ACGIH®: Dedicated to Development of Exposure Guidelines for the Professional

Presented at AIHce

May 15, 2006

Chicago

RT 203

Forum Overview

- Bob Soule – Welcome and Opening Comments
- Dennis Casserly – TLV®-CS Committee
- Tom Bernard – TLV®-PA Committee
- Larry Lowry – BEI® Committee
- Jim Price – ACGIH® TLV®/BEI® Development Process

Opening Comments
&
Overview of the Organization

Robert D. Soule
Chair, ACGIH®
Indiana University of Pennsylvania

State of the Organization

- Roll out of Marketing Plan
  - ✓Chair's Letter
  - ✓Brand Promise
  - ✓Tag Line
- New/Expanded Educational Services
  - ✓Webinars
  - ✓Symposia
  - ✓Workshops
- Strategic Plan

Chair's Letter

- Investment in market research
- Market strategy based on results
- Development of brand promise & tag line
- Defined position to drive everything we do
- Roll out in conjunction with AIHce
- Goal: Confirm that ACGIH® has been trusted source since 1938 and will continue to be connection to timely, objective scientific information

Brand Promise

ACGIH® advances worker protection by providing timely, objective scientific information to occupational and environmental health professionals.

New Tag Line

ACGIH®: Defining the Science of Occupational and Environmental Health

Webinars

- Four webinars planned for 2006
  - ✓Heat Stress and Strain – conducted April 27, 2006
  - ✓Endotoxins – August
  - ✓PAH Exposure – September
  - ✓TLV®-CS: Definitions, Notations and Appendices - November

Symposia

- "Health Effects of Occupational Exposure to Emissions from Asphalt/Bitumen"
- June 7-8, 2006
- Dresden, Germany
- Purpose: Provide opportunity to share key research regarding emissions from asphalt/bitumen, emphasizing evaluation of exposure and carcinogenic risk

2006 Workshops

- Fundamentals in Industrial Ventilation – March and September
- Practical Applications of Useful Equations – March and September
- Mold, Moisture and Remediation – April and November
- Indoor Environmental Quality – June and October

Continuing Interaction with AIHA

- Proven joint/cooperative efforts
  - ✓AIHce
  - ✓JOEH
  - ✓Interaction Committee
- Exploring issues of common interest, e.g., ethics, credentialing
- Examining means by which together we can better serve the industrial hygiene profession

Threshold Limit Values for Chemical Substances (TLV®-CS) 2006

Dennis Casserly
TLV®-CS Committee
University of Houston at Clear Lake

This presentation will focus on the following:

- TLV® and *Documentation* revisions for 2006
- Particles Not Otherwise Specified (PNOS)
- Minimal Oxygen Content
- Inhalable Fraction and Vapor Endnote
- TLV® development process using Toluene Diisocyanate (TDI)

Revisions or Additions for 2006

- 677 TLV®-TWAs or TLV-Ceilings in the TLV®-CS section
- Under Study List
  - ✓ 104 substances
  - ✓ Group Guidance Values for Refined C_5 - C_{15} Aliphatic and Aromatic Petroleum Hydrocarbons
  - ✓ Reciprocal Calculation Procedure
- 15 *Documentations* and associated TLVs® adopted in 2006
- 15 *Documentations* and associated TLVs® withdrawn due to insufficient data or replaced by new entries in 2006
- Notice of Intended Changes (NIC) for 2006
  - ✓ 3 new substances
  - ✓ 28 updated
  - ✓ Proposed withdraw of 1 *Documentation* and associated TLV®
  - ✓ Appendix F: Minimal Oxygen Content
  - ✓ Appendix G: Substances Whose *Documentation* and Adopted TLVs® Have Been Withdrawn

TLVs® Adopted in 2006

- Calcium sulfate
- Carbon disulfide
- Coumaphos
- Fenamiphos
- Fenthion
- Fonofos
- Iron oxide
- 2-Methoxyethanol
- 2-Methoxyethyl acetate
- Monochloroacetic acid
- Propylene
- Propylene dichloride
- Ronnel
- Silica, Crystalline
  - ✓ α-Quartz
  - ✓ Cristobalite
- 1,1,2,2-Tetrabromomethane

Documentations & Associated TLVs® withdrawn in 2006

Due to insufficient data

- Magnesite
- Perlite
- Silica, Amorphous - Diatomaceous earth (uncalcined)
- Silica, Amorphous
  - ✓ Precipitated silica
  - ✓ Silica gel
- Silica, Amorphous
  - ✓ Silica fume
- Silica, Amorphous
  - ✓ Silica fused
- Silica, Crystalline - Tripoli
- Silicon
- Tetrasodium pyrophosphate
- Vegetable oil mist

Replaced by New Entries with New TLVs®

- Acetylene tetrabromide
- Iron (Fe_2O_3) dust & fume, as Fe
- Rouge
- Silica, Crystalline – Cristobalite
- Silica, Crystalline – Quartz

2006 NOTICE OF INTENDED CHANGES (NIC)

Alachlor
Aldrin
Arsine
Beryllium and compounds
Carbaryl
Copper and inorganic compounds
Diglycidyl ether [DGE]
Dimethyl carbamoyl chloride
Dimethyl disulfide
3,5-Dinitro-o-toluamide
Ethyl amyl ketone
Hexafluoropropylene
Hydrogen sulfide
Hydroquinone
Methyl demeton
1-Methyl naphthalene and
2-Methyl naphthalene
Methyl propyl ketone
α-Methyl styrene
Mineral oil
5-Nitro-o-toluidine
Portland cement
N-Propanol
Sulprofos
1,1,1,2-Tetrachloro-2,2-difluoroethane
1,1,2,2-Tetrachloro-1,2-difluoroethane
Tetraethyl pyrophosphate [TEPP]
Thiram
Toluene
Toluene-2,4- or 2,6-diisocyanate
Trichloroethylene
Vanadium pentoxide

2006 NIC
TLVs® to be Withdrawn

- Calcium carbonate – Insufficient data
- Copper, fume, dust, mist – Name change and new TLVs®
- Dinitolmide – Name change and new TLV®
- Oil mist, mineral – Name change and new TLV®

Appendix F: Minimal Oxygen Content 2006 NIC

- Sensitive tissues:
  - ✓ Brain and myocardium
- Initial symptoms:
  - ✓ Increased respiration and cardiac output
- Ensuing symptoms:
  - ✓ Headache
  - ✓ Impaired attention and thought processes
  - ✓ Decreased coordination
  - ✓ Impaired vision
  - ✓ Nausea
  - ✓ Unconsciousness, convulsions and death

Increased Respiration and Increased Cardiac Output Occur When the:

- Hemoglobin oxygen saturation is reduced below 90%.
- Partial pressure of oxygen (ρO_2) in pulmonary capillaries drops below 60 torr.
- Corresponds to 120 torr ρO_2 in the ambient air, due to anatomic dead space, CO_2 and H_2O vapor

Expressing Oxygen Requirements in Percent can be Problematic

- $\%O_2$ does not change with altitude
- It is the ρO_2 in the lung that is important and therefore the ambient ρO_2 not the percent O_2
- ρO_2 of the atmosphere:
  - ✓decreases with increasing altitude
  - ✓decreases with the passage of low pressure weather events
  - ✓decreases with increasing water vapor

19.5% O_2 Equivalent at Sea Level

- Corresponds to 148 torr ρO_2, dry air
- Provides an adequate amount of oxygen for most work assignments
- Includes a margin of safety for altitudes less than @ 8000 ft
- Represents a concentration of 7.5% (75,000 ppm) of displacing gases
- Some displacing gases may have flammable properties or may produce physiological effects, so that their identity and source should be thoroughly investigated.

2006 ACGIH® Recommendation

- Oxygen deficiency: ambient ρO_2 <132 torr
- Recommends additional work practices when the ambient oxygen partial pressure is less than 132 torr
- Considers the use of 19.5% O_2 equivalent at sea level (148 torr) a useful guide that is protective against inert displacing gases and oxygen-consuming processes for altitudes up to 5000 feet and is protective for most weather conditions up to approximately 8000 feet

When the Ambient Oxygen Partial Pressure is Less than 132 torr, Additional Work Practices are Recommended:

- Thorough evaluation of confined spaces
- Use of continuous monitors integrated with warning devices
- Use workers acclimatized to altitude of work
- Use of rest-work cycles with reduced work rates and increased rest periods
- Training, observation and monitoring of workers
- Easy and rapid access to properly maintained oxygen supplying respirators

Nuisance Dust → PNOC → PNOS

- 1964: Nuisance dust introduced
  15 mg/m^3 or 50 mppcf, whichever less
- 1968: Nuisance Particulate Appendix added
- 1972: 10 mg/m^3, total dust, or 30 mppcf
- 1976: 5 mg/m^3, respirable added
- 1988: Appendix dropped, substances listed
- 1989: Changed to Particles Not Otherwise Classified (PNOC)
- 1995: 10 mg/m^3, inhalable and 3 mg/m^3, respirable (insoluble)
- 2001: Changed to Particles Not Otherwise Specified (PNOS)

Nuisance Dust Rationale

- Excessive concentrations may…
  - ✓Seriously reduce visibility
  - ✓Cause unpleasant deposits in eyes, ears, & nasal passages
  - ✓Cause injury to the skin or mucous membranes by chemical or mechanical action or rigorous skin cleaning

(Also states that there is no particulate that does not provoke some response when inhaled in sufficient amounts)

Misuse of the “Inert” or “Nuisance Particulates” or “PNOC” TLV®

- Ignoring toxic constituents with TLVs
- Use for toxic materials which do not yet have a TLV®
- Inappropriate use on MSDSs
- Adoption by regulatory agencies

Appendix B: PNOS

- Do not have an applicable TLV®
- Insoluble or poorly soluble
- Low toxicity (i.e. not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, not radioactive or a sensitizer, or toxic other than by inflammation or the mechanism of "lung overload")

➢ 3 mg/m^3, respirable

➢ 10 mg/m^3, inhalable

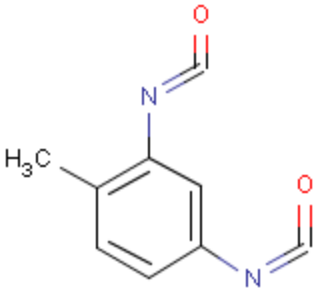
Inhalable Fraction and Vapor (IV Endnote)

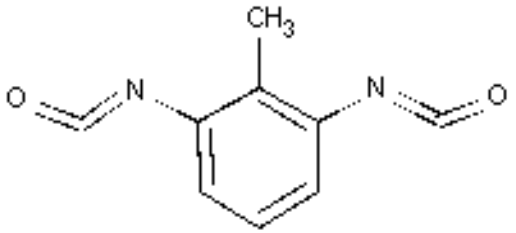
- Material present in both particle and vapor phases
- Saturated Vapor Concentration (SVC)/TLV-TWA
- Also, consider both particle and vapor phases:
  - ✓ For spraying operations
  - ✓ For processes involving temperature changes
  - ✓ When a significant fraction of the vapor may be dissolved into or adsorbed onto particles of another substance (such as water-soluble compounds in high humidity environments)
  - ✓ In selecting sampling techniques to collect both states of matter

Toluene Diisocyanate (TDI)

$CH_3C_6H_3(NCO)_2$

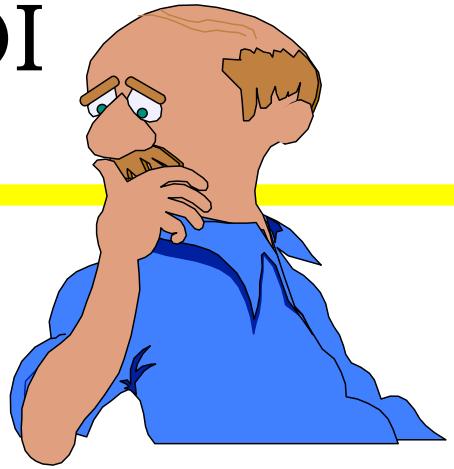
- 2,4- and 2,6-TDI (mixtures also)
- Generally liquid, but may be solid
- Volatile, with acrid odor
- Chemically reactive, heat and light-sensitive
- Used in polyurethane plastics, coatings, elastomers





Current TLV-TWA	0.005 ppm
Current TLV-STEL	0.02 ppm

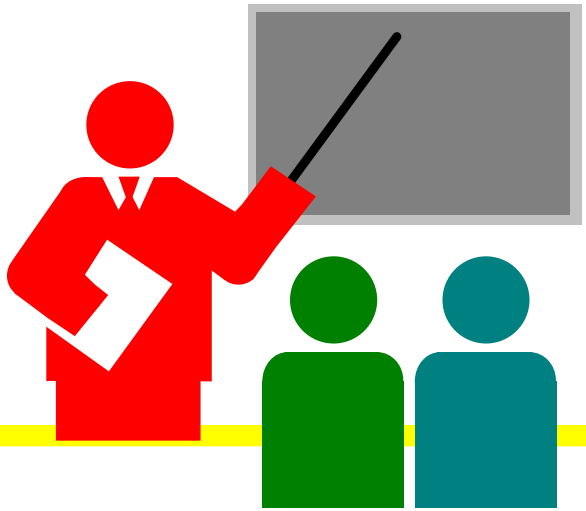
Some Important Issues in the Discussion of TDI



- Dose - response relationship for a sensitizer
- Evidence of sensitization
- Time-weighted average (TWA) *vs.* peak exposures
- Sensitized or susceptible individuals

ACGIH® TDI Symposium

- Held: April 22, 2002 (Cincinnati, OH)
- Presenters/Authors: Brown (and Burkert), Collins, Conner, Cummings (and Booth), Diller, Ott, Levine, Tarlo
- Published:
  Appl. Occup. Environ. Hyg.
  17(12): 838-908 (2002)



TDI Effect Levels

10 ppm	LC_{50} values
1 ppm	Delayed death
0.1 ppm	Inflammation, fibrosis, NOEL for reproductive effects
0.05 ppm	Sensory irritation
0.005 ppm	Cell adhesion, protein conjugation
0.002 ppm	FEV_1 reductions
???	OA

Ott (2002): Table 1
TDI Production Units

Study	Period	% OA*	TDI (TWA, ppm)
Adams, 1975 (N=565)	1961-70	5.6	decline % samples >0.02
Porter, 1975 (N=300)	1956-59	1.6	0.06 mean area
	1960-69	0.8	steady decline
	1970-74	0.3	<0.004 mean area
Weill, 1981 (N=277)	1973-78	1.0	0.0016-0.0068**
Ott, 2000 (N=297)	1967-79	1.8	0.0034-0.0101**
	1980-96	0.7	0.0003-0.0027**

* % OA (annual incidence)
** Range by job

Proposed TLV® for TDI

- TLV–TWA: 0.001 ppm (0.007 mg/m3), Inhalable fraction and vapor
- TLV–STEL: 0.003 ppm (0.021 mg/m^3), Inhalable fraction and vapor
- Skin
- Sensitizer (SEN)
- A3 — Confirmed Animal Carcinogen with Unknown Relevance to Humans

TLVs®

- More than just "THE NUMBER"
- *TLV® Documentation*:
  - ✓ Critical health effects
  - ✓ NOAELs and LOAELs
  - ✓ Quality of the data relied upon and areas of uncertainty
  - ✓ Possible sensitive subgroups
  - ✓ Type of TLV® (TWA, STEL, C) and reason for selection
  - ✓ Notations
    - SKIN
    - SEN
    - Carcinogenicity

Threshold Limit Values for Physical Agents (TLV®-PA) Committee

Thomas E. Bernard
Chair, TLV®-PA Committee
University of South Florida

Updates for 2006

- RF&MW: Note on Ultra-wide bandwidth
- Sub-RF Magnetic Fields: Note on Contact Currents
- Sub-RF Static Fields: Note on Contact Currents
- Noise: Note on Ototoxicity
- Note on carcinogenicity

NICs for 2006

- Visible and Near Infrared Radiation
- Heat Stress and Strain

Visible and Near Infrared Radiation

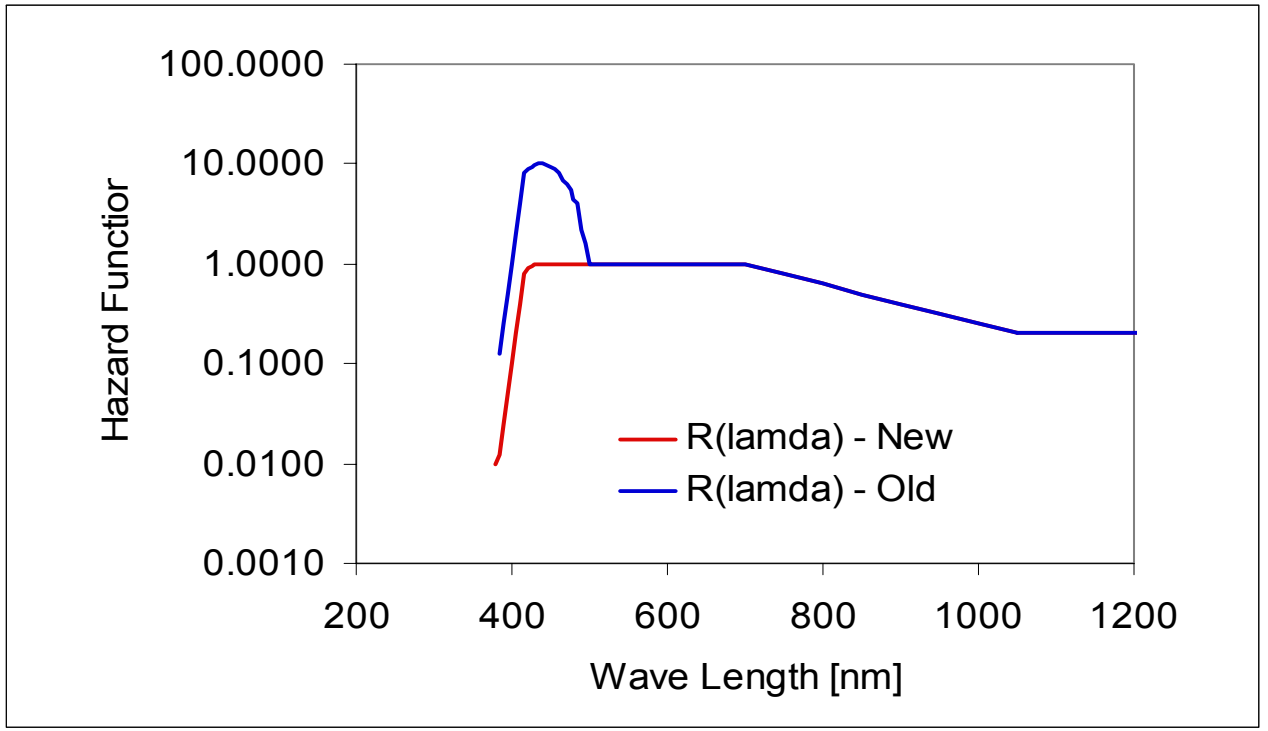
Thermal Effects Hazard Function

Overestimated Risk

- The risk of thermal effects between 380 and 500 nm was higher than necessary.

- The hazard function [R(λ)] in this range was reduced accordingly.

Graphically Speaking



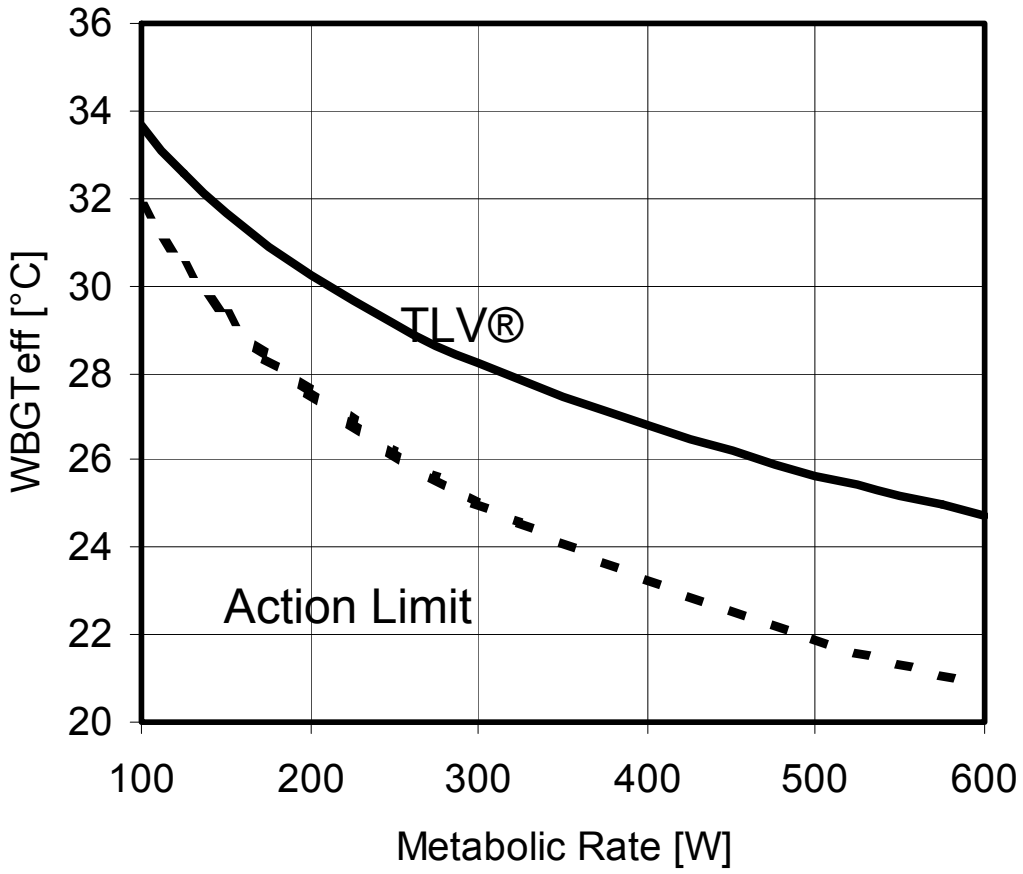
Heat Stress and Strain

Major Changes

Action Limit

- Action Limit
  - ✓Replaces the Unacclimatized TLV®
- Work below the Action Limit is presumptively low stress for any healthy worker.

TLV® for Heat Stress



Accounting for Clothing

- Clothing makes an environmental condition seem worse. It reduces both evaporative and dry heat exchange.

- Intuitively, there should be a factor that adjusts the environmental measures to an equivalent condition in work clothes.

Changed and Expanded for 2006

Clothing Adjustment Factors [°C-WBGT]

	Previous	2006
Work Clothes (Baseline)	0	0
Cloth Coveralls	3.5	0
Double Layer Cloth Clothing	5	3
SMS Coveralls	---	0.5
Polyolefin Coveralls	---	1
Limited-use Vapor-Barrier Coveralls	---	11

Environment Plus Clothing

Effective WBGT ($WBGT_{eff}$) =

Measured WBGT

+ Clothing Adjustment Factor (CAF)

Heat Stress and Strain TLV®

Process Flow

(See TLV® Decision Flow Chart)

Screening

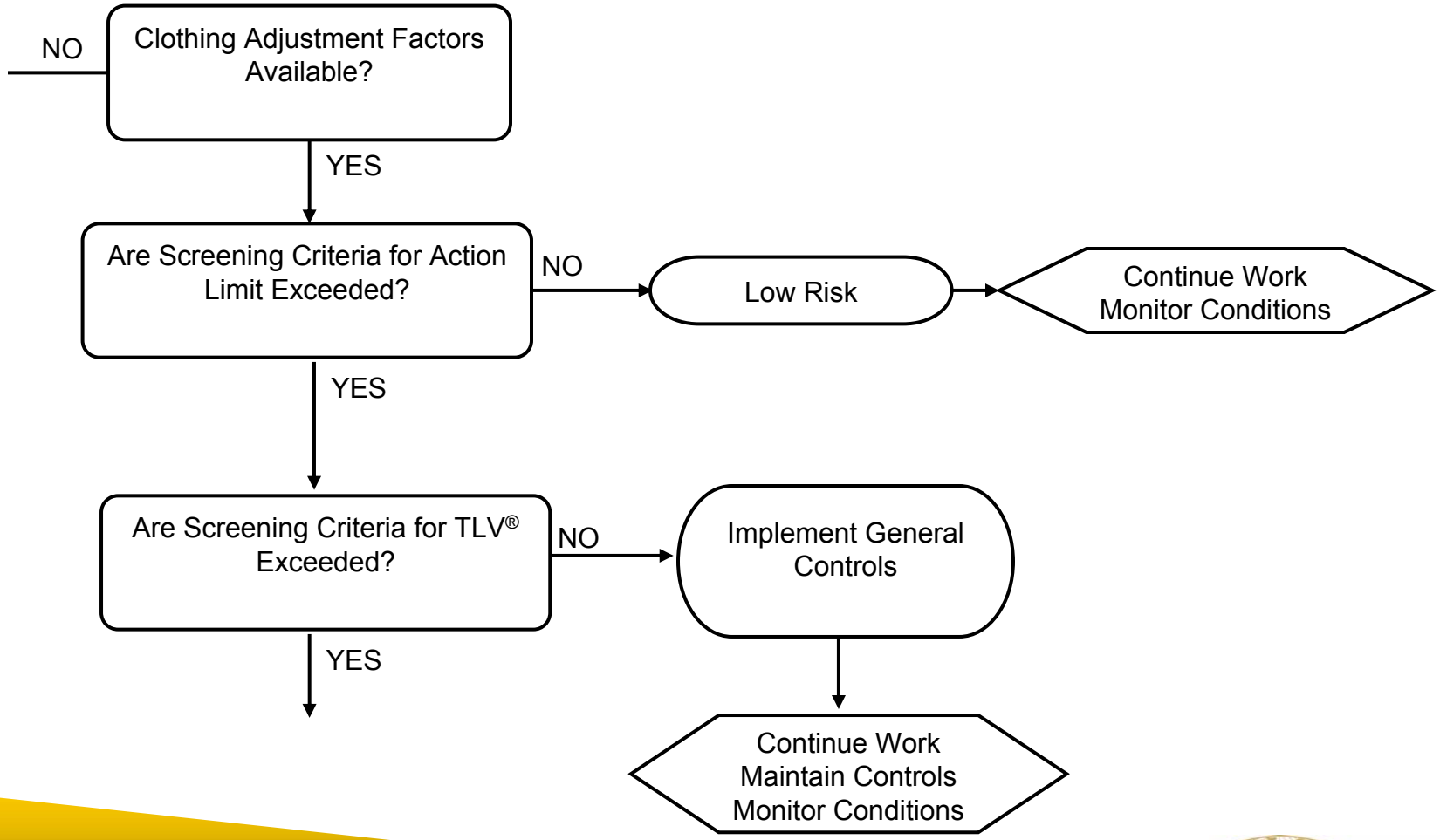

NO
Clothing Adjustment Factors Available?
YES
Are Screening Criteria for Action Limit Exceeded?
NO
Low Risk
Continue Work
Monitor Conditions
YES
Are Screening Criteria for TLV® Exceeded?
NO
Implement General Controls
YES
Continue Work
Maintain Controls
Monitor Conditions

Table Changes for 2006

- Assigned metabolic rate in each category has a lower value.
  - ✓Better reflects work physiology principles and other standards.
  - ✓Means higher WBGT values.

- Allocation of Work/Rest described as a range of % work in the cycle.

Metabolic Rate by Category

Reference Metabolic Rate [W]

	Previous	2006
Rest (Baseline)	115	115
Light	230	180
Moderate	350	300
Heavy	465	415
Very Heavy	580	520

Screening Action Limit

%Work	L	M	H	VH
75 to 100	28.1	25.0	--	--
50 to 75	28.7	26.0	24.2	--
25 to 50	29.3	27.2	25.7	24.6
0 to 25	30.0	28.8	27.8	27.0

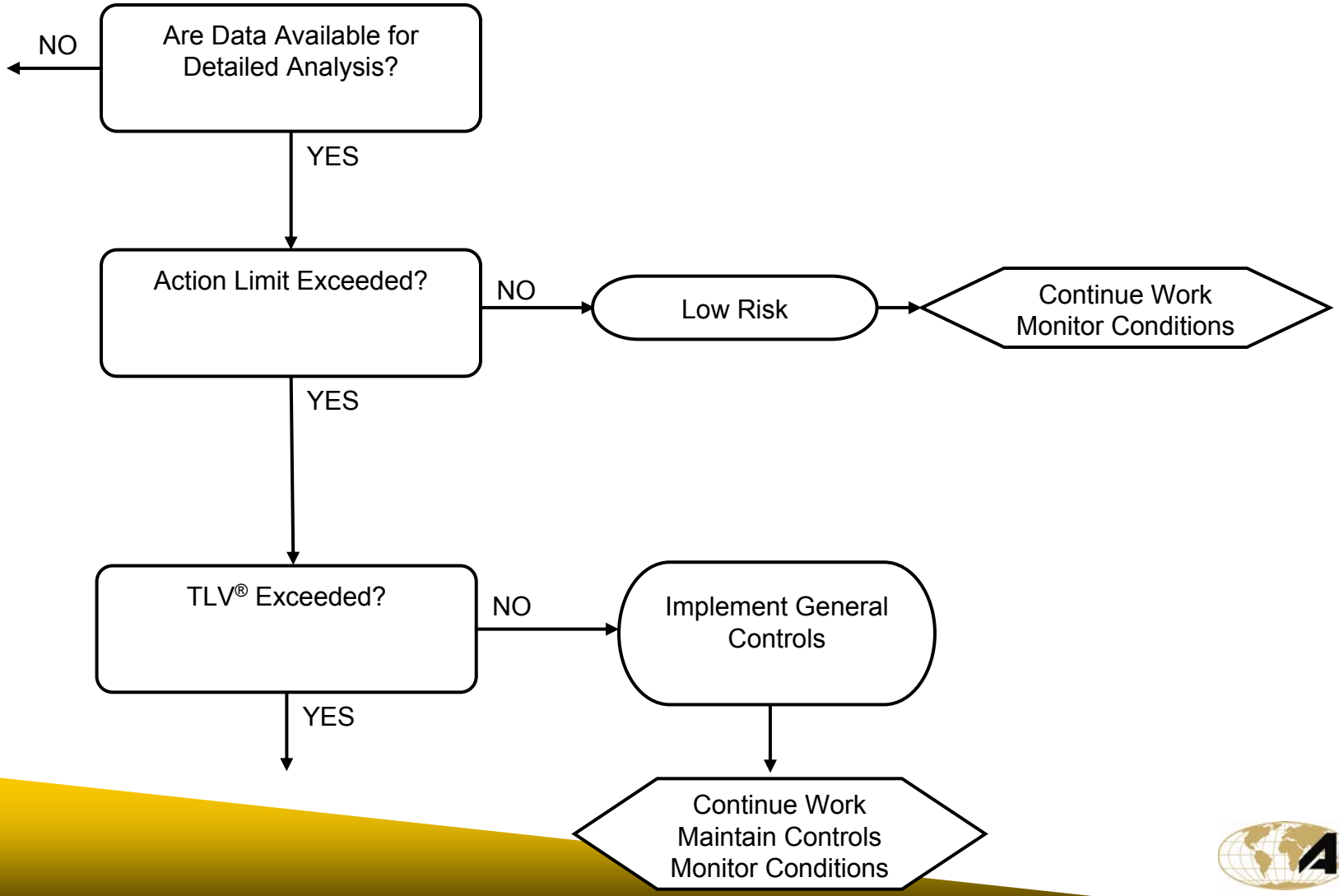
Note: *TLVs® and BEIs®* Book rounds these numbers to the nearest 0.5 °C-WBGT

Screening TLV®

%Work	L	M	H	VH
75 to 100	30.8	28.2	--	--
50 to 75	31.2	29.0	27.6	--
25 to 50	31.8	30.1	28.8	27.9
0 to 25	32.3	31.3	30.5	29.8

Note: *TLVs® and BEIs®* Book rounds these numbers to the nearest 0.5 °C-WBGT

Detailed Analysis



Task Analysis

- Breakdown by Location
- Breakdown by Homogeneous Activities
- Time Assigned for Each Location/ Activity

Metabolic Rate Categories

- Light
  - ✓ 180 W
  - ✓ sitting, standing, light hand/arm work
- Moderate
  - ✓ 300 W
  - ✓ walking, moderate lifting
- Heavy
  - ✓ 415 W
  - ✓ heavy materials handling
- Very Heavy
  - ✓ 520 W
  - ✓ pick and shovel work

Potential Error

- **Broad Range**
- **Over-Estimation**

ISO Estimation Method

Earlier Methods in NIOSH Criteria Document

Components of Metabolic Rate

- ✓Basal (Base) Metabolism (B)
- ✓Posture (P)
- ✓Type of Work (W)
- ✓Walking (D)
- ✓Climbing (C)

Total Metabolic Rate (M) = B + P + W + D + C

Clothing Adjustments to WBGT

$WBGT_{measured}$

\+ Clothing Adjustment

$WBGT_{eff}$

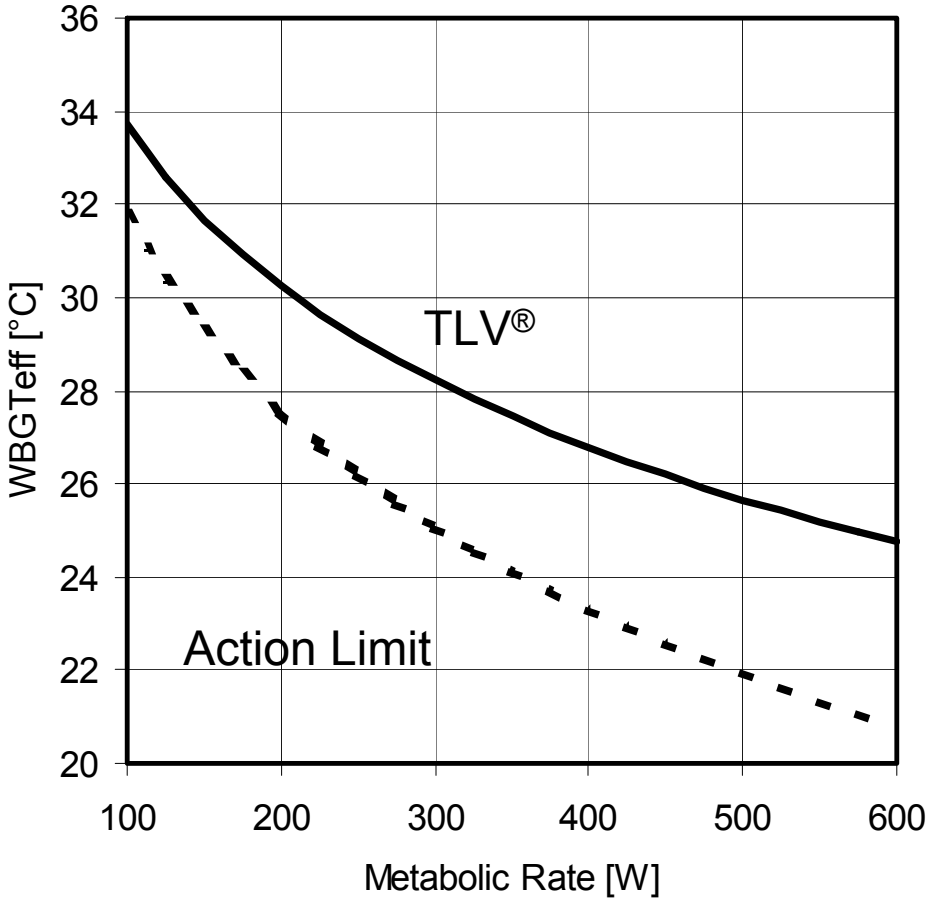
Time-Weighted Average

$$\text{TWA-WBGT}_{eff} = \frac{\text{WBGT}_{eff1} \times t_1 + \bullet\bullet\bullet + \text{WBGT}_{effn} \times t_n}{t_1 + \bullet\bullet\bullet + t_n}$$

$$\text{TWA-M} = \frac{M_1 \times t_1 + \bullet\bullet\bullet + M_n \times t_n}{t_1 + \bullet\bullet\bullet + t_n}$$

Over one to two hour time period.

Where is the job?

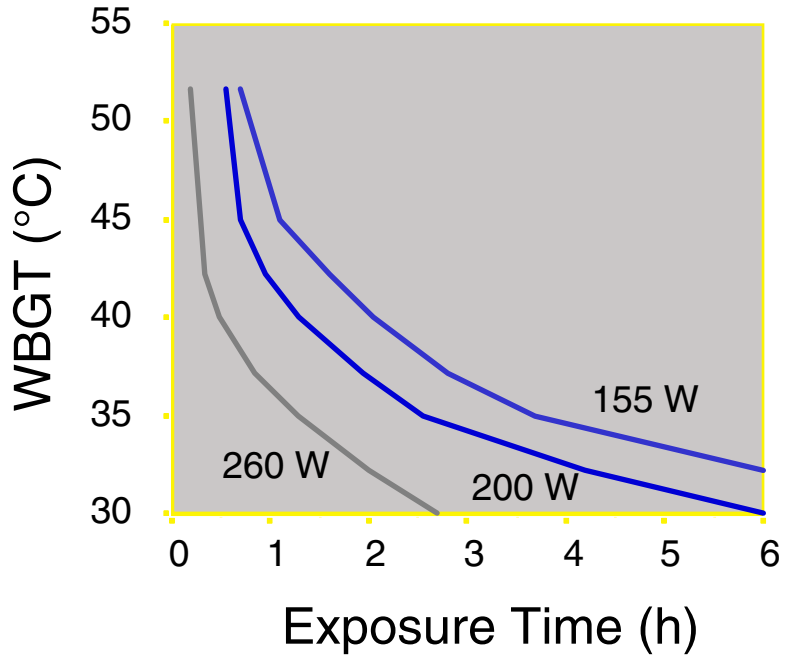


Job Risk Factors

- Traditional
  - ✓Environment
  - ✓Work Demands
  - ✓Clothing Requirements
- Plus Time

Empirical Time Limits

US Navy PHEL Charts



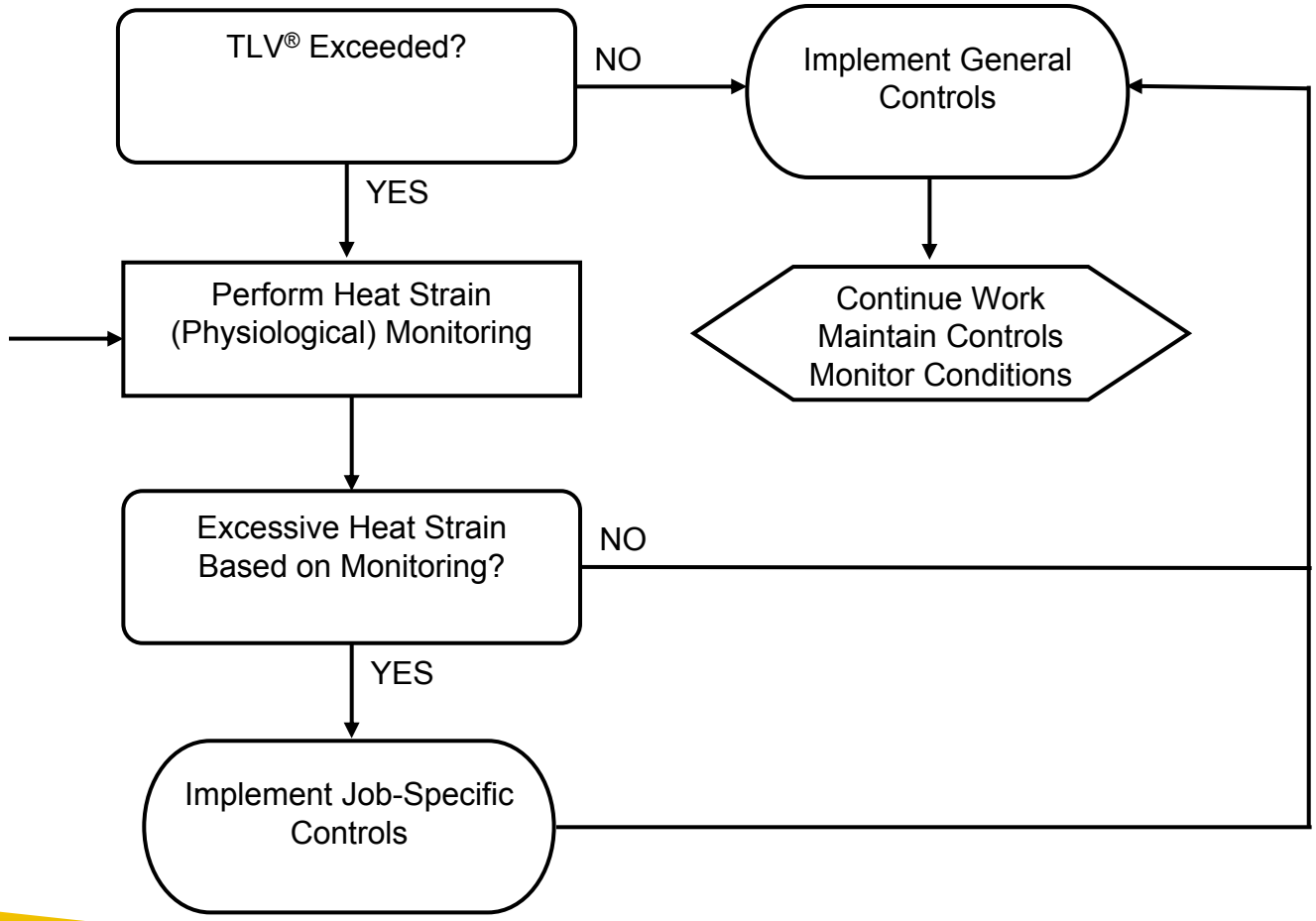
Rational Time Limits

- ISO 7933 (2004)
- PHS: Predicted Heat Strain

Heat Strain Monitoring

When working above the TLV® or under conditions when a detailed analysis cannot be performed.

Heat Strain Monitoring



Body Core Temperature

- Acceptable Limit
  - ✓Acclimatized, Healthy, Experienced: 38.5 °C
  - ✓Unacclimatized and Unselected: 38 °C
- Oral Temperature
  - ✓No recent drinks/food, mouth closed
  - ✓Core is Oral plus 0.5 °C

Heart Rate

- Sustained heart rate greater than (180 - Age)
- Recovery heart rate greater than 120 bpm at one minute

Symptoms

- Sudden or severe fatigue, nausea, dizziness, or lightheadedness.

MEDICAL EMERGENCY

- Disorientation, irritability, malaise, chills, unconscious.

Patterns of Strain

- No pattern of excessive strain
- Pattern of excessive strain

Under Study*

- Ergonomics
  - ✓ Hand-Arm Vibration
  - ✓ Localized Fatigue
- Lasers
- Nonionizing Radiation
  - ✓ Light and Near Infrared
  - ✓ Radiofrequency and microwave radiation
  - ✓ Static Magnetic Fields
  - ✓ Ultraviolet Radiation
- Cold Stress

*Refer to the ACGIH® website for the up-to-date list. This list is evergreen and can change during the year.

Thank You

Thanks to
the Committee members

BEI® Committee Update Feasibility Assessments

Larry K. Lowry
Chair, BEI® Committee
The University of Texas Health Center at Tyler

Topics for discussion

- BEI® Committee Activities
- Basis of BEIs®
  - ✓TLV®-CS
  - ✓Health effects
- BEI® development process
- Feasibility assessments
- Examples

BEI® Committee Activities

- 45 substances with BEI® determinants
- 17 substances with negative feasibility assessments

2005 Actions

- 14 substances and 3 other issues Under Study (as of 4/3/06)*
- 6 NIC (2 for new substances, 4 to update BEIs®)

*Refer to the ACGIH® website for the up-to-date list. This list is evergreen and can change during the year.

BEI® Committee Activities

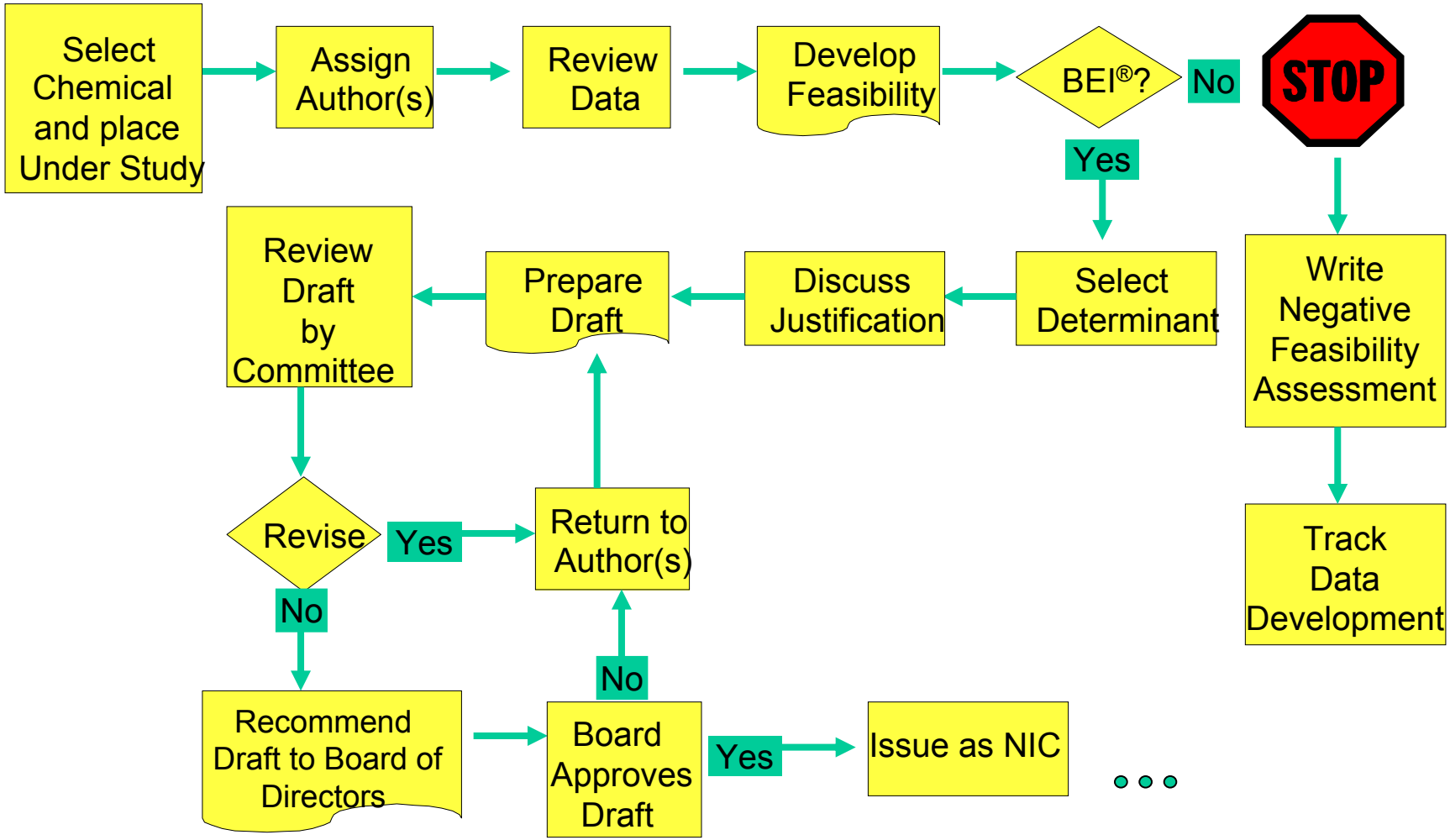
2005 Actions (cont.)

- 2 new *Documentation* updates w/o change to BEIs®
- 2 Adaptations
  - ✓1,3-Butadiene
  - ✓2-Propanol
- 1 new feasibility assessment – Methyl Formate

Basis of BEIs®

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

BEI® Development Process



What are feasibility assessments?

- An initial assessment of the quantity and quality of data for a possible BEI®
- An initial written assessment
  - ✓Is there sufficient data to establish a BEI®?
- A means to manage critical Committee resources

Criteria for feasibility assessments

- Use and use trends
- Availability of data for a BEI® basis
- Data on occupational routes of exposure and the selection of determinants
- Data on metabolism and rates of excretion
- Health risks
- Analytical methods

What now?

- Positive feasibility assessment
  - ✓Proceed with the development of a BEI®
- Negative feasibility assessment
  - ✓Listed in the *TLVs® and BEIs* ® book – chemical considered
  - ✓Stimulate interest and new data for possible future BEIs®

Negative Feasibility Assessments

- Acrylonitrile (1994)
- Antimony (1996)
- Beryllium (2002)
- Chlorpyrifos (1996)
- 1,4-Dichlorobenzene (1994)
- 2,4-Dichlorophenoxyacetic acid (1994)
- 2-Ethyl hexanoic acid (2001)
- Hydrazines (1994)

More negative FAs

- Inorganic borates (1995)
- Manganese (1995)
- Methyl t-butyl ether (1993)
- Methyl n-butyl ketone (1995)
- Methyl formate (2005)
- Nickel (1996)
- Selenium (1995)
- Trimethylbenzene (1999)
- Vinyl chloride (2002)

Format for BEI® Feasibility Assessment Document

- Occupational exposure and use
- Health risks
- Toxicokinetics
- Biological sampling and methods
- Relationship to TLV® or health risks
- Summary
- References

Methyl Formate (2005)

- Use and occupational exposure
  - ✓ Increasing use as catalyst, binding agent
  - ✓ Traditional use: fumigant, solvent, intermediate
  - ✓ Vapor pressure 476 torr, inhalation risk
  - ✓ Standards/guidelines
    - OSHA PEL 100 ppm
    - ACGIH® and NIOSH TLV®/REL TWA: 100 ppm, STEL: 150 ppm
    - German MAK 50 ppm, no BAT

Methyl Formate-Health risks

- Animals
  - ✓Narcotic and pulmonary irritant, LD_{50} 1600 mg/kg, rabbit
  - ✓Variety of acute studies, most with no serious effects below 1500 ppm
- Humans
  - ✓One study (1958) visual disturbances, narcosis, irritation at 1500 ppm

Methyl Formate, Toxicokinetics

- No skin notation, but dermal exposure expected
- Metabolized to methanol and formate resulting in 2 formate molecules
- Metabolism not linear
- Elimination expected to be passive
- Kinetics: elimination complete 16 hrs after end of exposure

Methyl Formate

Biological sampling issues

- End of shift sampling indicated
- Both metabolites (methanol and formate) produced endogenously, a background level or “B” notation
- Formate elevated in smokers, and after eating high protein and carbohydrate meals

Methyl Formate and TLV®

- Berode et al. study of 2000
  - ✓Two foundries
    - Foundry 1, n=9, median exposures 58 ppm
    - Foundry 2, n=19, median exposure 47 ppm
  - ✓Volunteer study
    - N=20, median exposure 100 ppm
  - ✓Pre-, post-shift and next morning urine samples for MeOH and Formic acid

Results

- Formic acid in urine
  - ✓Pre-shift samples higher than controls
  - ✓Post-shift samples similar in both foundries and volunteers, no dose response
- Methanol in urine
  - ✓No difference in pre-shift specimens from controls
  - ✓Post-shift specimens similar in both foundries and volunteers. No dose response

Methyl Formate and Health Risks

- No studies found

Summary

- No BEI® proposed due to:
  - ✓Insufficient data on small numbers
  - ✓Lack of a dose response
  - ✓Non-linear kinetics
  - ✓High background due to exogenous metabolism

References

- 10 references to original research
  - ✓7 before 1985
  - ✓3 recent but with limitations
- 3 references to NIOSH or ACGIH® documents

ACGIH®

TLV®/BEI® Development Process

James H. Price
ACGIH®, Director of Science

Agenda

- Introduction to ACGIH®
- Statement of Position
- Conflict of Interest
- TLV®/BEI® Development Process and **Important Changes**
- Basis and Limitations of TLVs®/BEIs®
- Providing Input to ACGIH®
- Sources of Information

ACGIH®

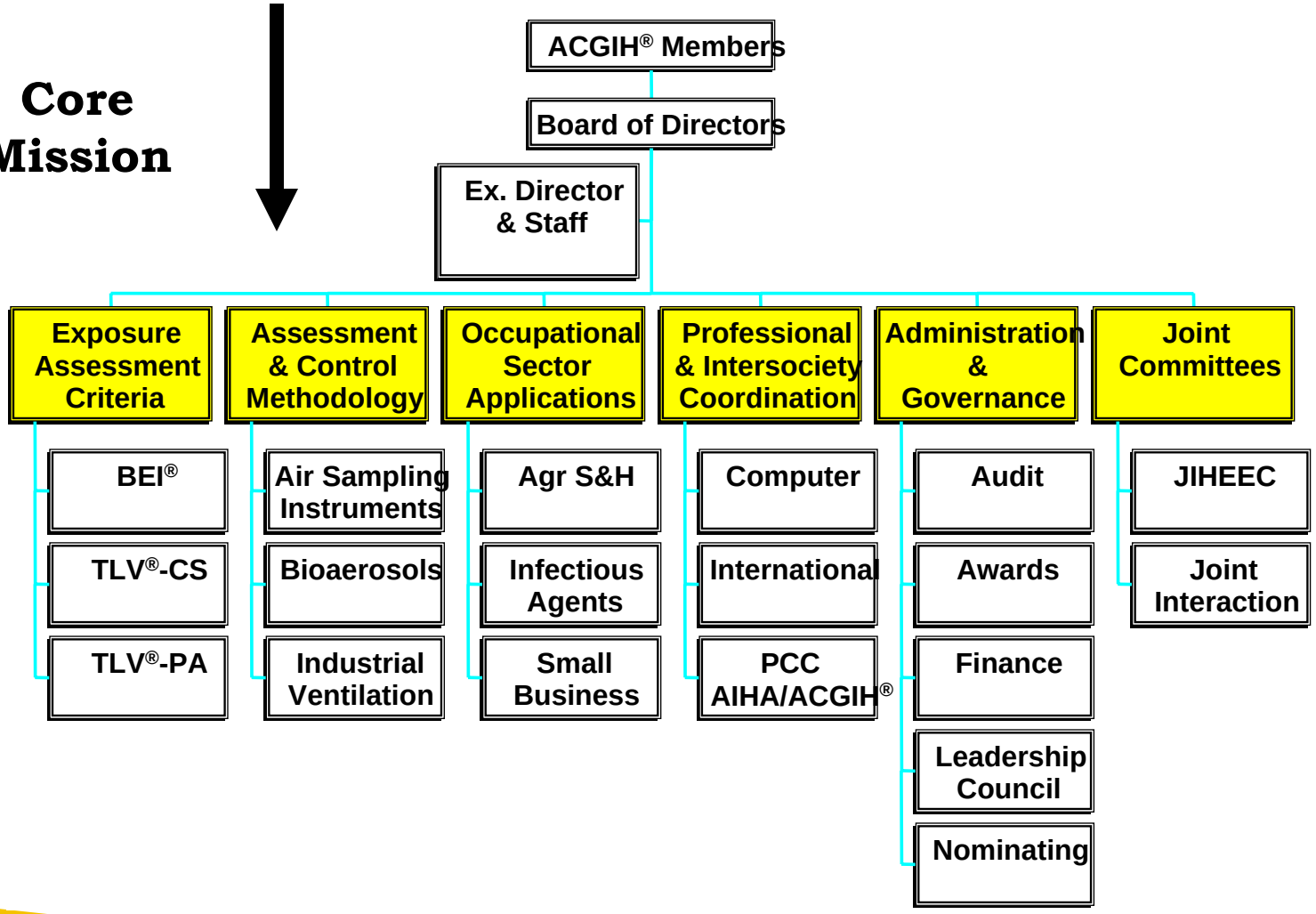
- New Position and Tagline for ACGIH®
  - ✓ **ACGIH® Brand Promise:**
    - •ACGIH® advances worker protection by providing timely, objective scientific information to occupational and environmental health professionals.
  - ✓**ACGIH® Tagline:**
    - •ACGIH®: Defining the science of occupational and environmental health
- ACGIH®: Membership-based organization
- ACGIH® Committees: Provide technical expertise and knowledge fundamental to ACGIH®

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 and environmental health professional
  - ✓ Committee expenses (travel) are supported by ACGIH®
  - ✓ Time is donated by the members

Committees

Core Mission



Policies and Processes for Limiting Conflict of Interest

Conflict of Interest

- Committee members serve as individuals, not as representatives of 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

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® —

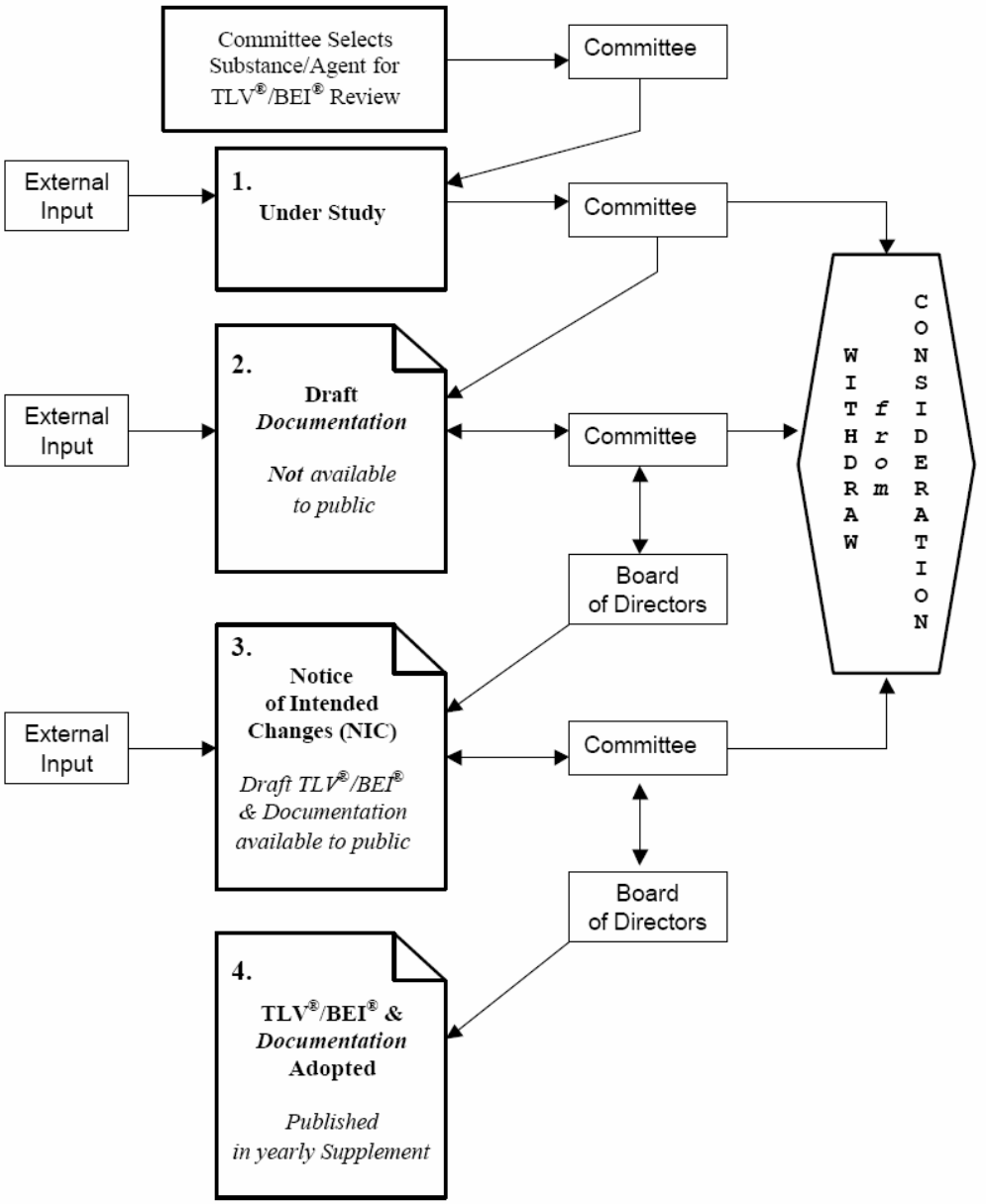
- Are an expression of scientific opinion.
- Are not consensus standards.
- Are based solely on health factors; it may not be economically or technically feasible to meet established TLVs® or BEIs®.

ACGIH® Statement of Position

TLVs® and BEIs® —

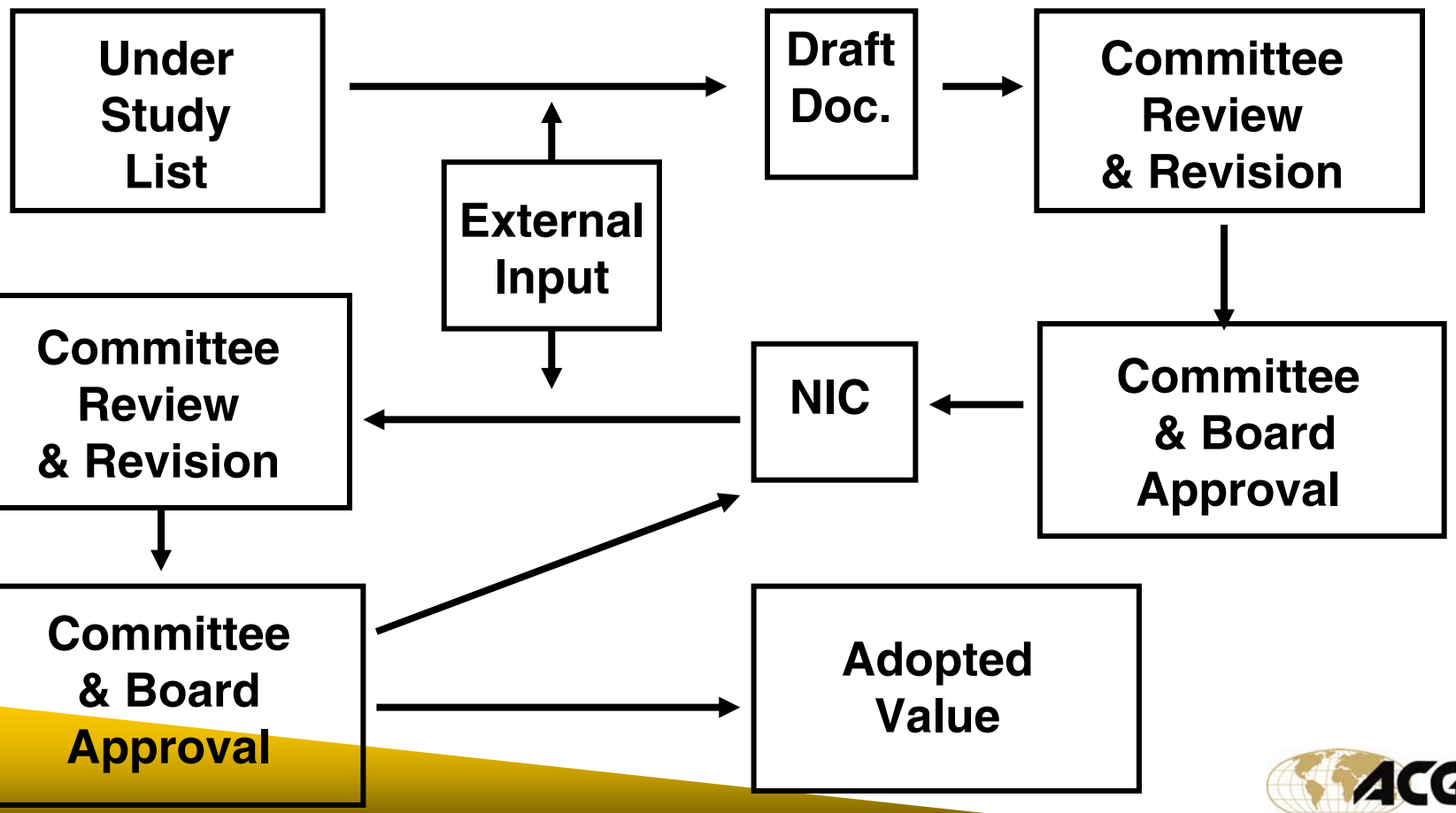
- Should **NOT** be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions.
- Can provide valuable input into the risk characterization process. The full written *Documentation* for the numerical TLV® or BEI® should be reviewed.

TLV®/BEI® Development Process



December 20, 2004

TLV® Development Process



TLV®/BEI® Development Process Important Changes

- **Under Study List:** Beginning 2006 provide additional information on status of substances and agents on Under Study List.
- **NIC and NIE Comment Period:** Beginning 2007 limit comment period to firm six-month period, running from February 1 to July 31 of each year.

Under Study List Change - 2006

- Continued Practice: Publish general Under Study List by February 1 of each year
- Added Practice beginning 2006: Publish updated two-tiered Under Study List by July 31 of each year
  - ✓ Tier 1: Substances and agents that may move forward as an NIC or NIE in upcoming year
  - ✓ Tier 2: Substances and agents that will not move forward, but will either remain on, or be removed from list in upcoming year
  - ✓ Two-tier list will remain for balance of year
- Above practice: Will start over each year
  - ✓ General list by February 1
  - ✓ Two-tiered list by July 31

NIC and NIE Change - 2007

- Restructuring comment period to ensure receipt of comments in time for full consideration
  - ✓Comment period closes July 31 for that year's Committee deliberations regarding outcome for possible adoption of a NIC or NIE.
  - ✓Comment period runs from February 1 to July 31.
  - ✓Draft *Documentation* available for review during this full six month comment period.
- Ongoing Process
  - ✓ACGIH® reviews all comments regarding substances/agents on Under Study, on NIC or NIE or currently adopted BEIs® or TLVs®
  - ✓Comments received after July 31 for a NIC or NIE will be considered in the following year.

Basis of TLVs®/BEIs®

Scientific Literature

- Published/Peer Reviewed Science (Principal Source)
- Reviewed 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

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)*
- *TLVs® and BEIs®* 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 Committees Operations Manuals
- ACGIH® Annual Presentation at AIHce

Questions/Discussion