act revision which included the 1968 ACGIH list of TLVs
- 1973: OSHA was required to follow the 6(b) rulemaking process:
  - more data gathering
  - individual assessments
  - public notice and comment
  - justification for promulgating standards
- ~ 450 Federal PELs, but only 16 new or revised since 1971(!)

Updating PELs – why so slow?

- U.S. Supreme Court and Court of Appeals' opinions, Executive Orders
- Regulatory impact requirements
- Paperwork Reduction Act requirements
- Regulatory Flexibility Act requirements
- Executive branch memoranda on plain language
- U.S. Administrative Procedures Act requirements
- Information Quality Act requirements
- And more….

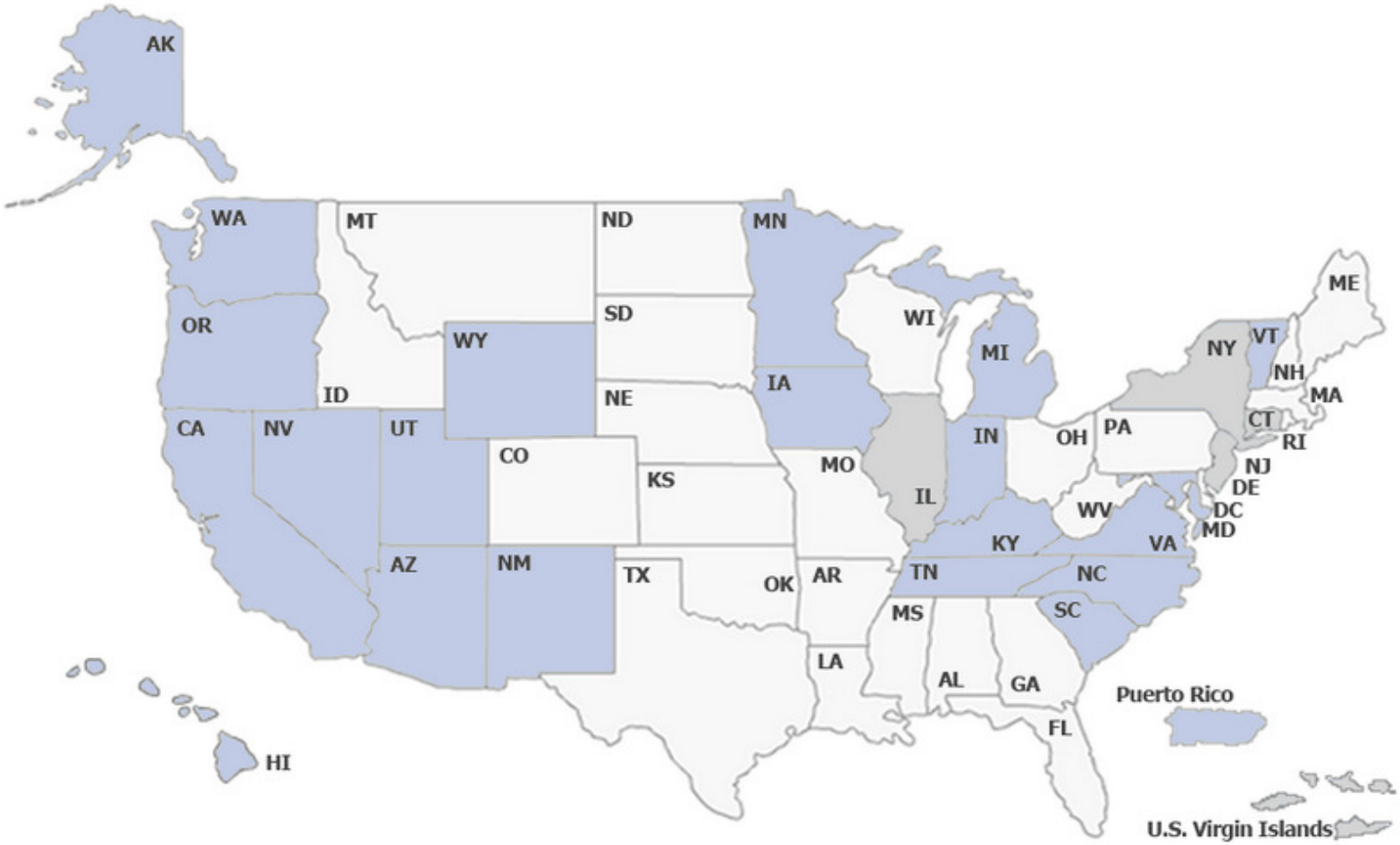
Other Organizations' OELs

- NIOSH – during the last half of the 1970s issued ~ 100 'criteria documents' with RELs (Recommended Exposure Limits)
- Only 10 Criteria Documents have been issued since 1990
- NIOSH is currently proposing an update of their "Carcinogenic Classification and Target Risk Level Policy for Chemical Hazards in the Workplace" to align with assessment schemes used by the NTP, EPA and IARC (benchmark of 1:1000 risk of cancer at the 95th lower confidence limit over a 45 year working lifetime)

More Organizations' OELs…

- 1984: AIHA began the development of Workplace Environmental Exposure Levels (WEELs)
  - Needed for chemicals with a potential for larger worker populations being exposed, but chemicals not sold into commerce in large quantities
  - Currently are ~ 120 WEELs
- ACGIH
  - Their process for setting the TLVs is the best recognized internationally, and considered by many IHs to be the "Gold Standard"
  - Currently are ~700 TLVs/BEIs, updated annually

OSHA State Plan States



- *Blue shaded states cover both private and public sector workplaces; Gray cover public only*

Notable State Plan PELs

- MN Department of Labor & Industry has only adopted PELs that have been published by Federal OSHA
- 1988-89: PELs set by Federal OSHA remain in effect in Minnesota, even though they were overturned (at the Federal level) following lawsuits filed by both labor and industry groups
- California OSHA – has ~ 750 PELs

Federal OSHA Annotated PEL Table – Examples 1 & 2

OSHA Annotated Table Z-1

		Regulatory Limits			Recommended Limits	
		OSHA PEL		Cal/OSHA PEL	NIOSH REL	ACGIH TLV
Substance	CAS No.	ppm	mg/m^3	8 Hour TWA (ST) STEL (C) Ceiling	Up to 10 Hour TWA (ST) STEL (C) Ceiling	8 Hour TWA (ST) STEL (C) Ceiling
Butyl mercaptan	109-79-5	**10**	35	**0.5 ppm** ***(same as MN)***	**(C) 0.5 ppm [15-min]**	**0.5 ppm**
2-Ethoxyethanol (Cellosolve)	110-80-5	**200** ***(same as MN)***	740	**5 ppm**	**0.5 ppm (1991)**	**5 ppm (2014)**

Federal OSHA Annotated PEL Table – Examples 3 & 4

OSHA Annotated Table Z-1

		Regulatory Limits			Recommended Limits	
		OSHA PEL		Cal/OSHA PEL	NIOSH REL	ACGIH TLV
Substance	CAS No.	8 Hour TWA	(ST) STEL	8 Hour TWA (ST) STEL (C) Ceiling	Up to 10 Hour TWA (ST) STEL (C) Ceiling	8 Hour TWA (ST) STEL (C) Ceiling
Ethylene Oxide	75-21-8	**1 ppm**	**5 ppm**	**1 ppm (ST) 5 ppm**	**<0.1 ppm (C) 5 ppm [10-min/day]**	**1 ppm (no ST or C)**
Formaldehyde	50-00-0	**0.75 ppm**	**2 ppm**	**0.75 ppm (ST) 2 ppm**	**0.016 ppm (C) 0.1 ppm [15-min/day]**	**0.3 ppm (C)**

Federal OSHA Annotated PEL Table – Example 5

OSHA Annotated Table Z-2

Regulatory Limits					Recommended Limits		
OSHA PELs					Cal/OSHA PEL	NIOSH REL	ACGIH TLV
Substance	8 Hour Time-weighted average (TWA)	Acceptable Ceiling Concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift				
			Concentration	Maximum Duration	8 Hour TWA (ST) STEL (C) Ceiling	Up to 10 Hour TWA (ST) STEL (C) Ceiling	8 Hour TWA (ST) STEL (C) Ceiling
Beryllium and beryllium compounds	**2 µg/m³ (Same as MN)**	**5 µg/m³ (Same as MN)**	**25 µg/m³ (Same as MN)**	**30 min**	**0.2 µg/m³ (C) 25 µg/m³**	**(C) 0.5 µg/m³**	**0.05 µg/m³ (IHL)**

The Bottom Line

- In some cases, the "old" PELs are not that different from other OELs
- BUT, in many cases, more recent scientific information has resulted in significant discrepancies between them
- Of approximately 7000-8000 chemicals in commerce at relatively high volumes, only **about 1 %** *even have* an OEL

Some Strategies

- Always check your OELs to make sure you are aware of which is most current (!)
- Always understand the basis of your OELs (e.g. read the Documentation of the TLV) and set monitoring priorities accordingly
- Scan TLV NICs (Notices of Intended Changes) to help prioritize future IH monitoring
- Scan the OSHA preambles – lots of good info about what actually influenced decisions for final PELs

More Strategies

- If sampling and analytical methods make demonstrating compliance using Bayesian statistical methods unattainable, document this information in your report to management
- If a health-based OEL is dramatically lower than a regulatory-based OEL:
  - Engage management in the organization – they need to understand the difference, and provide buy-in (or not) on meeting the health based standard
  - Important to outline cost differences between meeting the Health-OEL vs. Reg-OEL

More Strategies

- Be proactive - engage management in your company / organization in a discussion about adopting ACGIH TLVs (?) as an internal policy – the 'default' OEL unless extraordinary circumstances require otherwise – and have a management process!
- If you have identified a chemical of concern without an OEL, consider have a 'provisional' or 'working' OEL derived (if possible) by an independent source (conferring with Occupational Medicine and Toxicology professionals)

Future Considerations

- AIHA released their first position paper on PELs in 1998, updated in 2002
  - Sound advice for updating PELs, but little has come to fruition, mostly due to political gridlock
- U.K. and Control Banding
  - Fewer professional IHs in the EU than the U.S.
  - Data to fully validate most control band schemes are lacking
  - Can also be a useful tool for prioritizing IH monitoring efforts

Future Considerations

- Do we even need numerical OELs? There is a significant difference of opinion in the IH community, especially U.S. v. OUS
- Long history of this in the radiation safety community – "ALARA" or "as low as reasonably achievable"

Rosin-core solder thermal decomposition products - an example of "no OEL" in U.S.

- No Federal OSHA PEL
- Current ACGIH TLV Documentation:
- *"Some workers inhaling just a few breaths of the solder smoke exhibit an immediate asthmatic reaction."*
- *"…exposed workers were symptom-free for an average time of 6 years, after which they developed permanent asthma."*
- *"…workers who had left their jobs after their original diagnosis, only 2 were free of symptoms on follow-up…most had a considerable reduction in their quality of life as a result of continuing asthma"*

Rosin-core solder thermal decomposition products - an example of "no OEL" in U.S.

- Historically, ACGIH suggested formaldehyde sampling/analysis as a surrogate, but has since been invalidated (but, MN OSHA still refers to it)
- Now, the TLV Documentation just says *"ACGIH recommends that exposure to workplace air concentrations of colophony be maintained as low as possible using engineering controls and appropriate personal protective equipment"*
- So…do we ALWAYS recommend local exhaust ventilation (~$800 - $2000 per workstation)? What about if soldering is done once per month? Or once per year?

Future Considerations: Effects of Globalization

- Different requirements among countries for occupational health and safety requirements (including OELs) affect the cost of producing goods and services
- As the term ‘sustainable’ incorporates more OH&S facets into production operations for multi-national companies, may drive *de facto* OEL adoption
- WHO or ISO may have a role?
- Will a “GHS-Like” approach eventually be taken to OEL development that “harmonizes” the US and OUS OELs?

Future Considerations: Global "PR" Effects

- Apple Corp. recently announced that it was banning the use of n-hexane, but, only in the final stage of assembly - after 137 workers suffered adverse neurological effects following exposure to n-hexane in Taiwan
- An earlier study in Hong Kong reported an outbreak of peripheral neuropathy in an offset printing factory where workers were exposed to 63 -132 ppm n-hexane (OSHA's PEL for n-hexane is 500 ppm, which is 10X those of ACGIH and NIOSH)

Future Considerations

- Possible changes in Agency / Advisory council / organizational roles:
- EPA vs. OSHA?
  - Jurisdictional changes?
  - EPS's AEGLs modified to supplement PELs?
- More involvement by the National Advisory Committee on Occupational Safety and Health (NACOSH)?
- Resurrection of ANSI's Z-37 committee?

Risk-Based (Quantitative) OELs

- Nordic Expert Group has been developing them successfully for about 25 years in Scandinavia
- Dr.'s Jimmy Perkins, Mike Jayjock and Adam Finkel (and others in U.S.) have been conducting a series of teleconferences called "Risk@OEL" to explore this issue. Some of their background/opinions:
  - IH leadership in U.S. less inclined toward risk assessment
  - Aversion to RA by labor unions, OSHA, NIOSH, etc.;
  - RA a scapegoat for delays in the regulatory process;
  - Belief by some that RA is overly conservative;
  - Increase in "control banding" as an alternative;
  - At concentrations above or below most OELs, knowledge about *how* safe or *how* dangerous can't be communicated.

Future Considerations – OSHA RFI

- Will "*initiate a dialogue that will engage stakeholders in a process to help the Agency develop the best approaches to reduce and prevent occupational illnesses*"
- Seeking input about:
  - Possible new approaches for streamlining risk assessment and feasibility analyses;
  - Alternative and additional new approaches for managing chemical exposures, including hazard banding, task-based approaches, and informed substitution;
  - Comment docket closes in early April, 2015.

Questions??

Comments??

References/Credits

- "*Occupational Exposure Limits—Do They Have a Future?",* Adkins, et.al; Published by the International Occupational Health Association, 9/18/2009
- "*Occupational Exposure Limits*", Paustenbach, J.; Encyclopedia of Occupational Health and Safety, 2011
- "*The Future of Occupational Exposure Limits*," Meagher, J.; July 2002, EHS Today
- "*Setting Occupational Exposure Limits: Are we living in a post-OELworld*?; Howard, J. ; Univ. of Pennsylvania Journal of Labor and Employment Law; Vol. 7, Issue 3, 2005.
- "*The Hierarchy of OELs: A New Organizing Principle for Occupational Risk Assessment*"; Chris Laszcz-Davis, C., Maier, A., and Perkins, J.; AIHA Synergist, March 2014
- Various citations from www.osha.gov
- Blog of Mike Jayjock, PhD, CIH: http://jayjock-associates.blogspot.com
- "*Building a Bridge to the 20th Century: The Case for Risk-Based Occupational Exposure Limits*"; Conference Call of the "Risk@OEL" Working Group; May 8, 2014; Finkel, A., Sc.D., CIH