

ACGIH® Guidelines for Chemical
Substances, Physical Agents,
Biological Exposure Indices, and
Bioaerosols

Presented at AIHce
May 24, 2005
Anaheim, CA
RT 217

Forum Overview

- Cindy Coe Laseter – Welcome and Opening Comments/Lawsuit Update
- Lisa Brosseau – TLV[®]-CS Committee
- Tom Armstrong – TLV[®]-PA Committee
- Larry Lowry – BEI[®] Committee
- Paula Vance – Bioaerosols Committee
- Jim Price – ACGIH[®] TLV[®]/BEI[®] Development Process

Welcome and Overview of ACGIH[®] Mission and Committee Structure

Cindy Coe Laseter

U.S. DOL/OSHA

Atlanta, GA

Chair, ACGIH[®] Board of Directors

ACGIH[®] Mission

The ACGIH[®] community of professionals advances worker health and safety through education and the development and dissemination of scientific and technical knowledge.

What is ACGIH®?

- Membership Society (founded in 1938)
- Not-for-profit, Non-governmental Association (501(C)(6) organization)
- Multi-Disciplinary Membership
- Membership Open to all Professions

ACGIH[®] Membership Benefits

- Free TLV[®]/BEI[®] Book each year
- Annual Subscription to JOEH (Journal of Occupational and Environmental Hygiene)
- Five Free TLV[®]/BEI[®] *Documentation Downloads*
- Membership Discounts on all ACGIH[®] Signature Publications and Educational Events

Online ACGIH[®] Resources

www.acgih.org

- Products and Services
- Membership (Including the new Organizational Membership category)
- Educational Events
- TLV[®]/BEI[®] Resources

LAWSUIT UPDATE

May 2005

Plaintiffs:

- International Brominated Solvents Association
- National Mining Association
- Aerosafe Products, Inc.
- Anchor Glass Container Corporation, Inc.

Defendants:

- American Conference of Governmental Industrial Hygienists (ACGIH®)
- U.S. Department of Labor (DOL)
- U.S. Department of Health and Human Services (DHHS)

Allegations:

- Count 1 – Violation of Federal Advisory Committee Act Against All Defendants
 - ***ACGIH[®] DISMISSED*** – March 11, 2005
 - ***DOL DISMISSED*** – March 11, 2005
 - ***DHHS DISMISSED*** – March 11, 2005

Allegations (Continued)

- Count 2 – Violation of the Administrative Procedures Act Against All Defendants
 - ***ACGIH[®] DISMISSED*** – March 11, 2005
 - ***STILL PENDING AGAINST DOL***
 - ***STILL PENDING AGAINST DHHS***

Allegations (Continued)

- Count 3 – Deceptive Trade Practices Act Against Defendant ACGIH®
 - ***STILL PENDING AGAINST ACGIH®***
- Count 4 – Tortious Interference with Business Relations Against Defendant ACGIH®
 - ***ACGIH® DISMISSED*** – March 11, 2005

TLVs[®] for Chemical Substances
Committee
Recent Recommendations and
Innovations

Lisa M. Brosseau, ScD, CIH

University of Minnesota

Past Chair, ACGIH[®] TLVs[®] for Chemical
Substances Committee

Statistics

- 677 TLV[®]-CS substances with TWA or Ceiling
- 2005 Actions:
 - 115 Under Study
 - 37 NIC (3 for new substances, 28 to update TLVs[®])
 - New Appendix Proposed: “Substances Whose *Documentation* and Adopted TLVs[®] Have Been Withdrawn”
 - 15 Adoptions

Acrylamide

Borate compounds

1-Bromopropane

n-Butyl glycidyl ether

Dichloroacetic acid

Ethylene

Fensulfothion

Gallium arsenide

Hydrogen fluoride

Phorate

Sulfotepp

Temephos

Tetrahydrofuran

Wood dusts

Tetrakis phosphonium salts

Committee Activities

- TLV[®] Basis
- *Documentation* Last Major Revision Date
- Chemical Substance Selection
 - As part of TLV[®] Basis activity, reviewed all *Documentation* for input to chemical selection process
- Joint Cooperative Activities
 - Nordic Group, German MAK, AIHA
WEEL

D&I Activities

- Educational forum (with WEEL)
 - Pros and cons of PNOS
- Updating PNOS documentations

PNOS – The Issues

Toxicity

- No generic set of tests for toxicity of dusts
 - No clear definition of “soluble”
 - No clear definition of “clearance”
- Shape, size, and durability all play a role in toxicity
 - Ex (shape): Silicon carbide non-fibrous vs. fibrous
 - Ex (size): Titanium dioxide (ultrafine)
 - Ex (size): Asbestos vs. other fibers

What is a “Particulate”?

- Dusts come in a wide variety of forms, chemical composition, and source
 - Mineral dusts
 - Synthetic dusts
 - By-products of industrial processes
- Nothing generic about dusts in any of these categories
 - Example: Process can make a big difference (diatomaceous earth—uncalcined and calcined)

Informal Survey

- 30 industrial hygienists
 - 7 consultants, 12 industry, 5 academia, 6 government
- 6 countries
 - 16 USA, 3 UK, 6 Germany, 3 Netherlands, 1 Brazil, 1 Malaysia
- Range of business size

Responses

- Who determines the applicable OEL?
 - MSDS (5)
 - EH&S professional (16)
 - Non-EH&S professional (9)
- What criteria used to assign PNOS OEL to a substance?
 - Particle size (13)
 - All 3 criteria (8); 2 criteria (4); 1 criterion (11)
 - None of the appropriate criteria (7)

Discontinue PNOS?

- “Some substances will never have enough data for an OEL – we need a default level.”
- “All particles are likely to have adverse effects. We need a maximum limit to protect workers from high concentrations that could cause lung overload and reduce lung function.”

Discontinue PNOS?

- “There should be a maximum for all dusts, even if it doesn’t provide enough protection for small particles.”
- “Can’t abandon this guideline because people would still use it, even if it’s inappropriate.”

HOC Activities

- Group Guidance Values
- Reciprocal Mixture Formula

MISCO Activities

- Finishing large list of organophosphates
- Reviewing trichloroethylene carcinogenicity
- Reviewing isocyanates for new data on sensitization
- Finishing series of sulfides and mercaptans
 - Reviewing health vs. nuisance properties

How To Keep Up With New TLVs[®]?

- Review TLV[®]/BEI[®] Book every year:
 - Notice of Intended Changes
 - Substances and Issues Under Study
 - Introduction and Appendices
- Request *Documentation* for new and proposed TLVs[®]
- Send comments to ACGIH[®]
(science@acgih.org)

Become a Member

- Application on-line with resume/CV
- Commitment to attend 3 meetings/year, prepare at least 2 *Documentations*/year
- Must be a member of ACGIH®
- Should have good writing skills and previous experience on committees

ACGIH[®] Physical Agents Committee Ergonomic TLV[®] Initiatives

Thomas J. Armstrong, PhD, CIH
University of Michigan
Center for Ergonomics
TLV[®]-PA Committee

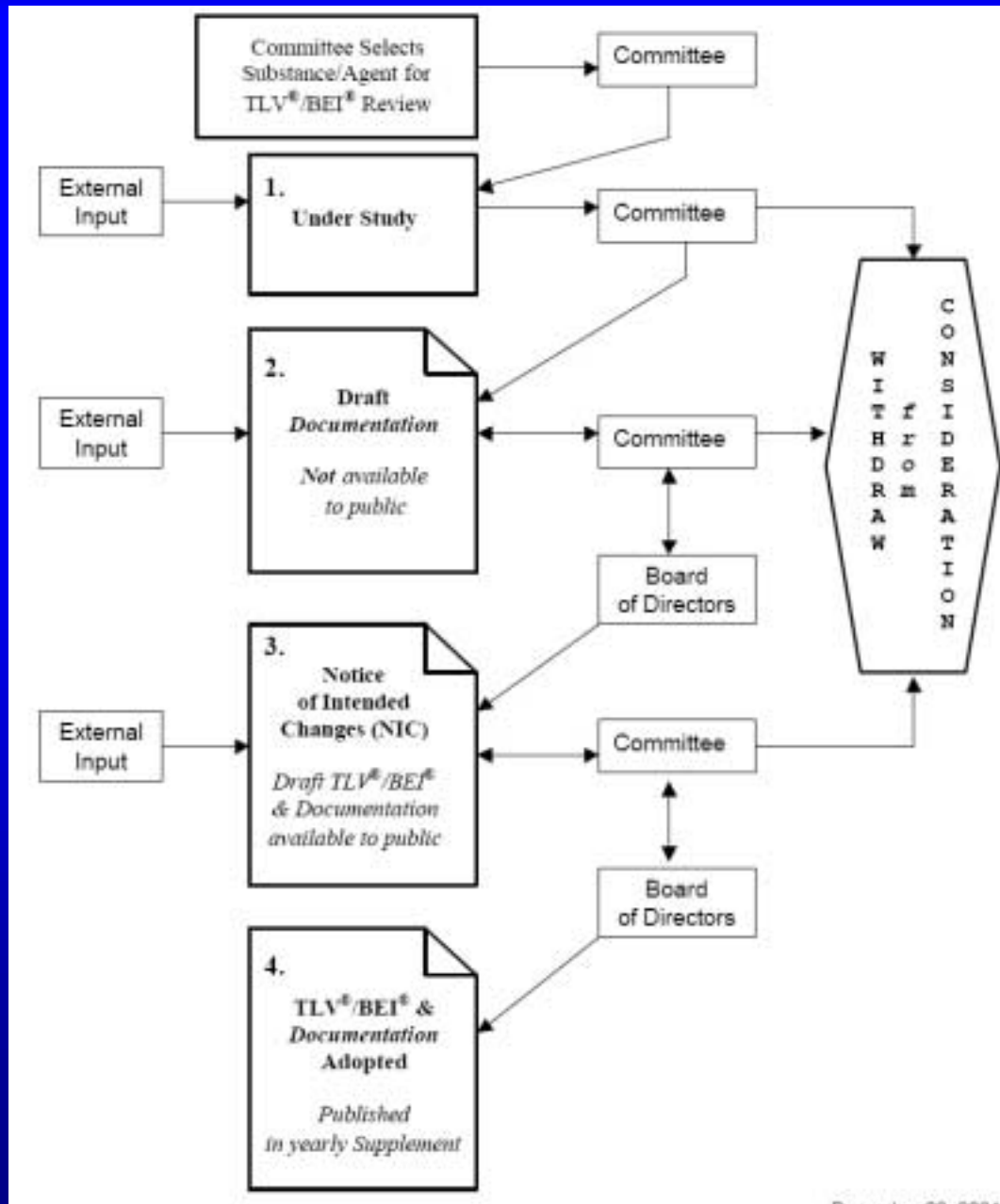
Outline

- ACGIH[®] TLV[®] development process
- Physical agents (ergonomic) understudy
 - Localized fatigue
 - Hand-arm vibration
- Schedule

TLV[®]/BEI[®] Development Process

See:

<http://www.acgih.org/TLV/DevProcess.htm>



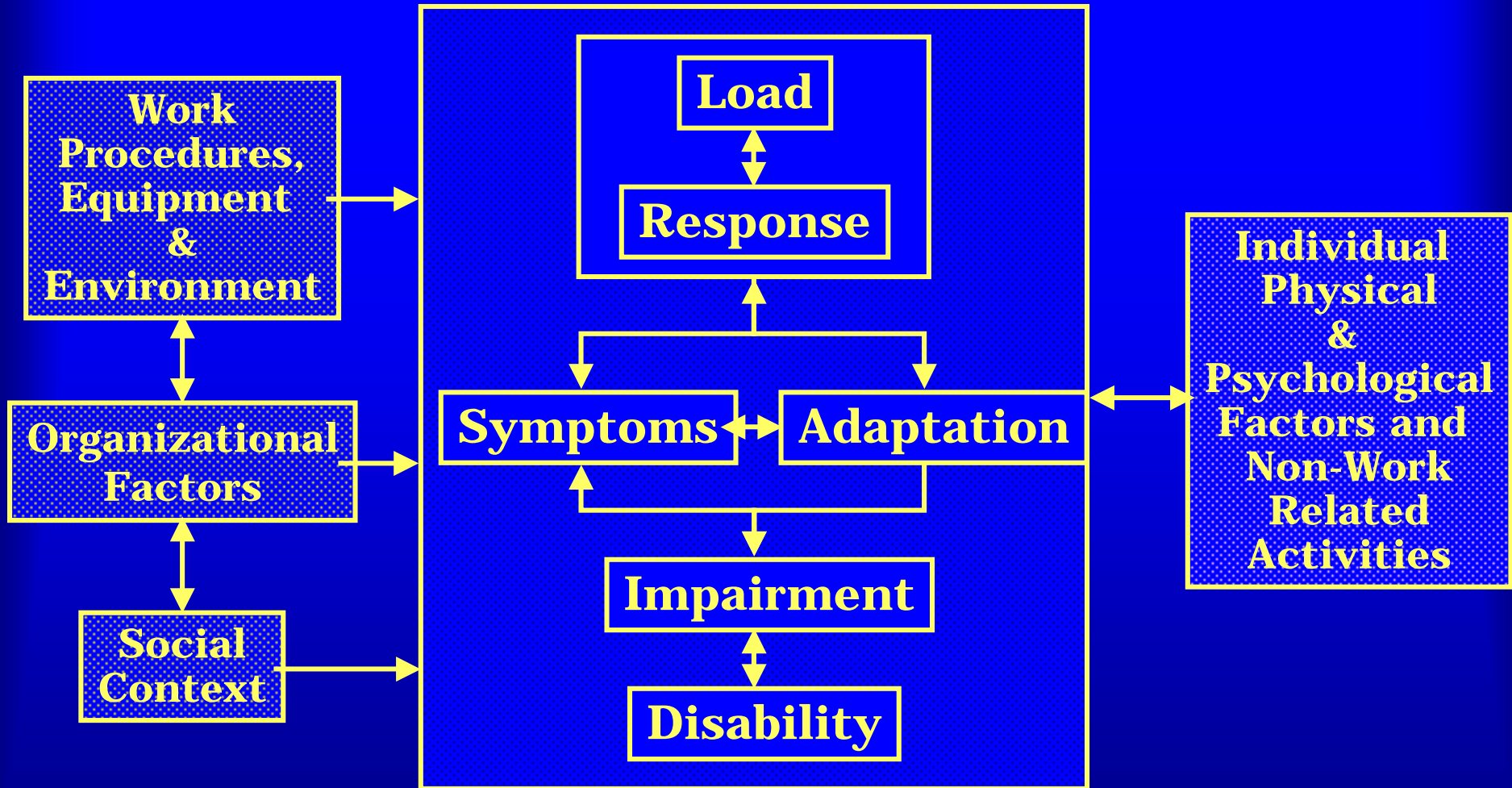
Recent initiatives

- ACGIH[®] recently produced two ergonomic TLVs[®]. One is a TLV[®] for monotask handwork and one is a TLV[®] for materials handling.

Under study

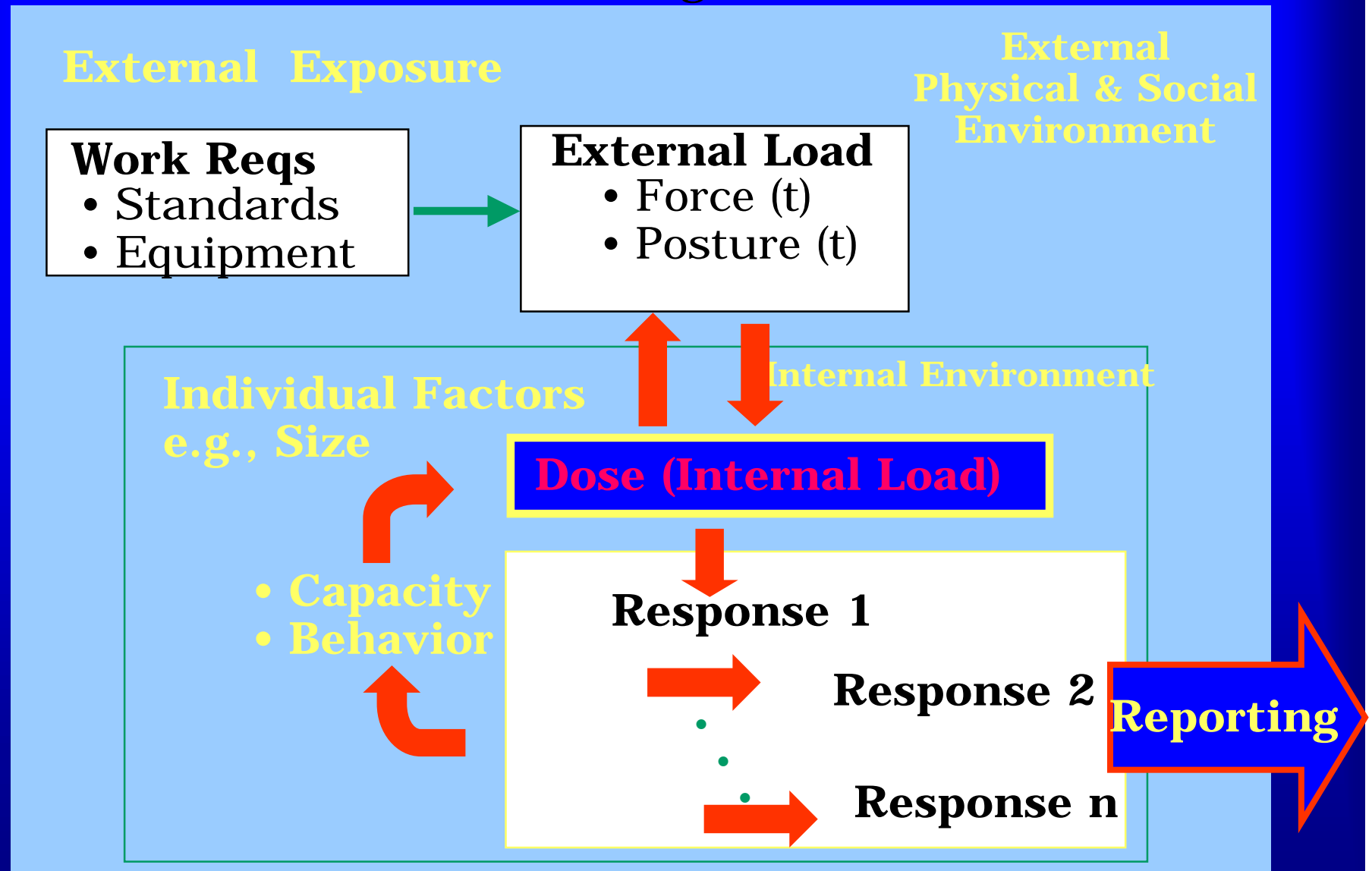
- Localized fatigue
- Hand-arm vibration

NAS 1999, 2001



Work-Related Musculoskeletal Disorders: A Review of the Evidence.
National Research Council, National Academy Press, 2101 Constitution
Avenue N.W., Washington, D.C. 20418, 1998. [Http://www.nap.edu](http://www.nap.edu)

A "Model"
from: Armstrong et al. (1993)



Localized Fatigue

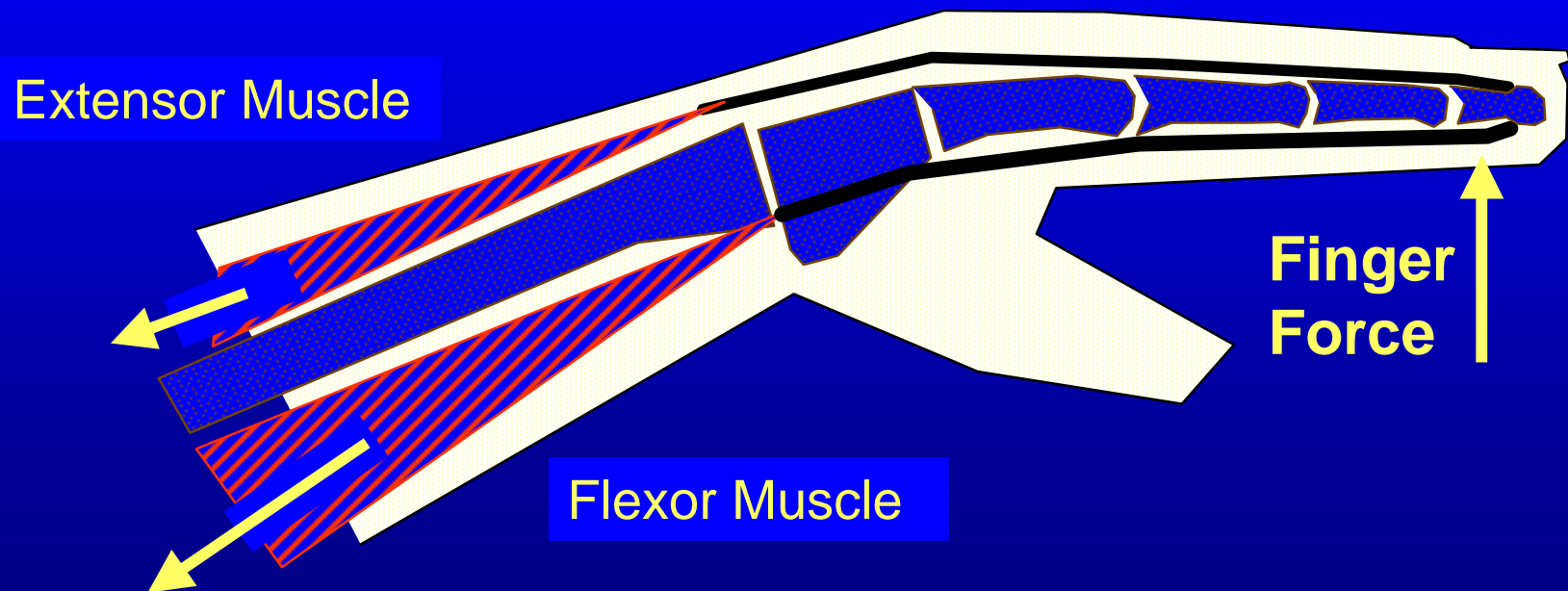
- Mechanical and physiological process
- Pain and impaired work performance
- Develops in seconds, minutes or hours
- Recovery should be complete within minutes or hours after cessation of work
- Symptoms may be hard to distinguish from those of other disorders
- Workers should seek help if symptoms persist from one day to next or interfere with activities of work or daily living.

Localized fatigue

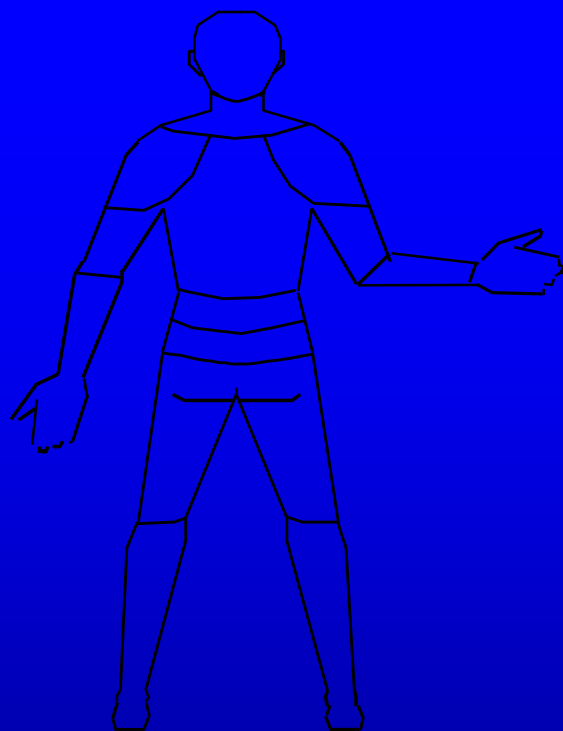
- To some extent affects all workers – some very much
- A localized fatigue TLV[®] would be relevant to all body parts, e.g., forearm, arm, shoulder, neck, back, legs, etc.
- May be an important harbinger of chronic muscle, tendon and nerve injuries
- May be a precursor of chronic muscle, tendon and nerve injuries
- May be difficult to distinguish between effects of fatigue and those of chronic muscle, tendon and nerve disorders

Localized fatigue

- Intramuscular
- Extramuscular



Relevant to all body parts



Corlett, E. & Bishop, R.: The ergonomics of spot welders. *Applied Ergonomics*, 9:23-32, 1978.

Hand-arm Vibration

- Many workers are exposed
- Often occurs in combination with repeated forceful exertions and extreme postures
- Can be difficult to separate effects of vibration from ergonomic stressors
- Many studies have been published since the TLV[®] for hand-arm vibration was last changed
- Some studies address relationship between vibration and localized fatigue

Gathering Information

- Individuals on the TLV[®]-PA Committee may attend and participate in national and international meetings to identify experts in fatigue and vibration
- Individuals on the TLV[®]-PA Committee may also participate in special sessions concerning fatigue and vibration and development of exposure guidelines
- ACGIH[®] may organize a symposium on fatigue and vibration that would bring together experts to summarize the state-of-the-art
- Symposium would be open to the public
- The TLV[®]-PA Committee would use information from symposium and literature to facilitate development of documentation and recommend a TLV[®]

Schedule

- Depends on budget
- Important meetings: ICOH, IEA and HFES 2006
- Possible Symposia 2006 or 2007
- Draft documentation and recommended TLV[®] circa 2007 or 2008

Thank you

- Further information:
 - www.acgih.org
 - <http://www.acgih.org/TLV/DevProcess.htm>
- Comments: science@acgih.org

Biological Monitoring Without Limits

What is N_q

Larry K. Lowry, Ph.D.

Chair, BEI[®] Committee, ACGIH[®]

The University of Texas Health
Center at Tyler

Topics for Discussion

- Biological monitoring and BEIs[®]
- What about BEIs[®] without numbers?
- Definition of N_q
- Rationale for N_q
- Examples
- A case study
- Other guidelines

General Reasons for Biological Monitoring

- Assess exposure and uptake by all routes
 - TLV[®] not protective for systematic effects from skin absorption - skin
 - Includes workload
 - More closely related to systemic effects
- Assess effectiveness of PPE
- Legal or ethical drivers
 - Regulations
 - Control workers' compensation costs

Basis of BEIs[®] -Traditional

- Relationship between airborne exposure at TLV[®] and biomarker of exposure
 - Most volatile organics
- Relationship between health effects and biomarker of exposure
 - Lead, Cadmium, Mercury

What About These Cases?

- Chemicals readily absorbed through the skin or carcinogens with long lag times between exposure and cancer
 - EGME, Cyclohexanol, MBOCA, PAHs
- Cannot relate to airborne limits
 - Irrelevant
- Cannot relate to health effect
 - Wrong timeline
- Chemicals with good BM methods and “associations” with health effects or exposure

BEIs[®] without numbers – N_q

Biological monitoring should be considered for this compound based on the Committee's review of the literature; however, a specific BEI[®] could not be determined due to insufficient data

Criteria for an N_q

- Dermal route of exposure significant
- Good measurement methods
- Good qualitative data on human exposure and biomarker concentration
- Poor quantitative data relating exposure and biomarker
 - Dermal exposure and biomarker
 - Long lag time between exposure and early health effect

Rationale for use

- There are good analytical methods
- There are documented human workplace studies showing efficacy of biomarkers of exposure
- Background levels are low
- Dermal exposure may be the principal route of exposure
- Suggestions often given from literature
 - Not sufficient data for a numerical BEI[®]

Examples - Cyclohexanol

- BEI[®] - 1,2-Cyclohexanediol and Cyclohexanol in urine
- Primary route of exposure – dermal
- Good methods and data on exposure
- Limited data on dose-response

2-Methoxyethanol (EGME)

- BEI[®] - 2-Methoxyacetic acid in urine
- Primary route of exposure - dermal
- Good methods and data on exposure
- Limited laboratory data on human hematological & reproductive effects
- Limited human field data

4,4'-Methylene-Bis (2-Chloroaniline) [MBOCA]

- BEI[®] - MBOCA in urine
- Principle route of exposure - dermal
- Alleged health effect in humans - cancer
- Good methods and human data on exposure, good practice & controls
- Industry practice guidance from the UK HSE

Polycyclic Aromatic Hydrocarbons (PAHs)

- BEI[®] - 1-Hydroxypyrene in urine
- Human health effects – cancer
- 1-HP a marker of pyrene content
- Association with 1-HP and smoking
- Good methods and human data on exposure - response
- More info – concurrent roundtable

A Case Study, Methyl Parathion

- Inappropriate use of methyl parathion as a household insecticide
- Metabolized like parathion to p-nitrophenol
- BEI[®] for parathion – applicability to MP?
 - Pharmacokinetics differences?
- Assess exposure – above NHANES II baseline ($< 2 \mu\text{g/g}$ creatinine, 90th percentile)
- Evaluate residents – if exceed baseline, look for source

Other Guidelines

- Levels in the general population (NHANES)
 - 1-Hydroxypyrene (<0.4 µg/g creat 90th percentile)
- Biological monitoring guidance values developed by HSE
 - MbOCA (< 35 µg/g creatinine)
- German EKA for carcinogens
 - No N_q substances listed

The Benchmark or Biological Monitoring Guidance Value - HSE

- Good analytical methods
- All specimens analyzed by one laboratory or with a single method
- Establish “good industry practice” using an upper 90% confidence limit of the “good” industries
- Benchmark or biological monitoring guidance value - provide users with assessment of their results

Questions

- How to deal with an N_q BEI[®]?
- What do I tell workers/managers that results mean?
- How do BEIs[®] with N_q relate to TLVs[®]?
- What actions are appropriate?

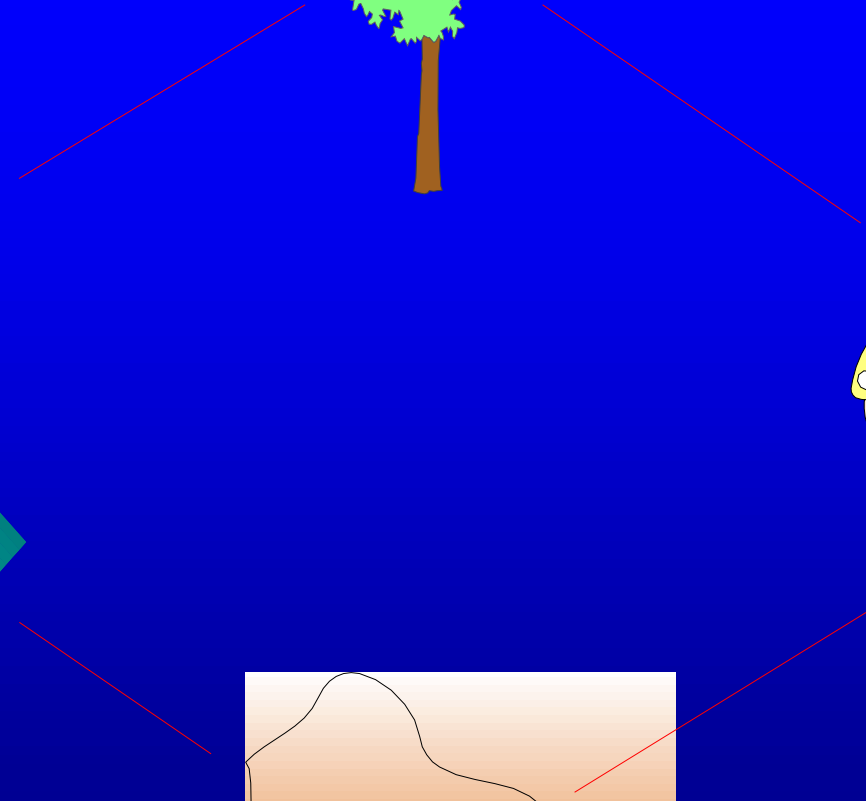
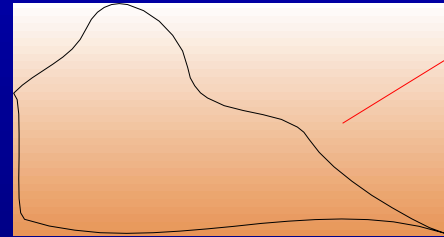
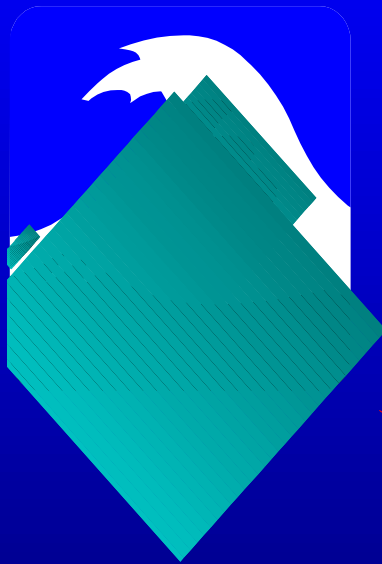
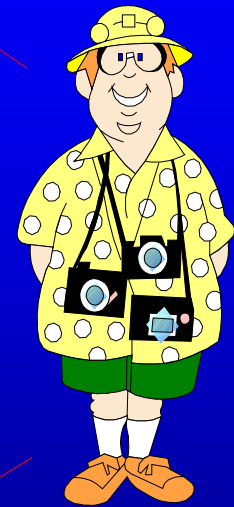
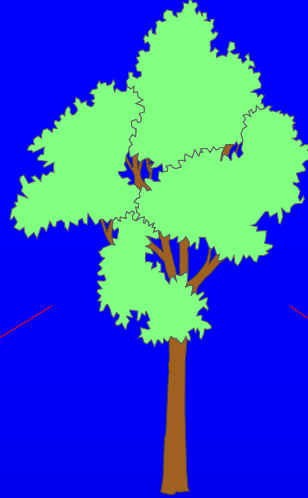
ACGIH[®] Bioaerosols Committee

Paula Vance, SM (ASCP), SM (NRM)

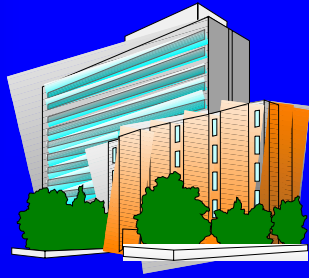
ACGIH[®] Bioaerosols Committee

Committee Members

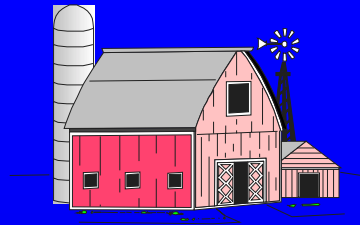
- Kenneth F. Martinez, MSEE CIH, Chair
- Jonathan Bernstein, MD
- Donald Milton, MD, DrPH
- Carol Rao, ScD, MS
- Stephen Reynolds, PhD, CIH
- Linda Stetzenbach, PhD
- Paula Vance, SM (ASCP), SM (NRM)



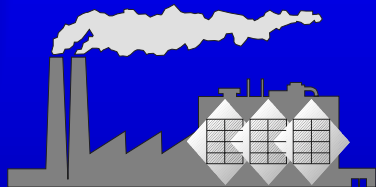
Where



Indoor Environments



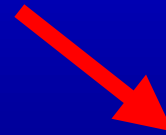
Agriculture



Biotechnology



Health Care



- Infectious Disease Outbreaks
- Bioterrorism

No Numeric Criteria for
Interpreting
Environmental
Measurements!

Why Not Scientifically Supportable?

Total Culturable or Countable Bioaerosols

- Not a single entity
- Human responses cover wide range
- No single sampling method exists
- No exposure/response relationships exist

Why Not Scientifically Supportable?

Specific Culturable or Countable Bioaerosols - other than infectious

- Data are derived from indicators rather than actual effector agents
- Concentrations vary widely
- Low statistical power in cause-effect relationship studies

Why Not Scientifically Supportable?

Infectious Culturable or Countable Bioaerosols

- Dose-response data limited to a few agents
- Air sampling limited to research
- Administrative and engineering controls remain the primary defenses

Why Not Scientifically Supportable?

Assayable biological contaminants

- Some dose-response relationship data available
 - Experimental studies
 - Epidemiologic surveys
- Assay methods improving
- May be appropriate in the future

2005 Objectives

- Enhance ACGIH[®] website
 - www.bioaerosols.org
- Explore options for “Mold Course”

Future Directions?

- Recommendations of abandonment for exposure thresholds
- Symposium – guidance on data interpretation
- Update Bioaerosols book

ACGIH®

Inside the Organization

James H. Price, CIH
ACGIH®, Director of Science

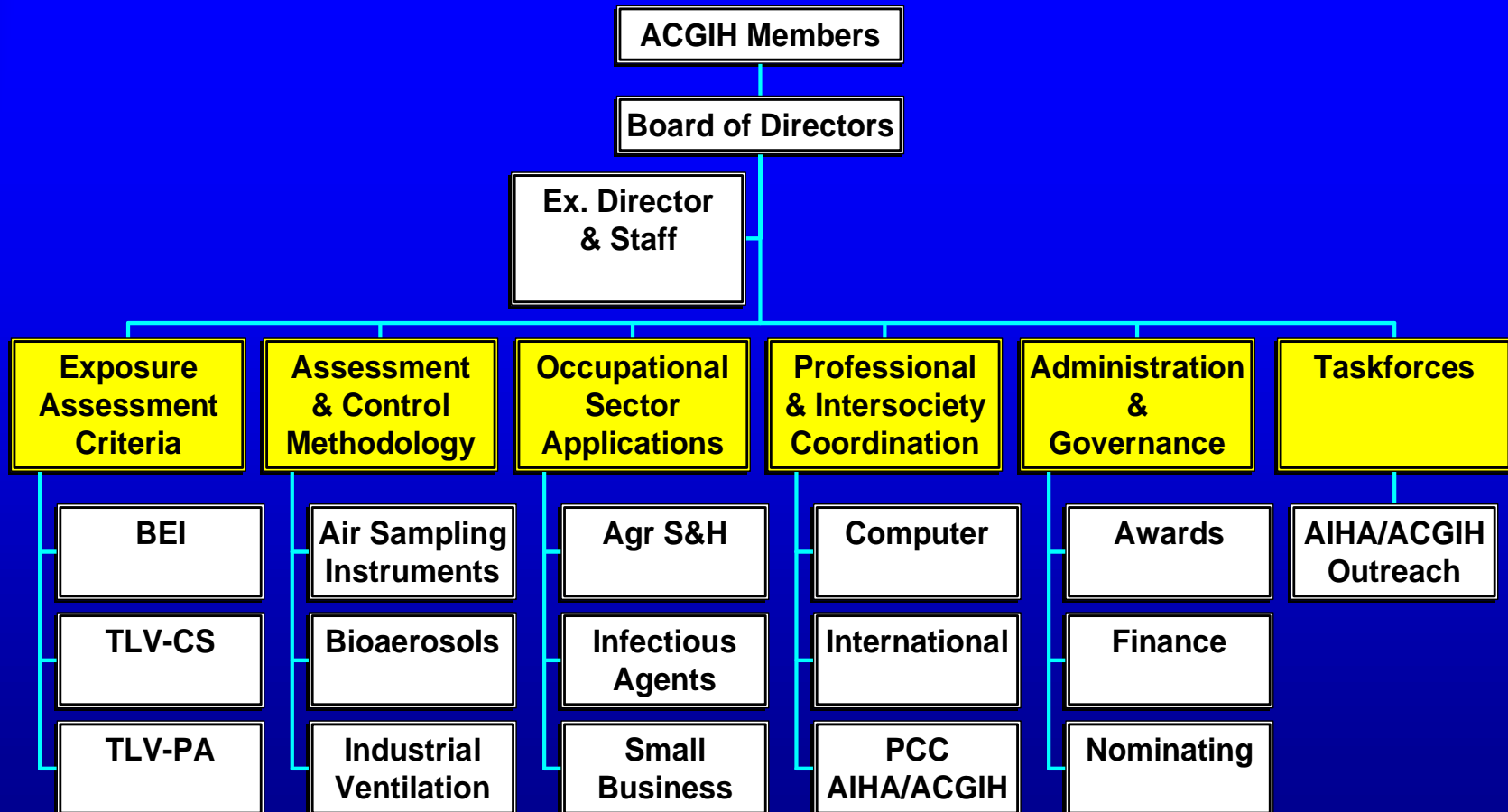
Technical Committees

Committees provide the creativity, initiative, and technical expertise that has made ACGIH[®] what it is today and what it will be tomorrow.

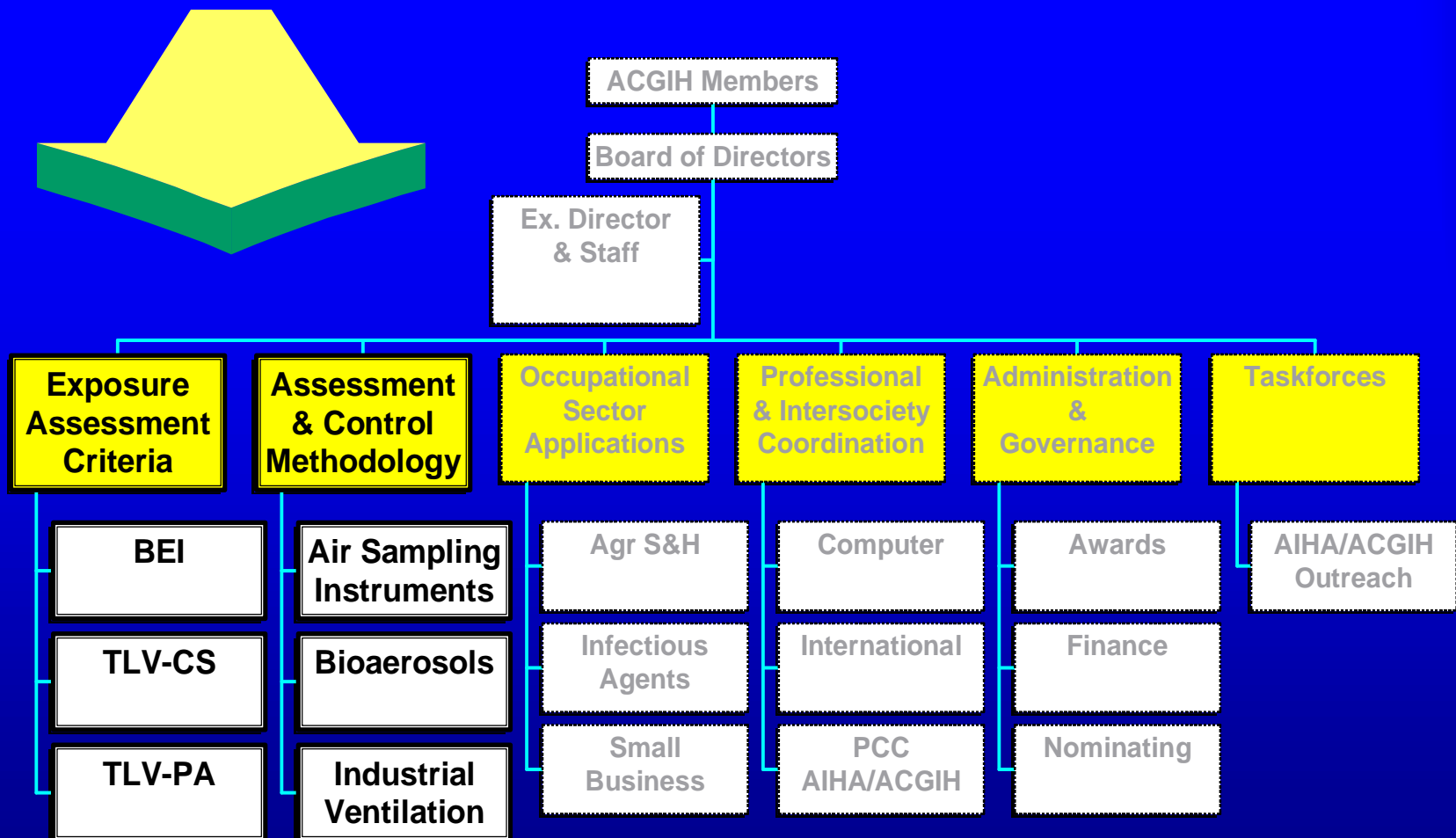
ACGIH® Committees

- Committees consist of members, who volunteer time toward developing scientific guidelines and publications
 - Primary goal is to serve the scientific needs of occupational hygienists
 - Committee expenses (travel) are supported by ACGIH®
 - Time is donated by the members

Committees



Core Mission



ACGIH[®] Statement of Position
adopted by the ACGIH[®] Board of Directors on
March 1, 2002

ACGIH[®] is not a standards setting body.

TLVs[®] and BEIs[®] —

- Are an expression of scientific opinion.
- Are not consensus standards.
- Are based solely on health factors; it may not be economically or technically feasible to meet established TLVs[®] or BEIs[®].

ACGIH[®] Statement of Position

TLVs[®] and BEIs[®] —

- Should **NOT** be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions.
- Can provide valuable input into the risk characterization process. The full written *Documentation* for the numerical TLV[®] or BEI[®] should be reviewed.

Policies and Processes
for
Limiting Conflict of Interest

Conflict of Interest

- Committee members serve as individuals
 - they do not represent organizations and/or interest groups
- Members are selected based on expertise, soundness of judgment, and ability to contribute

Conflict of Interest

- Annual discussion of conflict of interest in full committee
- Annual declaration by each member
 - Professional employment background
 - Current professional activities
 - Consulting
 - Research funding
 - Financial holdings

Conflict of Interest

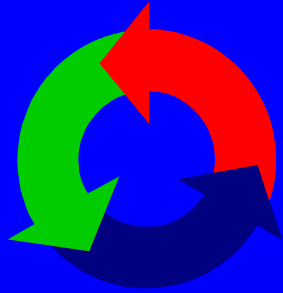
- It is each Member's responsibility to ensure they have considered and addressed any conflicts
- Failure to report conflict of interest can result in immediate termination of membership on the Committee

Example Committee

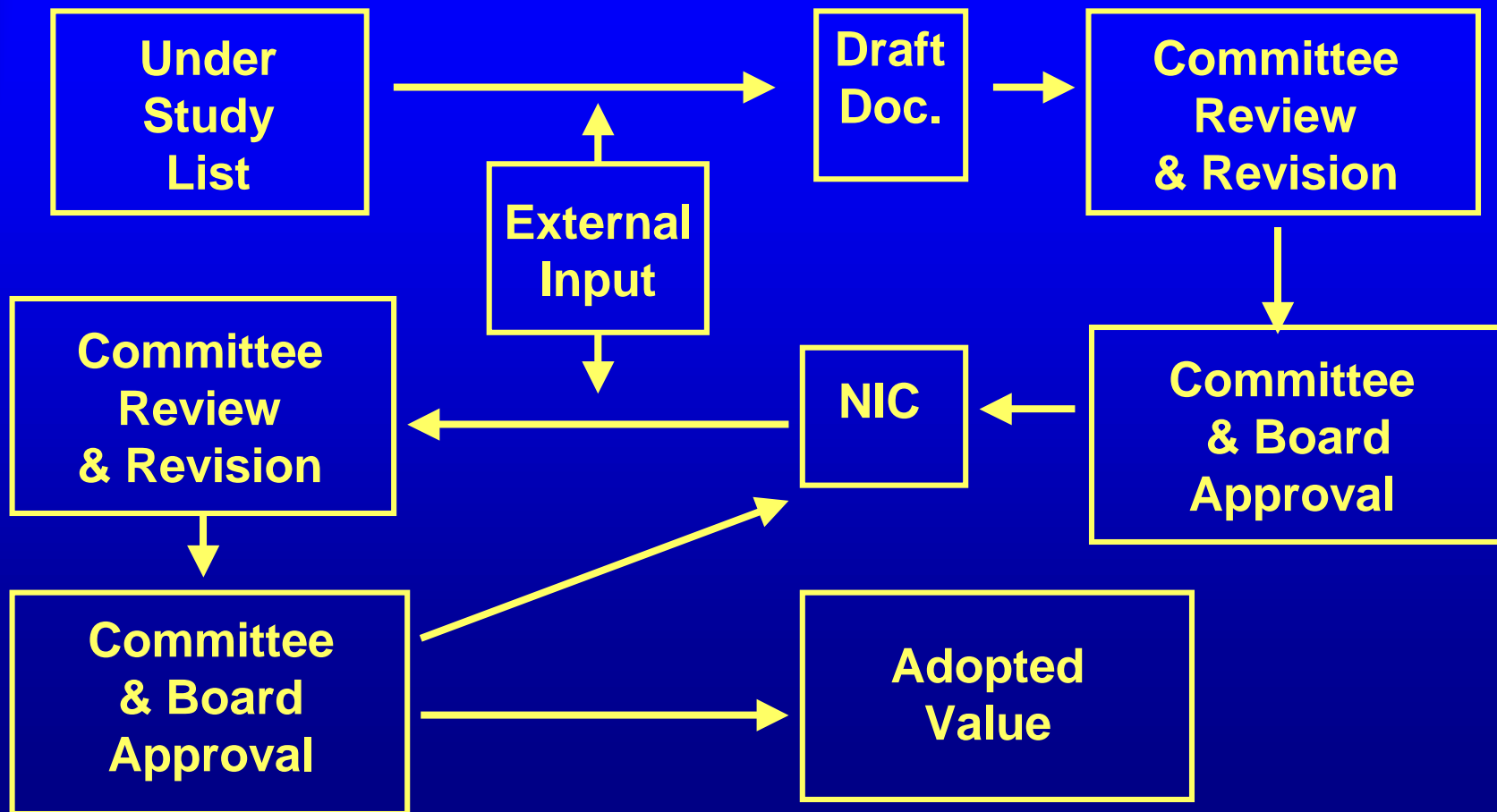
Chemical Substances TLV[®] Committee

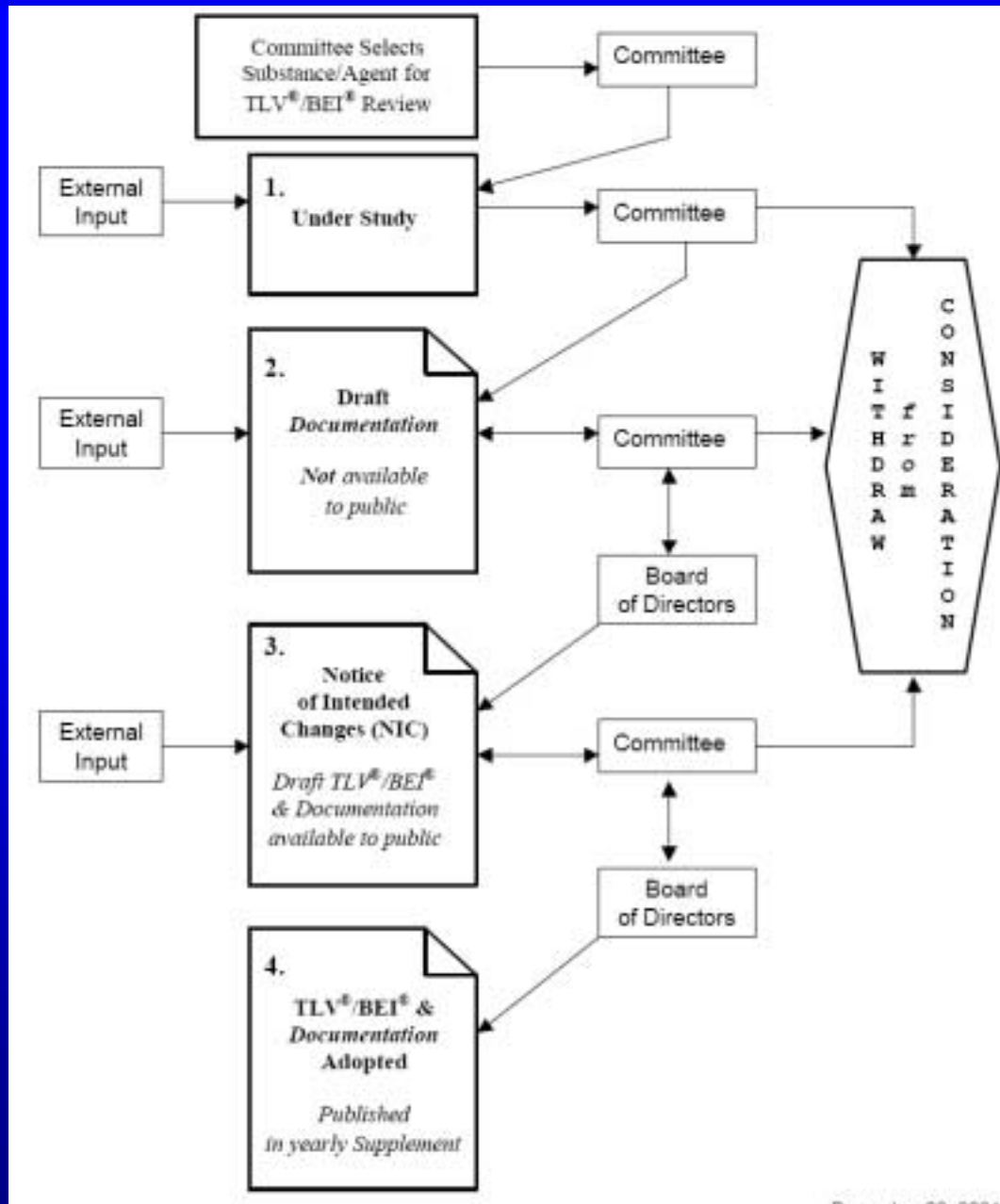
Chemical Substance Subcommittees

- Membership from academia, government, unions, industry
- Membership represents four key disciplines:
 - Industrial Hygiene
 - Toxicology
 - Occupational Medicine
 - Occupational Epidemiology



TLV[®] Development Process





Basis of TLVs[®] / BEIs[®]

Scientific Literature

- Published / Peer Reviewed Science (Principal Source)
- Review Articles (Secondary)
- Unpublished Science (Secondary)
 - Before Use: Owner must provide ACGIH[®] permission to use and cite the report, and release the report to a third party
 - Consideration of TLVs[®] are not deferred pending completion of on-going or planned research
- Not a review of all available literature
 - Emphasis on peer-reviewed literature
 - Emphasis on literature pertinent to the issue

External Committee Communications

How Stakeholders can Participate

- **Send written comments and input to ACGIH[®] (Principal Method):**
 - Provide sufficient detail and explanation
 - Support with published, peer-reviewed science
- **Can request to make presentation (by Exception only)**
 - Submit request to ACGIH[®]
 - Must demonstrate:
 - Information is significantly new and different
 - Information has received appropriate scientific peer review
- **Send to Science Group at science@acgih.org**

TLVs[®] Defined

- TLV[®] — more than just
“THE NUMBER”
- *Documentation* describes:
 - Critical health effects
 - Quality of the data relied upon and areas of uncertainty
 - Possible sensitive subgroups
 - Type of TLV[®] (TWA, STEL, C) and reason for selection
 - Notations

Warnings

- NOT to be used as an index of relative toxicity
- NOT for estimating toxic potential of continuous, uninterrupted exposures or other extended work periods
- NOT as proof/disproof of existing disease
- NOT to evaluate or control air pollution
- NOT legal standards

How/When Interested Parties Can Most Effectively Provide Input to the TLV[®] / BEI[®] Development Process

- Under Study stage
- NIC Stage
- Submit published, peer-reviewed science
- Unpublished works: Write an article and get it published
- Relevant unpublished studies: Submit to ACGIH[®] with permission to use, cite and release study

Information Sources on TLV[®]/BEI[®] Recommendations Ratified by ACGIH[®] Board

For Adopted and Notice of Intended Changes
(NIC) Recommendations:

- ACGIH[®] Annual Report
(January/February)*
- ACGIH[®] Website (January/February)*
- TLV[®] / BEI[®] Book (Spring)*

* Also identifies substances and agents Under
Study

Online ACGIH[®] TLV[®] / BEI[®] Resources

www.acgih.org

- Conflict of Interest Policy
- TLV[®] / BEI[®] Policy Statement
- TLV[®] / BEI[®] Position Statement
- TLV[®] / BEI[®] Development Process
- Under Study List
- Notice of Intended Changes (NIC) List
- BEI[®]/TLV[®] - CS Committee Operations Manual
- ACGIH[®] Annual Presentation at AIHce

Questions / Discussion