Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB)

A Literature Review and Critical Analysis

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
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FOREWORD

When the U.S. Congress passed the Occupational Safety and Health Act of 1970 (Public Law 91–596), it established the National Institute for Occupational Safety and Health (NIOSH). Through the Act, Congress charged NIOSH with recommending occupational safety and health standards and describing exposure levels that are safe for various periods of employment, including but not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience. NIOSH communicates recommended standards to regulatory agencies (including the Occupational Safety and Health Administration [OSHA]), health professionals in academic institutions, industry, organized labor, public interest groups, and others in the occupational safety and health community through criteria documents. Yet limited resources, incomplete data, and the ever-expanding inventory of chemical hazards in the workplace and global commerce make it infeasible to develop standards for all possible hazards. Consequently, NIOSH has also been tasked with assessing and providing technical solutions and promising intervention strategies to protect the safety and health of workers.

One such emerging strategy has gained increasing attention among safety and health practitioners: a qualitative risk characterization and management strategy, also referred to as control banding (CB). This strategy groups workplace risks into control bands based on evaluations of hazard and exposure information. The utility of CB is recognized by a number of international organizations, and widening interest can be gauged by the growing literature describing qualitative risk assessment and management strategies. Despite limitations, in the absence of recommended standards, CB may be a useful strategy for assessing and controlling occupational hazards as part of a comprehensive safety and health program.

This document is generated from literature reviews of recent developments describing such exposure-characterization and risk-management strategies in occupational settings. In particular, this document summarizes the literature describing qualitative risk assessment and strategies of risk management. The intent of this review is to provide a broad description of qualitative strategies to reduce risk of exposure to occupational hazards, recognizing that a deliberate and extensive review of the literature on this topic will help guide decisions for where CB applications may be most effective. Also important is finding where limitations in our understanding may require additional research or modification or may preclude the use of CB strategies altogether. In meeting these objectives, this document intends to inform its audience—mostly occupational safety and health practitioners, researchers, policy and decision makers, employers, and workers in potentially hazardous work places—of the concepts of CB and the promise it holds as a tool for use within a broader comprehensive occupational safety and health program.

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EXECUTIVE SUMMARY

The majority of chemical substances in commerce have no established occupational exposure limits (OELs). In the absence of established OELs, employers and workers often lack the necessary guidance on the extent to which occupational exposures should be controlled. A strategy to control occupational exposures that may have value when there are no relevant OELs is known as control banding (CB). CB is a qualitative strategy for assessing and managing hazards associated with chemical exposures in the workplace. The question about the utility of the CB strategy for workplaces in the United States has been raised, warranting a critical review of its concepts and applications. This report is the result of a review of the published literature and related proceedings on CB.

The conceptual basis for CB is the grouping of chemical exposures according to similar physical and chemical characteristics, intended processes/handling, and anticipated exposure scenarios (amount of chemical used and how workers would be exposed). Based on these factors, appropriate control strategies (that is, risk management options) are determined for each of these groupings. In one of the least complex forms, a four-level hierarchy of risk management options for controlling exposures to chemicals includes—

1. good occupational hygiene practices, which may be supplemented by use of appropriate personal protective equipment (PPE)
2. engineering controls, including local exhaust ventilation (LEV)
3. containment
4. seeking specialist advice

To determine the appropriate control strategy, one must consider the characteristics of a particular chemical substance and the potential for exposure (based on quantity in use, volatility [for liquids], or dustiness [for solids], and the relative hazard as described in what is known as a risk phrase, or R-phrase). Determining potential exposures for airborne particulates or vapors involves characterizing the process or activity in which the chemical substance is used. Work processes help in assigning the chemical substance to a CB. These CBs provide guidance for various control options and recommendations for PPE based on a qualitative assessment of the chemical exposure.

The published literature on CB revealed different models, each with varying levels of complexity and applicability. The utility of qualitative risk management strategies such as CB has been recognized by a number of international organizations. Widening interest in this strategy can be gauged by the growing literature describing elements of qualitative risk assessment and management strategies and in some cases, very well-developed models of practice. This report attempts to capture the state-of-the-science of CB as reflected in research and practice. From the published literature and information gleaned from proceedings of recent international workshops, symposia, and conferences on this subject, the following major themes related to CB have emerged:

- Factors influencing the evolution of qualitative risk characterization and management of occupational hazards
- Strategies of practice
- Applicability and limitations of practice
- Needs for future research, evaluation, and validation

These themes are based on interpretations of current studies and an understanding of the topic. By providing the appropriate background information and resources, this literature review can serve as a means to educate employers, workers, safety and health practitioners, and other audiences about the concepts of CB and to stimulate further dialogue about its potential usefulness in the United States.

The scope of this document includes CB strategies, presented within the context of qualitative occupational risk management concepts. The risk management strategy associated with CB is characterized by selection and implementation of appropriate control solutions, often in the absence of OELs, to reduce work-related exposures that may lead to occupational disease, illness, and injury. The use of R-phrases or their equivalents in the Globally Harmonized System (GHS) for Classification and Labeling of chemicals in CB is a useful practice, but it is not intended to replace OELs, exposure assessment, or classic Industrial Hygiene protocol (i.e., hierarchy of controls) on which CB is based. This review indicates that CB is a potentially valuable tool for risk management of some chemical agents and other occupational hazards; however, continued research and validation efforts are needed. Investigation and application of CB principles to other hazardous agents also appear warranted. If CB is to be useful in the United States, it is recommended that the following actions occur:

1. Increase awareness and standardization of concepts associated with CB.
2. Ensure validation of qualitative risk assessment and management strategies, tools, and control-focused solutions.
3. Coordinate efforts for developing, implementing, evaluating, and disseminating qualitative risk assessment and risk management strategies to improve awareness and utility of task-specific, hazard-control guidance.
4. Foster national and international coordination on applications for control-focused solutions for high-risk tasks, industries, and small businesses.
5. Consider CB models for broader application to address additional workplace hazards (e.g., more complex chemical exposures, dermal exposure hazards, ergonomic hazards, other physical hazards). The CB process should be expanded to include occupational safety components to address injury and illness prevention.
6. Incorporate economic analyses into the process of selecting exposure control methods, with the goal of developing a more complete understanding of the relationship between the hierarchy of controls and their cost effectiveness.

In summary, this review and analysis have led to recognition of the following key messages:

- Control banding is a potentially valuable tool for risk management of source chemical agents and other occupational hazards.
- Despite limitations, in the absence of OELs, CB may be a useful strategy for assessing and controling occupational hazards as part of a comprehensive safety and health program.
- CB is not meant to be a substitute for OELs.
- The use of CB does not alleviate the need for environmental monitoring and industrial hygiene expertise.
- CB strategies may be useful for providing hazard control guidance to small and medium size enterprises (SMEs); larger businesses may find CB strategies of greatest utility for prioritizing hazards and for hazard communication.

Additional development, evaluation, and discussion are required before widespread implementation of CB in the United States can be recommended. This document is intended to set the stage for that discussion. At this time, the existing toolkits for CB may not be appropriate for the United States and will need modification before being applied. Critical is the need for a dynamic system that incorporates changing factors over time for both control implementation and managerial oversight. It is recommended that a taskforce of safety and health professionals, labor and management, and government representatives be established to advance the research and development needs for CB in the United States.

CONTENTS

ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BOHS	British Occupational Hygiene Society
CB	control banding
CEFIC	Conseil Européen de l'Industrie Chimique (European Chemical Industry Council)
CGS	control guidance sheet
CHIP	Chemical Hazard Information and Packaging
CIA	Chemical Industry Association
COSHH	Control of Substances Hazardous to Health
CS	control strategy
dB	decibels
DREAM	Dermal Exposure Assessment Method
EASE	Estimation and Assessment of Substances Exposure
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EMKG	easy-to-use workplace control scheme for hazardous substances
EPA	U.S. Environmental Protection Agency
EPL	exposure predictor bands for liquids
EPS	exposure predictor bands for solids
ES&H	Environmental Safety and Health
EU	European Union
GHS	Globally Harmonized System for Classification and Labeling of chemicals
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HCS	Hazard Communication Standard
HSE	Health and Safety Executive (of the United Kingdom)
ICBW	International Control Banding Workshop
ICCT	International Chemical Control Toolkit
IH	industrial hygiene
ILO	International Labor Office
INRS	Institut National de Recherche et de Sécurité
IOHA	International Occupational Hygiene Association

IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
ITG	International Technical Group
KCT	Korean Control Toolkit
KOSHA	Korean Occupational Safety and Health Agency
LEV	local exhaust ventilation
LOAEL	lowest observed adverse effect level
MAK	Maximale Arbeitsplatzkonzentration (maximum concentration of a substance in the ambient air in the workplace)
MSDS	Material Safety Data Sheet
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
OEB	occupational exposure band
OEH	Occupational and Environmental Health
OEL	occupational exposure limit
OHSAS	Occupational Health and Safety Assessment Series
ORM	Occupational Risk Management
OSHA	Occupational Safety and Health Administration
PPE	personal protective equipment
ppm	parts per million
PRIMAT	Psychosocial Risk Management toolkit
R-phrases	risk phrases
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RSC	Royal Society of Chemistry
S-phrase	safety phrase
SME	small and medium enterprise
SOBANE	Screening, Observation, Analysis, Expertise
SQRA	Singapore's Semi-Quantitative Risk Assessment
TLV	Threshold Limit Value
TWA	time-weighted average
U.K.	United Kingdom
WHO	World Health Organization
WHOCC	WHO Collaborating Centers
WIND	Work Improvement in Neighborhood Development
WISE	Work Improvement in Small Enterprises

GLOSSARY

control banding (CB): A strategy that groups workplace risks into control categories or bands based on combinations of hazard and exposure information. The following four main CBs have been developed for exposure to chemicals by inhalation:

Band 1: Use good industrial hygiene (IH) practice and general ventilation.
Band 2: Use local exhaust ventilation.
Band 3: Enclose the process.
Band 4: Seek expert advice.

This qualitative strategy to assess and manage risk focuses resources on exposure controls and describes how strictly a risk needs to be managed.

COSHH Essentials: A CB strategy developed by the British Health and Safety Executive (HSE) to assist small- and medium-sized enterprises in complying with Control of Substances Hazardous to Health (COSHH) regulations. The COSHH Essentials guidance is available in both a published document and in a Web-based model known as *e*COSHH Essentials [www.coshh-essentials.org.uk].

KjemiRisk: Assessment of chemical health risk based on experience and practice in the Norwegian oil industry.

Occupational Risk Management (ORM): The process of using a combination of knowledge, training, and resources of IH practice to address hazards in the workplace. This process may encompass the use of a variety of toolbox strategies, which are defined below, (and within these, toolkits), including qualitative risk assessment and control-focused strategies to minimize hazardous exposures.

Toolbox: A collection of strategies for the control of worker exposures and may be comprised of multiple toolkits. The toolbox concept is presented as a receptacle of various toolkits used to address various workplace hazards associated with specific industries and tasks. As such, the toolbox provides a mechanism for managing occupational risk and is currently referenced as an ORM or CB toolbox. Toolboxes with relevance for ORM in the United States include the broad (Environmental Safety and Health Toolbox), the industry-specific (Construction Toolbox), and the occupation-specific (Hair Dressers Toolbox).

Toolkit: A narrowly defined, solutions-based strategy for the control of worker exposures that is focused to a discrete task or series of tasks.

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1

Challenges of Traditional Risk Management Using Occupational Exposure Limits

The traditional approach to protecting worker health was pioneered in the late 19th century when the first occupational exposure limits (OELs) were established in Germany [Jayjock et al. 2000]. Sampling and analysis of airborne contaminants was performed, and results were compared with OELs. In 1946 the American Conference of Governmental Industrial Hygienists (ACGIH) published its first list of exposure limits for 148 chemicals, then referred to as Maximum Allowable Concentrations and renamed to Threshold Limit Values (TLVs) in 1956 [ACGIH 2007]. In the following decades, this sampling-and-analysis approach to risk management was adopted by many of the industrialized nations and, as a result, contributed to the improvement of working conditions, increased span and quality of life for workers, and decreased compensation costs. As a case in point, for the years 1972 and 2000, records from the U.S. Department of Labor, Bureau of Labor Statistics, indicate a reduction in occupational injuries and illnesses per 100 workers from 10.9 cases to 6.1 [Swuste and Hale 1994; NIOSH 2002, 2004]. However, the proportion of injuries and illnesses related to chemical hazards is not known.

Strict reliance upon sampling and analyzing airborne contaminants and comparing results with OELs has become increasingly difficult in recent decades because of the growing number of hazardous chemicals. The increasing number far outweighs the ability and resources—of government and other agencies external to chemical manufacturers—to determine associated OELs. To address this concern, the European Commission promulgated regulations known as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which would shift the burden of proof of chemical safety to manufacturers and would apply to most chemicals in commerce [EC 2001].

Also contributing to the increasing difficulty to protect worker health is the large variability in exposure measurements, both within and between workers. Because of these challenges, individual companies, trade associations, and government agencies have developed innovative strategies to protect both worker health and the environment.

2

Problems Implementing Measures to Limit Workplace Exposures

To control workplace exposures to hazardous chemicals, in the late 1980s the United Kingdom Health and Safety Executive (HSE) developed a simplified strategy to assess health risks in the workplace called Control of Substances Hazardous to Health (COSHH). Despite much optimism that these regulations would "bring greater emphasis on the assessment of risks to health in industry" [Parker 1989], their effective implementation met many challenges [Winterbottom 1987]. An unpublished survey of 2,000 companies, taken shortly after COSHH promulgation, showed "widespread ignorance of the new regulations and their implications among smaller concerns…" [Seaton 1989]. Through the 1990s, there were many reports of deficiencies and needs of many workplaces in complying with COSHH regulations, particularly in healthcare settings [Hutt 1994; Menzies 1995; Fraise 1999; Barker and Abdelatti 1997; Cooke et al. 1991; Harrison 1991; Waldron 1989; Aw 1989].

In an effort to understand better the problems with implementation of COSHH, HSE conducted market research to characterize industry's perception of OELs and the degree to which decisions on control measures were affected by OELs [Topping et al. 1998; Tischer 2001b]. Telephone interviews were conducted about chemical use, sources of information, risk management, and understanding of COSHH and OELs among 1,000 randomly selected chemical users and 150 safety and health representatives of trade unions. The majority (75%) of respondents worked at facilities with fewer than 10 full-time workers, mirroring the makeup of British industry, although the majority of trade union representatives worked at companies employing more than 100 workers. The findings follow:

- Decisions on control measures were based largely on information from suppliers and on personal experience.
- Most respondents took measures to protect workers, primarily by making personal protective equipment (PPE) available, followed by process controls. This finding indicates that failure to comply results more from lack of knowledge than from unwillingness to meet the requirements.
- Only 35% of the respondents were aware of COSHH; only 19% truly understood OELs.
- Trade union representatives tended to have greater understanding

of COSHH and its requirements than the chemical users from small firms.

- Larger chemical companies and occupational safety and health professionals understand the COSHH requirements, yet “many small firms wanted to be told exactly what they need and do not need to do” [Topping 2001].

According to Oldershaw [2003], the problem of failing to understand and comply with COSHH regulations and OELs was greater for microenterprises (<5 workers).

- Microbusinesses are not just smaller versions of larger businesses; unlike big business, they cannot afford occupational safety and health specialists.
- OELs may be of no practical use to microbusinesses.
- Measurement of workers’ exposure to chemicals is usually not possible because of cost, lack of availability, and difficulty in interpretation and application to microbusinesses.

These findings likely apply in the United States because the employment composition of U.S. businesses is similar to that of the United Kingdom.

Topping et al. [1998] concluded that, given the widespread lack of understanding about OELs, generation of additional lists of OELs would not be cost effective and that OELs should be limited to widely used substances of concern. Consequently, recognizing that OELs and other information about the chemical (e.g., physical properties, use) could be used to recommend appropriate control measures, these authors suggested a reappraisal of the traditional OEL system. Thus the birth of control banding.

3

The Origins of Control Banding for Chemical Agents

In the late 1990s the advancements made since the 1970s in risk and control strategies were combined to result in a simple but powerful concept:

Health Hazard + Exposure Potential → Generic Risk Assessment → Control Strategy

This equation indicates that information about the health hazard and exposure associated with a chemical substance and its use can be used to perform a qualitative risk assessment and determine the appropriate risk management or control strategy.

Control banding (CB) is a strategy for qualitative risk assessment and management of hazards in the workplace. The strategy involves a process to group workplace risks into control bands based on combinations of hazard and exposure information. CB strategies are not intended to be predictive exposure models.

The earliest CB strategies evolved based on the premise that, although workers may be exposed to a number of chemicals, only a few (generally four or five) categorical approaches exist to protect them (e.g., occupational exposure limits [OELs]). These strategies linked the hazard of a chemical substance, usually determined by a simple measure of toxicity, to a suite of control measures. Though this literature review focuses on chemical risk, CB strategies are expanding into other areas, such as physical hazards, ergonomics, and psychosocial factors.

CB has grown from a number of qualitative and semi-quantitative risk assessment strategies that began to appear in the 1970s [Money 2003; Lewis 1980; AIChE 1994; Nauman et al. 1996]. Examples of key elements in evolution of relevant strategies are presented in Table 1. Similarities are evident in these strategies because they borrowed elements from each other and built upon previous efforts [Money 2003] and because ideas were exchanged among occupational health practitioners and scientists in the pharmaceutical and chemical industries, governmental agencies, and professional and trade associations.

The influence of the pioneering efforts of the U.S. pharamaceutical industry in the 1980s and 1990s, including the origins of the concept of performance based exposure control limits (PBECLs) [Naumann et al. 1996], are undeniably tied to the evolution of CB strategies. Because such concepts were also quickly taking hold at the same time elsewhere among groups like the Royal Society of Chemistry and the Chemical Industry Association, it is sometimes difficult to distinguish the sources of additional advances. The professional interactions were such that CB concepts were evolving rapidly through technical exchanges of U.S. and European groups.

Table 1. Key elements in the evolution of qualitative occupational risk management and CB* concepts and their references in the literature

Element(s)	References
Safety risks from major facilities: risk matrices combining severity and frequency of event	ICE 1985; AIChE 1992
Simplified strategy for workplace health risk assessment (COSHH[†])	HMSO 1988
Application of safety risk concepts to workplace health (in laboratories): (*1*) categorization of hazard using R-phrases, (*2*) simple strategy to estimate exposure in laboratories or a workplace risk matrix using both to identify appropriate control solutions	RSC 2003; Money 2003
Health risk assessment for laboratories	RSC 2003, 1996
Use of hazard ratings (e.g., for prioritizing IH[‡] monitoring, installing engineering controls, selecting PPE[§])	Henry and Schaper 1990
Relationship between risk phrases (R-phrases) and OELs[¶]	Gardner and Oldershaw 1991
Use of carcinogenic ranking of aromatic amines and nitro compounds to suggest practical workplace controls	Gardner and Oldershaw 1991; Crabtree et al. 1991; Money 1992a; CIA 1993
Application of the RSC strategy beyond laboratories (e.g., the pharmaceutical industry); these strategies use R-phrases and simple algorithms to estimate exposures and combine both to suggest controls, representing the "first use of CB concepts for wider use in industry" [Money 2003]. These sector-specific strategies led to the idea that hazard classification could provide a basis for generic exposure control standards [Money 2003] and went beyond original categorization of carcinogens to include other toxic endpoints (e.g., CIA[††] [1993]). (Note: Strategies used in the pharmaceutical industry now include lacrymators, highly toxic substances, reproductive hazards, irritants, sensitizers, and mutagens [Tait 2004].)	Naumann et al. 1996; Money 1992a; CIA 1993
Application for specific product classes and families, allowing more detail in a more limited setting (ranking of carcinogens and linking with facility design and safe handling guidelines)	CIA 1992; Money 1992b
Health risk assessment for product classes and families. The CIA [1993] includes a table for colorants that includes hazard category (14), hazard classification (e.g., toxic, corrosive), associated R-phrase, guideline control level (8-hour TWA[‡‡]), and a separate set of recommendations for each hazard category.	Naumann et al. 1996; CIA 1993; HSE 2001

(Continued)

Table 1 (Continued). Key elements in the evolution of qualitative occupational risk management and CB* concepts and their references in the literature

Element(s)	References
Setting OELs and OEBs[§§] for pharmaceutical agents	ABPI 1995
Further development of RSC strategy	RSC 2003
Additional proposals for generic OELs[‡] or control strategies based on hazard categorization	ABPI 1995; CIA 1997; TRG 1996
Marketed chemicals in general	Russell et al. 1998; Brooke 1998; Maidment 1998; HSE 1999, 2000, 2001
Health risk assessment for industry	HSE 1999; IOM 2005
Safety, health, and environmental risk assessment for users of chemicals	UIC 1999
Strategies for the tiered and targeted risk assessment of chemicals	ECETOC 2002
Work Improvement in Small Enterprises (WISE)	ECETOC 2002
Work Improvement in Neighborhood Development (WIND)	ECETOC 2002

Adapted from Money 2003.
*CB=control banding
†COSHH= Control of Substances Hazardous to Health
‡IH=industrial hygiene
§PPE=personal protective equipment
¶OEL=occupational exposure limit
**RSC= Royal Society of Chemistry
††CIA=Chemical Industry Association
‡‡TWA=time weighted average
§§OEB=occupational exposure band

Development and implementation of a CB strategy requires five actions: creation of the strategy, its application, the installation and operation/maintenance of controls, postcontrol monitoring, and failure analyses at each step of the CB process, as follows:

Suppliers

- Assign risk phrase (R-phrase) (see Section 3.2.3) or other toxicologic rating to a substance.
- Assign R-phrase to appropriate hazard band (see Table 4).
- Report R-phrase on safety data sheets.
- Consider hazard statements of the Globally Harmonized System for Classification and Labeling (GHS) of chemicals.
- Determine boiling point for liquid substances and preparations.
- Establish better terms to discriminate low, medium, and high potential exposures for airborne particulates.

Users

- Acquire complete understanding of the strategy, including R-phrases, quantity of substance in use, and dustiness/volatility of substance.
- Construct strategy to combine quantity in use, dustiness/volatility, and other determinants, to predict exposure band.
- Use hazard information with task activities to determine the control guidance level.
- Select Control Guidance Sheet (CGS).
- Install/operate controls to reduce exposures.

Validation of a CB model will require that these activities be considered.

3.1 Core Principles of Control Banding

According to Money [2003], one basic tenet for CB is the need for a method that will return consistent, accurate results even when performed by nonexperts. Identifying key exposure determinants without relying on sophisticated sampling methods is an important step towards satisfying this requirement. Other core CB principles follow:

- The strategy must be understandable by workers to facilitate risk evaluation and communication.
- The strategy must be user-friendly.
- Required information (e.g., material safety data sheets [MSDSs]) must be readily available to workers, particularly at small and medium enterprises (SMEs).
- Guidance on how to apply the strategy must be practical.
- Workers must have confidence in the strategy and the output advice it provides.
- Presentation of advice must be transparent and consistent.

3.2 Possible Components of Control Banding

A key component of a CB strategy is the ability to categorize easily the toxicity of substances using information that is readily available, linking hazard category (1–4), hazard classification (e.g., toxic, corrosive), associated R-phrase, guideline control level (8-hour TWA), and recommendations for each hazard category.

3.2.1 Hazard Category

Traditionally, the pharmaceutical industry has established OELs for active ingredients using risk assessment methods. However, Naumann et al. [1996] investigated a new strategy because of (1) the increasing potency of these chemicals, (2) difficulties in establishing no effect levels for certain products, and (3) challenges in sampling and analyzing contaminants at very low exposure levels.

3.2.2 Hazard Classification

Based on biosafety-level concepts used in laboratories and on toxicologic and pharmacologic properties of chemicals used for various operations, Naumann et al. [1996] distinguished five hazard categories (performance-based exposure control limits). Compounds were placed into these categories based on the pharmaceutical active ingredients and on the engineering controls and administrative procedures known to be effective in controlling exposures to the necessary level.

3.2.3 R-Phrases

In 1998 the Annals of Occupational Hygiene published a series of papers outlining a CB strategy in which the hazard categorization, or hazard band, was combined with the potential exposure to determine a recommended level of control strategy. The hazard posed by exposure to a chemical via a given route was ranked according to the chemical's European Union (EU) risk phrases (R-phrases), and potential for exposure was estimated by the quantity in use and the volatility of liquids or, for solids, potential for airborne particulates.

Gardner and Oldershaw [1991] presented a comparison of the American (ACGIH TLVs) and German OELs to the designated R-phrases for volatile organic substances [EEC 1987]. They found (1) that the distributions of the OELs for substances consistent with grouping by R-phrase 23 (toxic by inhalation) and R-phrase 26 (very toxic by inhalation) best fit a log-normal distribution and (2) that the means for both R-phrase groups were not significantly different. They concluded that the R-phrases, though not OELs, could be referenced as Pragmatic Exposure-Control Concentrations and applied as guides to control inhalation exposure when other information was lacking. The authors suggested that such CB would be useful in cases where toxicologic data on substances were incomplete or the ability to understand such data was limited.

Tischer [2001a] noted that the assignment of R-phrases to hazard bands, described in Table 4, was still being debated in Germany in 2001 and might well result in a different model than the HSE characterization.

3.3 Early Models of Control Banding

Interest in CB strategies on the part of the European occupational hygiene community was spurred by the introduction of the Chemical Agents Directive in 1998 [Money 2003; EC 1998]. Several CB strategies resulted [Money 2003], along with other developments noted for their impact on chemical risk management:

1. REACH would shift the burden of proof of chemical safety to industry and would apply to most chemicals in commerce [EC 2001].
2. The European Chemical Industry Council (CEFIC) exposure management system [Money 2001] provides a guidance tool for SMEs to collect workplace exposure data that, when coupled with hazard information, delivers advice on risks and risk management, recommending whether exposure monitoring should be conducted (see Figure 1).
3. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) tiered and targeted risk assessment [ECETOC 2002] could aid in the registration of a large number of chemicals under REACH (see Figure 2). Tier 0 screens out chemicals not presenting an immediate risk to humans or the environment. Tier 1 identifies uses of a chemical that may present further risks to be investigated in greater depth in Tier 2. In Tier 1, margins of exposure are compared with generic OELs for the chemical's hazard category.

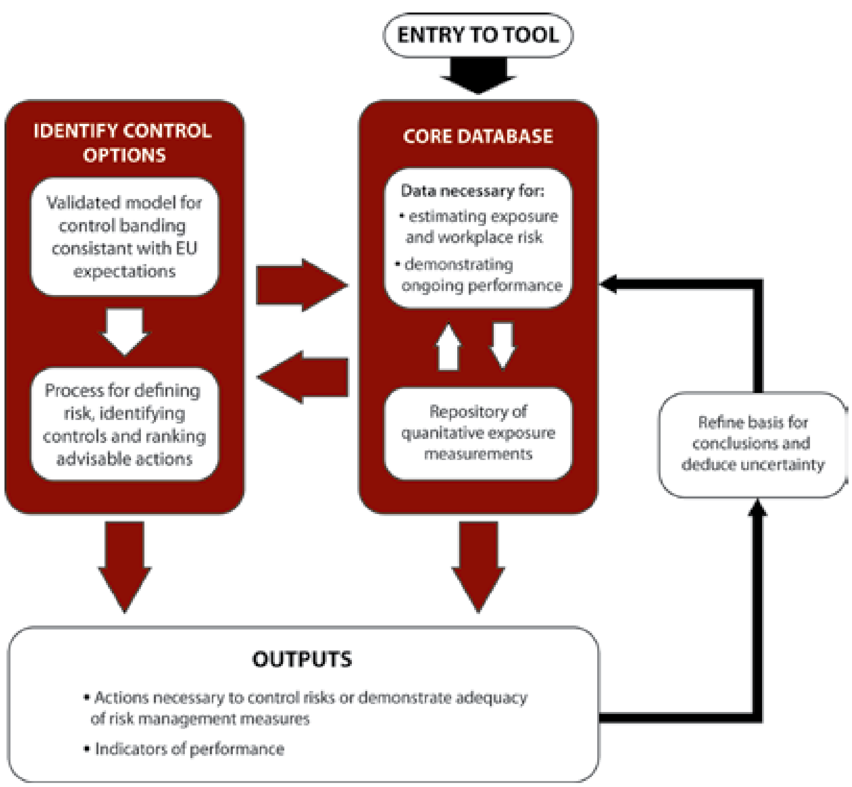

Figure 1. The CEFIC exposure management system. Source: Money 2003 (with permission from Oxford University Press, British Occupational Hygiene Society, and the author).

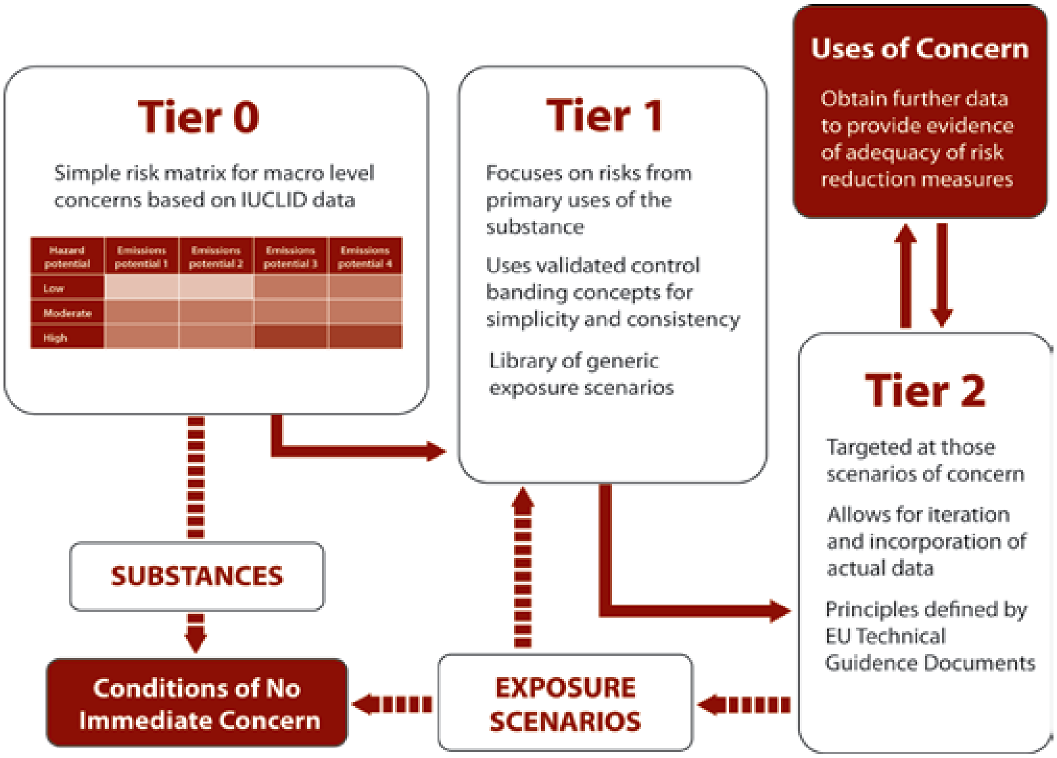

Figure 2. Key elements of the ECETOC strategy for the tiered and targeted risk assessment of chemicals. Source: Money 2003 (with permission from Oxford University Press, British Occupational Hygiene Society, and the author).

Tier 2 assessments are conducted in accordance with EU risk assessment principles.

3.3.1 COSHH Essentials

In the United Kingdom, the Health and Safety Executive (HSE) was faced with the reality that OELs would never be developed for a large number of chemical substances and that users at the majority of SMEs did not understand and did not have the resources to meet COSHH requirements to conduct risk assessments for chemicals used in the workplace [Topping et al. 1998; Menzies 1995; Palmer and Freegard 1996]. In response, HSE established a working group of key stakeholders—the U.K. Health and Safety Commissions' Advisory Committee on Toxic Substances—to develop a simple system of generic risk assessment [Topping 2001]. This strategy, which leads to selection of appropriate controls, was first published as *COSHH Essentials: Easy Steps To Control Chemicals* [HSE 1999].

HSE was faced with developing guidance that was practical for SMEs, based on readily available hazard information, and that was easy to use and understand. Figure 3 illustrates the general pattern of processing hazard information to derive appropriate control approaches, a pattern associated with the HSE model [Russell et al. 1998]. The model describes using R-phrases and simple predictors of exposure to conduct a generic risk assessment, which leads to

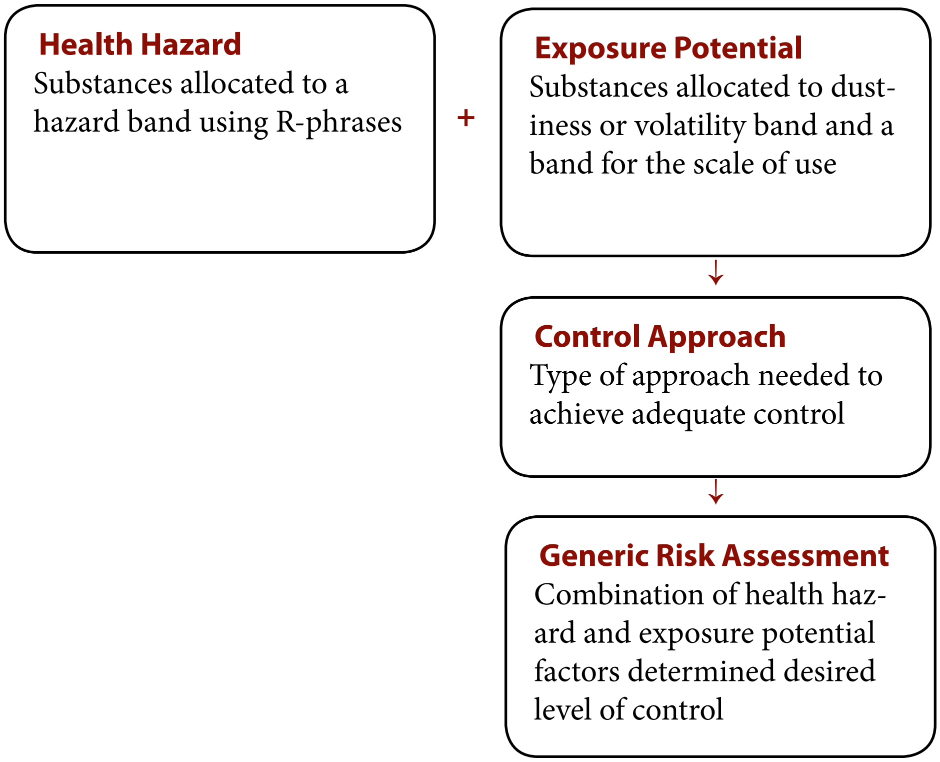

Figure 3. Factors used in HSE's core model [Russell et al. 1988].

straightforward recommendations on risk management (i.e., control strategies).

Because COSHH Essentials is limited to substances classified under Chemical Hazard Information and Packaging (CHIP) regulations, the model is not applicable to pesticides and pharmaceuticals nor is it applicable to process-generated hazards such as wood particulate and welding fumes. (Silica dust is also excluded, but has been addressed more recently with the HSE development of the silica hazard and task-specific guidance sheets.)

Hazard banding, exposure potential, and control methods are the key components of the COSHH Essentials strategy (see Figure 4).

COSHH Essentials is the most fully developed CB strategy for chemical assessment, and guides users in selecting the appropriate level of management based on the following:

- The type of task being performed (12 general levels)
- The assignment of the chemical substance to Hazard Band A–E (see Section 4.4 and Table 4), based on its hazard
- The volatility (3 levels) or potential for generation of airborne particulate (3 levels) of the chemical substance
- The quantity of the chemical substance used in the task (3 levels)

Control Approach 1—General ventilation. Good standard of general ventilation and good working practices.
Control Approach 2—Engineering control. Ranging from local exhaust ventilation to ventilated partial enclosure.
Control Approach 3—Containment. Containment or enclosure, allowing for limited, small scale breaches of containments.
Control Approach 4—Special. Seek expert advice.

Figure 4. Control approaches used COSHH Essentials [Russell et al. 1988].

COSHH Essentials then provides specific guidance in the form of a CGS for specific workplace procedures and the recommended CB. Hudspith and Hay [1998] agree with HSE to provide guidance in the form of CGSs, but they point out an additional obstacle to worker protection: communication barriers within companies. They recommend that HSE continue to stress the value of workforce involvement in safety and health issues. CGSs are available in paper format or in electronic database format on the Web at www.coshh-essentials.org.uk.

After an introductory passage titled "The sunset of exposure limits—and the dawn of something better?" [Ogden 1998], the Annals of Occupational Hygiene ran a series of articles [Russell et al. 1998; Brooke 1998; Maidment 1998] explaining the basic concepts of COSHH Essentials, toxicologic considerations, and occupational hygiene considerations.

COSHH Essentials is a valuable toolkit for protecting workers from airborne contaminants. In its original form it was limited to the inhalation route of exposure and to certain chemicals used in manufacturing (others being regulated in specific statutes). Work is ongoing to expand applications to other topics, including dermal hazards, process-generated hazards such as airborne crystalline silica, and asthmagens (see Section 6.0).

The COSHH Essentials builds on earlier strategies (as described below) [Naumann et al. 1996; CIA 1992, 1997; RSC 2003; Gardner and Oldershaw 1991; Money 1992a,b] but adds two significant developments: it is specifically developed for SMEs and it includes control advice.

3.3.2 France (Risk Potential Hierarchy)

The Institut National de Recherche et de Sécurité (INRS) research center in France reported on a system that uses simple and available information to prioritize risk assessment of chemicals at the company level, taking into consideration hazard and exposure factors (translated from French):

> This risk results from the conjunction of a hazard and an exposure. In the case of a chemical product, the risk corresponds to the toxicological properties of the product; the exposure is linked to a number of factors such as the quantity used, the conditions of use, the physical characteristics of the product, the means of prevention utilized, and the duration of exposure [Vincent and Bonthoux 2000].

Based on information derived from MSDSs and labels, chemicals are assigned to categories based on (*1*) hazard classification and labeling (I–V), (*2*) frequency of use (I–IV), and (*3*) quantity used (I–V). Quantity and frequency of use scores are combined to create a classification by potential exposure (I–V, based on expert opinion). The scores for hazard (D) and potential exposure (E) are combined based on the following equation:

$$\text{Product score} = 10^{(D-1)} \times 3.16^{(E-1)}$$

The resulting scores have been ranked by experts into three priority classifications (A=elevated, B=middle, and C=weak) that can be used at the plant level to prioritize chemical substances for further risk assessment. Internal validation of the model indicated overestimation in 19% of the cases and underestimation in only 1%. The authors concluded that another method of evaluation of the real risks at the workplace should be developed to complement this method.

3.3.3 Germany (Chemical Management Guide)

Germany is the third largest chemical producing nation in the world, and the largest chemical exporting nation [Adelmann 2001]. As such, it has taken measures to assist developing countries in managing chemicals by supporting implementation of the Rotterdam (prior-informed-consent) and Stockholm (Persistent Organic Pollutants) Conventions by building capacity and by conducting demonstration projects [Tischer 2002; Tischer and Scholaen 2003; Scholaen 2003]. Under its Convention Project on Chemical Safety, the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) has developed a Chemical Management Guide as part of its Pilot Project on Chemical Safety. The Chemical Management Guide describes a method to demonstrate and document how chemical safety in developing countries and SMEs can be improved and sustainability implemented in line with international standards. The guiding principles of the Chemical Management Guide include practicing sound management of chemicals, reducing company production costs, increasing product quality, protecting the environment, and ultimately reducing the risk to worker health. Its use has been implemented at sites in Argentina, Indonesia, and EU countries. (The guide is available via the Internet at www.gtz.de/en in English, French, and Spanish.) The GTZ Chemical Management Guide and training were also introduced as a pilot project in the United States in 2006 through a collaborative effort between the National Institute for Occupational Safety and Health (NIOSH), OSHA, the Kentucky Safety and Health Network, Murray State and Eastern Kentucky Universities, and local businesses in the Commonwealth of Kentucky [AIHA 2007].

Within the GTZ Chemical Management Guide, the first of three steps is to identify *hot spots* in a company's manufacturing processes (e.g., places where inefficient storage, handling, use, and disposal can be observed). Preparing a detailed chemical inventory is the second step. The last step is use of one or more of the following resources: basic risk assessment, description of control strategies, MSDSs, safety phrases for hazardous substances, and symbols for labeling hazardous substances. This strategy has been ground-tested in Indonesia and proved successful. Although CB may be too sophisticated for many small enterprises, field observations suggest that since the medium and larger enterprises have more MSDSs on site, they have a greater potential for conducting risk assessments using the International Labor Office (ILO) Chemical Control Toolkit (ICCT) [Tischer and Scholaen 2003].

Since 2005, another effort in Germany led by the German Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) has offered an easy-to-use workplace control scheme for hazardous substances (EMKG) as practical guidance for workplace risk assessment in SMEs [Packroff et al. 2006]. Applying information obtained from MSDSs to basic workplace conditions, the user of EMKG can derive control strategies to minimize exposure via inhalation or skin contact.

EMKG is similar to COSHH Essentials. The main differences between the two are some divergent allocations of R-phrases to hazard bands [German FMLS 2008] and a more detailed tool to assess dermal exposure [German FMLS 2006]. CGSs for typical tasks give guidance on precise control measures within the control strategy determined with the generic tool. In 2007 the generic control guidance sheets were supplemented with specific sheets for activities with chemicals in the rubber industry. Currently 36 CGSs offered on BAuA´s Web page are consistent with the analagous topics in COSHH Essentials. The EMKG offers nonregulatory guidance, but, like COSHH Essentials, is well supported by legal obligations and Codes of Practice from the tripartite Hazardous Substances Committee in Germany. In May 2008 an enhanced version of the scheme (EMKG 2.0) was launched on the BAuA Web site [Kahl et al. 2008]. EMKG 2.0 includes 300 additional substances with legal OELs in Germany. Users of the scheme begin the risk assessment with the OEL, which is aligned with a corresponding hazard band. Two possible practical implementations of the scheme are (1) to use the hazard group that directly relates to the target airborne concentration range that covers the OEL or (2) to use the hazard band below the OEL and the corresponding control strategy. In the first case the employer has to improve the observance of the OEL by applying workplace measurements, and in the second case the employer can waive workplace measurements.

The expansion of EMKG 2.0 to substances with OELs makes it adaptable for additional applications. EMKG can be used as a simple tool to derive exposure scenarios for substances to be registrated under the REACH regulation by using the derived no effect level, which is the REACH surrogate for an OEL. A more specific EMKG-based online tool is under development at BAuA to help producers and importers of chemicals to fullfil the REACH requirement to derive control strategies (CSs) and to recommend management measures (e.g., the corresponding CGSs).

Additional work in Germany relates to the GHS. A guideline to assist implementation of the chemical directive 98/24/EC [EC 1998] has been elaborated by a contractor of the European Commission and has been reviewed by an ad hoc working group on chemicals of the tripartite advisory board to German employment. This guideline is a recommendation to member states for implementation of 98/24/EC and is not mandatory. As of publication date of this review, the guideline was awaiting its final approval by the advisory body and then publication.

3.3.4 The Netherlands (Stoffenmanager)

Stoffenmanager, a Web-based tool for SMEs for working safely with chemical substances, factors exposure potential into its strategy through the use of an interactive chemical risk management method. It is available in English and Dutch at www.stoffenmanager.nl. Stoffenmanager was developed by ArboUnie and TNO Chemistry, a Dutch contract research organization. This tool was constructed by using "parts of methods from Germany, Austria, the United Kingdom, Sweden, and Finland" [Tijssen et al. 2004]. Stoffenmanager supports the requirements for maintaining inventory of hazardous substances, assessing and controlling risks in a risk inventory, obtaining a plan for control measures, making instruction sheets for the workplace, and helping to store chemicals according to guidelines. For the risk inventory, the employer uses R-phrases categorized according to COSHH Essentials. Then the employer completes a qualitative exposure assessment by responding to questions to determine the chemical's exposure class. The tool automatically calculates a risk score to complete the initial assessment of the health risk. The employer reviews the selection of various control measures based on the risk score, and chooses the most appropriate and effective one accordingly [Tijssen et al. 2004]. Stoffenmanager is currently generic, but the Dutch have plans to adapt it to fit into various industry sectors at a later date. Industry sector-specific tools would be very helpful and enhance its use [Tijssen et al. 2004].

3.3.5 Norway (KjemiRisk)

Developed through the cooperation of corporations within the Norwegian oil industry, KjemiRisk, based on experience and practice in this industry, is a strategy for the assessment of chemical health risk. The tool takes the following into account: physical properties of the chemical; the handling of the chemical; the appropriateness of the technical, organizational, and personal barriers established to control the chemical exposure; and the duration and frequency of the work task, using R- and S-phrases (safety phrases) as its bases. Chemicals are grouped into one of five health hazard categories based on R- and S-phrases. As part of the KjemiRisk application, 15 common tasks are defined, and the handling of the chemical, its physical state, duration and frequency of use, potential for exposure, and the appropriateness of controls in place are used in the conceptual strategy. The risk assessment is divided into two phases: the potential risk and the final risk. These are adjusted based on the reliability and appropriateness of the established controls. The risk assessment provides an evaluation of task-based work procedures that have the potential to cause illness related to lungs, internal organs, and skin [Smedbold 2004]. KjemiRisk is a rough risk assessment tool when used by line managers or safety and health generalists, and it is an expert tool when used by industrial hygienists. It is currently available in Norwegian and English as an individual or a network application when integrated with an appropriate server. Expansion of Web applications, increased reporting functionalities, and substitution of capabilities are currently being considered for improvement.

3.3.6 Belgium (Regetox and SOBANE)

A two-stage risk assessment strategy (Regetox) was developed and tested in Belgium [Balsat et al. 2002a,b, 2003] in response to the European Chemical Agents Directive 98/24/EC [EC 1998], which requires companies to assess and manage chemical risks in the workplace. To minimize the number of chemicals for which risk assessment must be conducted (and thus reduce costs), the first stage of the strategy uses the French (INRS) ranking of potential risk based on R-phrase, annual quantity in use, and frequency of use [Vincent and Bonthoux 2000], as described in Section 3.3.2. Only products receiving a rating of medium or high are carried forward to the second stage, which uses COSHH Essentials. When mixtures are being used, the risks are evaluated for each harmful component of the mixture by weight. For cases in which contaminants are generated during the process (e.g., aerosols generated during spray painting), the EASE (Estimation and Assessment of Substances Exposure) model is used. Feasibility studies conducted at two facilities revealed lacking or inadequate MSDSs. There was only one case in the two companies in which the strategy failed to reveal need for improvement in the work situation. The authors felt that simple examination of the work situation would have indicated the need for semi-quantitative risk assessment. Furthermore, they concluded that for companies not prepared to comply with the European Chemical Agents Directive the use of the Regetox strategy can be helpful; however, the Regetox strategy requires training of prevention advisors and planning to involve employers, staff members, and workers to assist in collecting basic information for the risk assessment.

The Screening, Observation, Analysis, Expertise (SOBANE) method is a four-level risk prevention strategy developed around 2004 by Professor Jacques Malchaire at the Université catholique de Louvain, Occupational Hygiene and Work Physiology Unit in Brussels, Belgium.

The objective of the screening stage is to identify the main problems at the worksite and solve the simple ones immediately. During the observation stage, the more complex problems from the screening stage are examined in more detail. Workers and management are assisted through the observation process by a nine-page guide. In analysis, if the problems remain after the first two stages, an occupational health practitioner carries out appropriate measurements to develop proper solutions. An expert is called in for the final stage to design a more sophisticated solution or improve an existing one.

3.3.7 Singapore (SQRA)

The Semi-Quantitative Risk Assessment (SQRA) was developed in Singapore by the Ministry of Manpower. The purpose of the SQRA is to help identify chemical hazards, evaluation exposure and its potential, determine risk level, and prioritize appropriate controls to address the identified risks. As the foundation for the SQRA, three methods are recognized for exposure evaluation: monitoring personal exposure, selecting exposure factors and parameters, and applying empirical and theoretical formulas to estimate exposures at the plant- or process-design stage. The ICCT, based on COSHH Essentials, was tested in parallel with applications of the SQRA to evaluate their utility and to perform comparisons based on theoretical and empirical aspects [Yap 2004]. Direct comparison of the two strategies can be stratified by their respective control strategies based on risk levels. The first control strategy of the ICCT (general ventilation) fits with SQRA risk level 1 (negligible risk) and level 2 (low risk), suggesting periodic reassessment and personal air monitoring requirements. The ICCT second engineering control strategy aligns with the SQRA level 3 (medium risk), indicating a need to implement and maintain controls, review the assessment every 3 years, and determine if training and personal air monitoring are necessary. The third control strategy for the ICCT (containment) is comparable with the SQRA level 4 (high risk), suggesting implementation of engineering controls, personal air monitoring and training, PPE requirements, and reassessment of risk after all controls are put into place. The ICCT fourth control strategy (special circumstances) aligns with the SQRA level 5 (very high risk), which directs users to consult specialists for advice, to comply with requirements for risk level 4, and reassess after controls are implemented.

In the theoretical comparison of the CB strategies, risk is calculated using variables of vapor pressure or particle size, ratio of the odor threshold to the applicable OEL, amount of chemical used and duration of work per week, and control measures. This result is then compared with the control strategy determined by the ICCT, given a direct evaluation of the consistency of the models because the ICCT does not take into account existing hazard control measures. To assess against the Toolkit's control strategy, the empirical comparison of the models uses actual personal air monitoring data that the SQRA method's risk level was based on. Selected processes at 27 SMEs received this comparison. The processes included metal working, paint manufacturing, chemical processing, printing, dry cleaning, and electronics industries. The results of the theoretical comparison indicate that the Toolkit and the SQRA method are somewhat consistent with a difference between the control strategy and risk level being one to two bands. In the majority of cases using the empirical comparison, it was determined that the ICCT estimates a higher risk than the SQRA, thereby suggesting a higher level of control [Yap 2004].

3.3.8 Korea (KCT)

The Korean Control Toolkit (KCT) for chemicals has been developed into a Web-based tool for SMEs by the Korea Occupational Safety and Health Agency (KOSHA). It is currently available through the KOSHA Web site at www.kosha.net/index.jsp; however, access is limited to members only. The KCT is a semi-quantitative assessment strategy that provides advice on controlling the hazards associated with specific chemicals. Currently the KCT is available for 12 chemicals, with plans to expand coverage to 30 chemicals that have frequently caused occupational diseases in Korea based on industrial disease statistics and epidemiologic investigations by KOSHA. The first survey effort on which the KCT is based took place in 516 systematically selected companies in 2006 for n-hexane, trichloroethylene, methyl bromide, dimethylformamide and n,n-dimethylacetamide, toluene diisocyanate and methylene diphenyl diisocyanate, and crystalline silica. Another set of six chemicals and 513 companies were surveyed in 2007. The chemicals were toluene, styrene, formaldehyde, acrylamide, lead, and nickel. Based on the results of these surveys, high-risk processes have been selected and appropriate controls developed.

The KCT was created by modifying the COSHH Essentials and the ICCT. To use the ICCT, the user may select 1 of the 12 chemicals from a display menu. The user will then enter the workplace conditions such as the R-phrase, quantity used, duration and frequency of use, and physiochemical properties. Based on the algorithm from the COSHH Essentials, the results will be displayed as a grade of risk (A–E) and a band class (1–4). The user selects the specific control tool, and the process-specific control suggestions are then provided. KOSHA has discovered that the current MSDSs do not communicate well the hazard information to employees because they are written in scientific and technical terminology rather than in simplified language. Therefore, the final component of the KCT project is to modify the MSDSs.

4

The Architecture on Which Control Banding is Based

The concept of CB grew out of the qualitative and semi-quantitative approaches that have been practiced as a complement to the traditional model of air sampling and analysis.

4.1 Occupational Exposure Bands and Occupational Exposure Limits

In their guidelines for safe handling of colorants (second version), the Chemical Industry Association (CIA) explored the five elements of CB: hazard category (1–4), hazard classification (e.g., toxic, corrosive), associated R-phrase, guideline control level (e.g., 8-hour TWA, OEL), and recommendations for each hazard category [CIA 1993] and took "the concept forward to link hazard categorization and exposure banding with structured guidelines for control of occupational exposure" [Guest 1998].

For chemicals without official OELs, the COSHH Approved Code of Practice advises facilities to set self-imposed working standards, but neither industry nor government could follow the recommendation. Three reasons for this inability include (*1*) the technical complexity of establishing OELs, (*2*) the lack of adequate toxicologic databases and experts, and (*3*) the sheer volume of substances covered in the European Inventory of Existing Commercial chemical Substances [Guest 1998]. Because industry and government could not follow the recommendations, the CIA developed chemical categorization guidelines [CIA 1997] for their member organizations.

Built on the 1993 CIA guidance and the work of Gardner and Oldershaw [1991], the new guidelines [CIA 1997] incorporate the CHIP R-phrases, guideline control levels, and data on adverse effects in humans (see Table 2). The purpose of these guidelines was to provide a simple, broad-based, integrated strategy for use by CIA members in classifying hazards. The categories were to be called occupational exposure bands (OEBs) and would only be developed when there were no other in-house, national, or international OELs. They would define the upper limit of acceptable exposure. Because the number of CSs is usually limited to perhaps three or four levels, this strategy was designed to cover six orders of magnitude plus a special category (shown in Table 3). The upper limits (OEB C for particulates, OEB D for gases/vapors) were designed to reflect *good occupational hygiene practice* and a threshold of particulate concentration: 10 mg/m^3. If not classified elsewhere, a particulate concentration equal to or greater than 10 mg/m^3 is defined as a substance hazardous to health, and COSHH applies.

Table 2. Selected criteria for assignment of particulate to OEBs*

OEB	Selected criteria for substances†
Category X	Should be handled according to COSHH‡ carcinogens ACoP§ (R45, R46, R49)
(Special considerations)	Respiratory and skin sensitizers (R42, 43)
	Substances showing adverse effects in humans at low dose: <0.05 mg/m^3 by inhalation or <0.01mg/kg/day¶
OEB A	Toxic to reproduction (R60, R61)
	Very toxic (R26, R27, R28)
OEB B	Toxic to reproduction (R62, R63)
	Toxic (R23, R24, R25, R48)
	Unknown toxicity not assigned to higher OEB
OEB C	Harmful (R20, R21, R22, R48)
	Dust not allocated to higher OEB

Source: Based on Guest 1998
* OEB=occupational exposure band.
†This rating system is opposite that used in the COSHH Essentials rating.
‡COSHH=Control of Substances Hazardous to Health
§Approved Code of Practice, current edition is from HSE 2002.
¶kg body weight

Table 3. OEB* and corresponding concentrations for gases and vapors (ppm) and dust (mg/m^3)

	Gases and vapors (ppm†)	Dusts (mg/m^3)
Category X	Special considerations	
OEB A	<0.5	<0.1
OEB B	0.5–5	0.1–1
OEB C	5–50	1–10
OEB D	50–500	Not applicable

Source: Derived from Guest 1998; CIA 1997
*OEB=occupational exposure bands
†ppm=parts per million

The main selection criteria for assignment to the bands were information about adverse effects in humans and the CHIP R-phrases, which were readily available in the United Kingdom. Classification was based on the most sensitive endpoint for which data are available. Table 3 summarizes the criteria.

Table 3 is based on a more comprehensive table from Guest [1998], in which three considerations are stressed: (1) reclassification of substances if/when more data become available, (2) other routes of exposure, and (3) requirements for health surveillance and occupational hygiene measurements for substances with limited toxicologic data. Guest says testing is necessary to "provide a high degree of confidence in the OEBs predicted." The relationship between OEBs and OELs shows that "the majority of substances . . . were correct to an order of magnitude and that, for approximately five percent of the substances reviewed, the OEB was less stringent than the OEL." Guest suggested that the possibility of the latter observation was acceptable due to the margin of safety built into most OELs and that the OEB guideline values were preferable to inadequate standards of control.

COSHH regulations on inhaled substances that do not have Workplace Exposure Limits require employers in the United Kingdom to control exposures to "a level to which nearly all the population could be exposed, day after day, without adverse effects on health" [ABPI 1995;HSE 2002]. The pharmaceutical industry, especially during product development, typically encounters many substances for which data to develop OELs are insufficient [ABPI 1995]. Thus the level of exposure recommended varies with the stage of product development and toxicity testing.

4.2 Levels of Facility Design and Construction Based on Carcinogenicity of Chemicals to Be Used

In an early report linking toxicologic data to an appropriate level of control, Money [1992b] presented a structured approach to design and operation of a chemical plant based on a carcinogenic ranking system for aromatic amines and nitro compounds. This broad approach ensures that appropriate measures are in place to control risks of exposure to these chemicals from both routine and abnormal operations; however, the report does not provide specific solutions and controls. The author suggests that the strategy, appropriate for both inhalation and skin contact, should be applicable to similar strategies ranking relative hazards of chemicals [Henry and Schaper 1990; Gardner and Oldershaw 1991; Woodward et al. 1991].

Money's system described by four categories of carcinogenic potential is based on a system of six developed by Crabtree et al. [1991] for which they considered both carcinogenic potency and weight of evidence. (Money argued that although distinguishing the potencies of different substances is important, in reality such a separation is artificial and impractical.) For these four levels of carcinogenic potency, Money identified four levels of controls, with each level building on the previous in its complexity and stringency.

After he considered eliminating known carcinogenic substances or substituting with safer alternatives, Money decided on the following levels for design and construction of facilities based on considerations of carcinogenicity.

- **Level 1** For all chemicals (regardless of carcinogenic potential), good basic IH practice, with a plant built to sound industrial standards.
- **Level 2** For suspected animal carcinogens of low to moderate potency, greater reliability and integrity than Level 1, plus containment of the plant (or isolation of specific processes) by physical or procedural measures, and possibly with health management systems.
- **Level 3** For moderate levels of suspected human carcinogens with slight carcinogenicity to animals, or low doses of proven or suspect animal carcinogens, a segregated plant with detoxification, high reliability and containment, and regular technical audits.
- **Level 4** For low levels of proven human carcinogens, suspect human/highly carcinogenic to animals carcinogens, or very low levels of proven or suspected animal carcinogens, an automated plant with bulk or semi-bulk transfers, process control, and plant audits.

4.3 Exposure Assessment

Among the considerable amount of research involving exposure prediction which occurred throughout the 1990s, Burstyn and Teschke [1999] reviewed 13 experimental and 32 observational studies describing methods for studying exposure determinants. Exposure determinants identified in the studies included work tasks, equipment used, environmental conditions, and existing controls. Volume of product used received little attention, and even less was devoted to physical characteristics of chemicals in use. The exposure determinants were classified as factors that

1. Directly increase exposure (e.g., processes producing airborne contaminants)
2. Directly decrease exposure (e.g., local exhaust)
3. Indirectly increase or decrease exposure (e.g., work location)

Another example of early consideration of exposure determinants in a risk management model is the Stoffenmanager (Section 3.3.4), which approaches the use of exposure assessment in a banding strategy [Tijssen et al. 2004]. Incorporating a systematic consideration of descriptive workplace activities and environment, an exposure model [Cherrie and Schneider 1999] is used to estimate exposure; the resulting exposure estimate correlates with analytical exposure measurements across 63 jobs and different agents (asbestos, toluene, mixed particulate, and man-made mineral fibers).

4.4 Toxicologic Considerations [Brooke 1998]

Brooke outlined the following criteria for the toxicologic basis of the U.K. strategy:

1. It had to be simple and transparent so that SMEs would be able to understand and consistently use it.

2. It had to make the best use of available hazard information.
3. The control strategies it recommended had to vary according to degree of health hazard of a substance.

The R-phrases that are agreed upon throughout the European Union facilitated these criteria as they address all relevant toxicologic endpoints. Such an idea had been proposed previously [Gardner and Oldershaw 1991] and formed the basis of similar strategies [ABPI 1995; CIA 1997; RSC 2003]. Brooke noted three differences between the previous strategies (i.e., ABPI, CIA, and RSC) and that of HSE:

1. COSHH Essentials includes alignment between particulate and vapor target exposure ranges, and the strategy taken to relate target exposure ranges to dose-level cutoff values ensures adequate margins between exposure and health effect levels for particulates and vapors.
2. COSHH Essentials is based on achievement of exposure levels anywhere in the target range, whereas the CIA recommends that exposures should be maintained "as low as reasonably practicable" [ABPI 1995; Guest 1998; CIA 1997].
3. The COSHH Essentials strategy was compared with health-based OELs (the CIA strategy was also evaluated per Guest [1998]).

Brooke's article [1998] achieved two goals: (1) it explained the assignment of R-phrases to the Hazard Bands A–E used in the COSHH Essentials and (2) it compared these assignments with health-based OELs. Each hazard band, which is based on toxicologic considerations, covers a log (10-fold) concentration range. Because the relationship between the ppm (parts per million) concentration and the mg/m3 concentration of a vapor is a function of its molecular weight (and also temperature and pressure, though not discussed in this article), the working group that oversaw development of this chemical classification decided to adopt a pragmatic strategy and to align the exposure bands as seen in Table 4. However, it must be noted that due to this alignment, in mg/m3 terms, the concentration range for substances in vapor form is substantially higher than that for the substance in particulate form, for the same toxicologic hazard band.

In general, allocation of substances into hazard bands is influenced by presence of an identifiable dose threshold, seriousness of the resultant health effect, and relative exposure level at which toxic effects occur. If a substance has more than one R-phrase, the R-phrase leading to the highest level of control governs. See Appendix B for a more detailed explanation of allocation of vapors to hazard bands.

To evaluate COSHH Essentials, the R-phrases and resulting target airborne concentrations and the relevant health-based OELs were compared (U.K. and German MAK [Maximale Arbeitsplatzkonzentration (maximum concentration of a substance in the ambient air in the workplace)] values). This comparison was conducted for 111 substances with recent, scientific-based OELs from the U.K. and MAK and with identifiable thresholds (thus excluding

Table 4. Allocation of Risk phrases to hazard bands

Hazard band	Target airborne concentration range (Note 1)	Risk phrases
A	>1–10 mg/m^3 particulate; >50–500 ppm vapor	R36, R38, all particulates and vapors not allocated to another band (Note 2)
B	>0.1–1 mg/m^3 particulate; >5–50 ppm vapor	R20/21/22, R40/20/21/22
C	>0.01–0.1 mg/m^3 particulate; >0.5–5 ppm vapor	R48/20/21/22, R23/24/25, R34, R35, R37, R39/23/24/25, R41, R43
D	<0.01 mg/m^3 particulate; <0.5 ppm vapor	R48/23/24/25, R26/27/28, R39/26/27/28, R40 Carc. Cat. 3, R60, R61, R62, R63
E	See specialist advice	R40 Muta. Cat. 3, R42, R45, R46, R49
S: skin and eye contact	Prevention or reduction of skin and/or eye exposure	R34, R35, R36, R38, R41, R43, Sk (Note 3)

Note: COSHH (Control of Substances Hazardous to Health) Essentials is regularly reviewed to reflect any changes to risk phrases.
Source: Brooke 1998

Hazard Band E, see Table 5.) Regarding particulates, for 33 substances (100%), the OEL was within or higher than the target airborne concentration range of the hazard band. For vapors, for 76 substances (97%), the OEL was within or higher than the target airborne concentration range. Only two vapors had target ranges above the OEL. For one (dipropylene glycol monomethyl ether), the OEL of 50 ppm was on the border between Hazard Bands A and B. The second (methyl ethyl ketone peroxide) had a very small toxicologic database, and the OEL was established based on analogy. Although concluding that the R-phrases can be used effectively to allocate substances to hazard bands, Brooke [1998] stresses that the process is not intended as a replacement for the health-based OEL-setting process.

Concerns have been raised about the accuracy of the EU classification of chemical substances [Ruden and Hansson 2003]. In a comparison of EU classifications for acute oral toxicity for 992 substances with those available in the Registry of Toxic Effects of Chemical Substances, Ruden and Hansson found that 15% were assigned too low a danger class and 8% too high. They were unable to determine the cause because of insufficient transparency of the process. It should be noted that Registry of Toxic Effects of Chemical Substances is

Table 5. Overall results for comparison of COSHH* Essentials hazard bands with health-based OELs†, using all hazard bands

	Dusts	Vapors	Total
Number of substances	33	78	111
Number for which OEL lies within target airborne concentration range of hazard band	14 (42%)	44 (56%)	58 (52%)
Number for which OEL is higher than target airborne concentration range of hazard band	19 (58%)	32 (41%)	51 (46%)
Number for which OEL is lower than target airborne concentration range of hazard band	0 (0%)	2 (3%)	2 (2%)
Number for which scheme recommends control equivalent to or better than that required by OEL	33 (100%)	76 (97%)	109 (98%)

Source: Brooke 1998
*COSHH=Control of Substances Hazardous to Health
†OEL=occupational exposure limit

merely a registry and does not necessarily provide an evaluation of chemical toxicity.

Brooke describes an important point regarding the proper use of the COSHH Essentials strategy:

> Given that the toxicologic basis which underpins the scheme relies on the use of R-phrases as the indicator of toxicologic hazard, the success of the scheme is crucially dependent on the accurate classification of substances by suppliers. It is the R-phrases applied to a substance or preparation which determine its allocation to a hazard band and thus the intended target airborne concentration range. Therefore, a responsible strategy to classification for all toxicologic endpoints is a key factor for the scheme to be used successfully to recommend control strategies which should, as far as possible, be appropriate to ensure that the hazardous properties of a substance are not expressed.

Equally important and essential to the successful implementation of CB strategies is the effort to standardize the categorization of hazards, a primary objective of the global harmonization initiative discussed in a later section.

4.5 Occupational Control Considerations [Maidment 1998]

In writing about the development of the control predictive strategy, Maidment stresses that, to control its complexity and applicability, the number of factors considered should be limited. The steps thus undertaken in developing the control predictive strategy are described below.

1. **Characterize Control Strategies** Control strategies can be collapsed into four main categories: general ventilation, engineering controls, industrial closed systems, and special controls.
2. **Characterize exposure potential** Characteristics of exposure potential can be summarized as those related to physical properties and those related to substance handling. With many parameters to consider, Maidment [1998] focused on the dustiness of solids and the volatility of liquids. The working group felt that three dustiness bands would adequately describe the properties of particulates and maintain the simplicity of the strategy: low, medium, and high. The volatility of liquids also can be in three bands—low, medium, and high. Placement into the appropriate band is accomplished by consulting a graph of boiling point versus operating temperature. Operational factors, or quantities used, were captured as the scale of the operation: small-, medium-, and large-scale.
3. **Develop exposure predictive strategy** This strategy was developed by combining bands for operational and physical exposure potential. They found that all combinations could be collapsed into four bands each for solids and liquids, as described in Tables 6 and 7.
4. **Establish relationship between exposure potential and hazard band** The working group then integrated the exposure predictor bands for solids (EPSs) and exposure predictor bands for liquids (EPLs) with the CSs 1–3, producing Tables 8 and 9.

   Because the strategy does not suggest the highest concentrations (i.e., >10 mg/m^3 for particulates, 500 ppm for vapors, which is near the highest HSE exposure limit of 1,000 ppm), the remaining five bands can be aligned with the five toxicologic hazard bands, as shown in Table 10.

Table 6. Definitions of EPS*

EPS	Description
EPS1	Gram quantities of medium/low dusty material
EPS2	Gram quantities of high dusty material; kilogram/ton quantities of low dusty material
EPS3	Kilogram quantities of medium/high dusty materials
EPS4	Ton quantities of medium/high dusty material

*EPS=exposure predictor bands for solids
Source: Maidment 1998

Table 7. Definitions of EPL*

EPL	Description
EPL1	Millimeter quantities of low volatility material
EPL2	Millimeter quantities of medium/high volatility material; m^3/liter quantities of low volatility material
EPL3	Cubic meter quantities of medium volatility material; liter quantities of medium/high volatility material
EPL4	Cubic meter quantities of high volatility material

*EPL=exposure predictor bands for liquids
Source: Maidment 1998

Table 8. Predicted airborne particulate exposure ranges (mg/m³)

Engineering CSs*	EPS4†	EPS3	EPS2	EPS1
CS1	>10	1–10	0.1–1	0.01–0.1
CS2	1–10	0.1–1	0.01–0.1	0.001–0.01
CS3	0.1–1	0.01–0.1	0.001–0.01	<0.001

Source: Maidment 1998
*CS=control strategy
†EPS=exposure predictor band for solids

Table 9. Predicted vapor-in-air exposure ranges (ppm)

Engineering CSs*	EPL4†	EPL3	EPL2	EPL1
CS1	>500	50–500	5–50	<5
CS2	50–500	5–50	0.5–5	<0.5
CS3	5–50	0.5–5	0.05–0.5	<0.05

Source: Maidment 1998
*CS=control strategy
†EPL=exposure predictor bands for liquids

Table 10. Relationship between exposure and hazard band

Exposure band—solid (mg/m³)	Exposure band—liquid (ppm*)	Hazard band
>10	>500	Not recommended
1–10	50–500	A
0.1–1	5–50	B
0.01–0.1	0.5–5	C
0.001–0.01	0.05–0.5	D
<0.001	<0.05	E

Source: Maidment 1998
*ppm=parts per million

5. **Substitute hazard band for exposure potential and invert strategy to produce control predictive strategy.** This produces an empirical model that can be used to predict the appropriate CS to achieve adequate control based on the hazard and the exposure bands (Tables 11 and 12).

In applying this strategy for truly short exposures (i.e., <30 minutes), the CS could be dropped by one level (e.g., from CS2 to CS1).

Even though this last strategy leans heavily on the work of previous models and strategies, it has a number of unique features, including an electronic version accessible via the Internet. In addition, it theoretically meets all six of Money's [2003] core principles: understandability, availability, practicality, user-friendliness, confidence on the part of users, and transparent, consistent output. Despite its attributes, validation and verification remain important requirements. Oldershaw [2003] has cautioned that the COSHH Essentials strategy could not be adopted uncritically by other countries; further, the strategy must be considered as a component supplemental to PPE, training, health surveillance, and other elements of a comprehensive safety and health program.

4.6 Providing Control Guidance to Users

CGSs form a key component of COSHH Essentials. The number of CGSs continues to grow to address the need for practical and effective guidance on control for COSHH Essentials users, particularly those in SMEs. Solbase, a databank of control solutions for occupational hazards, shows potential as a source from which CGSs could be developed. Using 535 new and existing solutions, Solbase has been tested throughout Europe, both for usability of the software and for suitability of the recommendations yielded [Swuste et al. 2003; Swuste 2002]. Most solutions relate to manual or material handling, noise and vibration, machine guarding, and other safety issues, with few addressing air contaminants. The databank can be queried either by production process or by hazard.

Table 11. Prediction of CS* from hazard band and exposure potential (solids)

Hazard band	EPS4†	EPS3	EPS2	EPS1
A	CS2	CS1	CS1	CS1
B	CS3	CS2	CS1	CS1
C	Special	CS3	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

Source: Maidment 1998
*CS=control strategy
†EPS=exposure predictor bands for solids

Table 12. Prediction of CS* from hazard band and exposure potential band for liquids

Hazard band	EPL4†	EPL3	EPL2	EPL1
A	CS2	CS1	CS1	CS1
B	CS2	CS2	CS1	CS1
C	CS3	CS3	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

Source: Maidment 1998
*CS=control strategy
†EP=exposure predictor bands for liquids..

5

Validation and Verification of Control Banding Strategies

A significant issue for the implementation of CB is the accuracy of the decision logic. Underprescription of control could lead to serious illness, even death, and overprescription could lead to unnecessary expense. Future identification of either case could lead to a loss of confidence in the system as a whole. Assurance can be provided by validation. Each step of the CB strategy may be validated independently of the others.

5.1 Variables for Validation

5.1.1 Exposure Prediction

The data used to calibrate the exposure prediction methodology probably came from workplaces that had at least general dilution ventilation. It is therefore reasonable to assume that exposures measured where general dilution ventilation exists can be used to test the system. In cases where engineering controls are already in use, they could be discontinued for the purpose of this test as long as workers are not put at risk. In order to characterize properly the entire range of workers' exposures for the task or process under study, measurements must be taken to assess interworker, intraworker, and interworksite variation. Repeated measurements involving several randomly selected workers are required, generally around 20 measurements on each of 10 workers when establishing the average and range. If it is considered necessary to focus on the top 5% or 10% of exposures, then larger numbers may be required, or perhaps a model can be introduced to evaluate the extreme range of the potentially log-normal distribution.

5.1.2 Hazard Prediction

Hazard is generally described in terms of the toxicologic endpoint of concern (e.g., the description associated with specific R-phrases). Such phrases give the critical endpoints of disease but say little about the relative severity of equivalent exposures to different chemicals with the same hazard identification. For example, acetic acid and trichloroacetic acid are both corrosive, and classified R35 (causes severe burns) by the European Union, but their ACGIH TLVs vary by an order of magnitude. Where additional toxicologic data exist, they can be used for further assessment of the hazard ranking methodology.

5.1.3 Control Recommendations

The accuracy of the outcome regarding control determinations derives from recommendations of subject matter experts.

The CB control recommendations can be tested by matching them against expert recommendations. This is best done using scenarios where the exposure predictions and hazard predictions have already been tested and found to be appropriate.

5.1.4 Training

A goal of CB is to provide a system that can be used by nonexperts in the field of IH practice, so training in the use of the methodology is an essential part of many CB strategies. Training programs should be evaluated with respect to the following: target (e.g., was the training provided to those with authority to recommend or make changes?), reception (e.g., was the training offered sufficiently often, by a source considered trustworthy, in an environment conducive to processing?), and outcome (e.g., was the training implemented, and was the system used in the correct manner?). Evaluation of training effectiveness is an important step to provide feedback addressing these and other relevant questions.

5.1.5 Control Implementation

Once controls have been implemented, it is necessary to discover whether they were correctly implemented and whether sufficient knowledge and expertise exist to maintain them and to evaluate their efficacy when necessary (e.g., when processes change). Routinely scheduled maintenance and evaluation can ensure this.

Validation of all proposed CB strategies is essential for determining credibility. Besides in-depth studies in the United Kingdom, researchers in Germany, University of California–Berkeley, and elsewhere have been examining the worth of CB strategies.

5.2 Studies Performed for Validation of Control Banding

5.2.1 Tischer et al. 2003; Brooke 1998; Kromhout 2002a,b; Topping 2002a

According to Tischer et al. [2003], three aspects of evaluation can be applied to COSHH Essentials:

1. Internal (conceptual) validation
    - Are the underlying assumptions plausible and consistent with established theories?
    - How uncertain are the strategy assumptions?
    - Are all relevant parameters considered?
    - Does the strategy correctly reflect the relationship between its parameters?
    - Does the conceptual structure of the model reflect the structure of the real phenomenon?
2. External (performance) validation
    - Do the strategy's estimates correspond to monitoring data or to the outcome of other strategies?
    - What is the accuracy and precision of the predictions?
3. Operational analysis
    - How can it be ensured that the target group uses the strategy correctly?

- Is the strategy understandable by, and of practicable value to, the target group?
- Does documentation of the resulting recommendations meet the needs of the target group (language, skills, background knowledge)?

Brooke's work [1998] in comparing the R-phrases and resulting target airborne concentrations with the relevant health-based OELs on national lists (U.K. and German MAK) begins to address the first evaluation category on internal validation. The work of Tischer et al. [2003], Maidment [1998], and Jones and Nicas [2004, 2006a,b], which is reported below, focuses on the external validation category and begins to answer some of the questions regarding external (operational) validation. However, many questions still need to be answered in all three categories.

Kromhout [2002a] took strong exception to the lack of exposure monitoring in "generic risk assessment tools like COSHH Essentials and expert systems like the Estimation and Assessment of Substances Exposure (EASE) . . . " as these ". . . are known to be inaccurate and they do not take into account the various components of variability in exposure levels . . ." Kromhout built a strong case, estimating the variability in 8-hour shifts to be between 3,000- and 4,000-fold and identifying the sources of variability as spatial, both among workers and among groups. He argued that although providing exposure controls without having measured exposure concentrations would save money in the short term, in the long run it would be "penny wise but pound foolish."

Topping [2002a] responded that these arguments ignored the range of competencies in the workplace, and the number of firms handling chemicals. He stated that COSHH Essentials is not intended to replace monitoring but rather to provide needed help to SMEs, pointing out that the cost of conducting the extensive monitoring suggested by Kromhout would be "astronomical" and that the capacity to do so does not exist. He allowed that the COSHH Essentials were designed to "err on the side of caution," that the strategy had been peer reviewed by the British Occupational Hygiene Society (BOHS), and that there had been no complaints about the recommended controls being too stringent. Kromhout [2002b] replied that he and the editor of *Annals of Occupational Hygiene* questioned the role of tools like COSHH Essentials in contributing to a "collapse of full time training of occupational hygiene professionals in Britain through lack of demand for expertise." Kromhout's strongest criticism was that COSHH Essentials and EASE had not been properly evaluated prior to release and that BOHS review could not replace the rigorous evaluation of testing for reproducibility and validity. He recommended that COSHH and EASE be used in the initial screening process.

5.2.2 U.K. Health and Safety Executive Studies [Maidment 1998]

The core model was validated by comparisons with exposure predictor bands for solids and for liquids (Tables 9 and 10), comparisons with measured data, and extensive peer review of the logic and content. According to the author, finding quality data for comparisons was extremely difficult, and, further, the information describing CSs often seemed to indicate that several were in use.

5.2.3 German Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Study

Researchers at the BAuA examined the external validity of COSHH Essentials and found that, in the majority of cases, compared with OELs, it provides equal or greater worker protection; however, the number of exposure scenarios compared was limited. Tischer et al. [2002, 2003] at the BAuA conducted the first complete evaluation of the COSHH Essentials based on independent measurement data. The primary empirical basis for their analysis was measurement data collected during BAuA field studies within the preceding decade. The chemical industry provided additional data. Given that the data were not descriptive of all possible exposure scenarios covered by COSHH Essentials, the BAuA researchers were unable to evaluate the full range of the strategy.

BAuA data were obtained from BAuA laboratories, and all workplace measurements were conducted according to the German Technical Rules. Sampling durations were usually 1–4 hours and were task-based (i.e., corresponding to a specific scenario). More than 95% were personal samples. Sources of uncertainty considered were volatility/dustiness, scale of use, and CS. For example, the uncertainty associated with volatility (of pure substances) was judged to be low, but quite complicated when mixtures were considered. Dustiness was considered to be a problem that requires additional attention. Scale of use was judged to be straightforward. (Most of the available data corresponded to the medium scale of use, with very little in the milliliter or ton ranges.) Based on data available (i.e., 958 data points—732 for liquids and 226 for solids), the researchers limited their analyses to scenarios in which the CS could be determined from the historical reports, assigning one of the four CSs.

Comparisons indicated that most of the measured exposures fell within the predicted ranges. The 95th percentile of data from different operations fit within the ranges predicted by the COSHH Essentials model [Balsat et al. 2003; Tischer 2001b]. Exceptions were noted where some of the limited data points were above the predicted range: activities associated with carpentry workshops and application of adhesives, both of which represent small-scale, dispersive operations; and handling of powdery substances in kilogram quantities under local exhaust ventilation (LEV).

Tischer et al. [2003] note that limited data, representing a limited number of possible combinations of Exposure Predictor Bands and CSs, were available for evaluation. In particular their data lacked description of scenarios involving the handling of milliliter or ton quantities of low or high volatility/dustiness substances.

5.2.4 University of California—Berkeley Study [Jones and Nicas 2004, 2006a,b]

Also receiving attention is the ICCT, produced as a result of collaboration among

HSE, International Occupational Hygiene Association (IOHA), and ILO. ICCT is based on the HSE COSHH Essentials and is adapted for use worldwide [Jones and Nicas 2004, 2006a]. This version incorporates the GHS.

Researchers at the University of California–Berkeley [Jones and Nicas 2004, 2006a] evaluated the ICCT and have three major objections to it:

1. Determined of safety margins (No Observed Adverse Effect Level [NOAEL] or Lowest Observed Adverse Effect Level (LOAEL), divided by the high air concentration of the hazard band) resulted in values less than 100 for Hazard Bands B and C, and less than 250 for Hazard Band D for vapors. They noted that these values should be in the range of 1,000–10,000 for R48/20 (Danger of serious damage to health by prolonged (inhalation) exposure), depending on if either of the adverse effect levels (NOAEL or LOAEL) was used as the basis of calculation.

   These calculations are based on the generic COSHH criteria to avoid any errors caused by incorrect assignments of hazard bands. Brooke [1998] reported that some categories of materials were arbitrarily assigned to a higher hazard category based on their toxicity characteristics, and this would provide an extra factor of 10. Also, it must be pointed out that the hazard band values are generally in the same order of magnitude as OELs (see Brooke 1998) and also that it is not uncommon for acceptable risk levels of OELs to be in the range of 10^{-4}–10^{-3}, in contrast to acceptable risk values in environmental settings of 10^{-6}–10^{-5} [Jayjock et al. 2000].

2. A comparison of the R-phrases (taken from the HSE "Approved Supply List" [National Chemical Emergency Centre at www.the-ncec/cselite]) assigned to commonly used solvents indicated that the hazard group ratings assigned by the ICCT were lower than in the COSHH Essentials for 12 of 16 solvents. In five cases, the ICCT included an S notation (skin hazard) that was not on the R-phrases. Jones and Nicas [2004, 2006a] suggested that the authors of the ICCT should reconsider the hazard classification plan as the variations among CB strategies reduce confidence in the toolkit among its users.

3. Jones and Nicas determined the appropriate control strategy and compared the actual measured exposures with the maximum value of the exposure band of the recommended exposure band. This comparison resulted in two types of control errors: situations in which insufficient exposure control occurred in the presence of LEV (under-control errors) and situations in which sufficient exposure control occurred in the absence of LEV (over-control errors). They found under-control errors in 96% of the 163 cases

> where LEV was present in vapor degreasing operations, and in 55% of the 49 cases where LEV was present in bag filling operations.

Besides the three objections listed above, Jones and Nicas formed multiple conclusions from their evaluation:

1. Recommended exposure bands do not provide consistent, or adequate, margins of safety.
2. The high rate of under-control errors highlights the need to evaluate the effectiveness of installed LEV systems using capture efficiency and/or air monitoring techniques.
3. The limited assignment of dustiness ratings to particulates complicates the process.
4. Specific guidance must be provided in cases where there is insufficient or inappropriate hazard information.
5. The R-phrase procedures criteria (specifically the use of minimum concentration values below which classification using the R-phrase values would not be applicable) are not compatible with U.S. regulatory practice.
6. Guidance about contacting professional assistance for engineering controls should be included on CGSs.

5.3 Expert Opinions on Control Banding

According to Money [2003]—

> No systematic assessment has been undertaken of the impact that control banding approaches have had on the management of risk at the workplace or other levels. Thus, in terms of future developments in the area, it would appear that before further refinements are considered, there needs to be an extensive and systematic evaluation of the uptake and impact of a number of the key approaches.

Swuste et al. [2003], referencing Kromhout [2002b], state—

> The COSHH Essentials has met some criticism in the literature, focusing on the lack of a proper evaluation before its introduction into the occupational arena, as well as the generic nature of the tool, which will lacks [sic] precision and accuracy in situations where these are required."

Tischer et al. [2003] have said that in the German occupational hygiene community—

> …there was consensus that the scheme (COSHH Essentials) had great potential for further development. On the other hand, with respect to the exposure predictive model it has been argued that, due to its generic character, reliability and accuracy (safety) may have been sacrificed for the sake of simplicity and transparency. However, this assumption is not based on real measurement but reflects the low degree of confidence generally associated with generic models.

Oldershaw [2003] has cautioned that the COSHH Essentials strategy cannot be adopted uncritically by other countries; further, the strategy must be seen in the context of personal protection, training, and health surveillance as elements of a comprehensive safety and health program.

With regard to assessing the impressions about general usability of a CB model, a telephone survey of 500 purchasers of the paper version of COSHH Essentials revealed that 80% of the purchasers had used it, and only 5% had found it fairly difficult to use. Three-quarters had enough confidence in the model to take action based upon its guidance, and 94% would recommend it to other businesses [Topping 2002b].

The American Industrial Hygiene Association (AIHA) convened a Control Banding Working Group to research and document the evolution and potential contributions of CB within the practice of IH. The resulting publication, titled *Guidance for Conducting Control Banding Analyses* [AIHA 2007], describes the development of methods based on control-focused strategies initially pioneered by pharmaceutical and chemical industries. This positive treatment of the topic describes the "foundations and major elements of Control Banding approaches in use today," and provides case studies and hazard-specific applications, as well as a "glimpse of the future—a discussion of the challenges and opportunities presented by domestic and international developments." It emphasizes that CB focuses primarily on initial risk characterization. Consequently, the authors acknowledge that CB outcomes (i.e., specific controls) should be reviewed by an industrial hygienist or other qualified professional to ensure that controls are appropriate, effective, and maintained.

Like the AIHA, the ACGIH also commissioned an Exposure/Control Banding Task Force to assess and document the CB topic for its membership. The resulting document, titled *Control Banding: Issues and Opportunities* [ACGIH 2008], focuses primarily on the COSHH Essentials and the ICCT and examines the four main components of CB: Hazard Group Prediction Model, Exposure Limit Prediction Model, Exposure Prediction Model, and Predefined Control Strategies. The document illustrates how varying information on health hazards and exposure characterization affect identification of CSs and their usefulness. The assessment of the Task Force is more critical of CB, cautioning that "users should not rely on Control Banding as it currently exists to identify the controls required to provide adequate protection to workers." The task force makes recommendations to address the shortcomings it identifies for each of the four main components of CB. Among these is the advice that users should recognize the critical role that occupational health professionals must play in the risk management process. This is a universal theme in critiques of CB strategies. Also, as with the AIHA document, the ACGIH recommends that CB represent an initial qualitative assessment as part of a more formal exposure assessment and control program.

Zalk and Nelson [2008] published a more recent review of the history and evolution of CB, citing and summarizing many of the resources recognized throughout this NIOSH document. They recognize that for CB strategies like COSHH Essentials, exposure bands do not always provide adequate margins of safety, there is a high rate of under-control errors, they work better with particulates than with vapors, an inherent inaccuracy in estimating variability exists, and outcomes of this model, taken together, may lead to potentially inappropriate workplace confidence in chemical exposure reduction. With the accuracy of the toxicologic ratings and hazard band classification currently in question, the proper reevaluation of exposure bands will be of great benefit to the reliability of existing and future CB models. The authors also suggest that a more comprehensive prospective research process will be important in understanding implications of the model's overall effectiveness. Consequently, they recommend further research to refine results and to build users' confidence in the utility of CB strategies.

These studies and expert comments presented in this section emphasize the need for collection of data under controlled scenarios to validate the predictions of the model. This validation must be seen as a separate activity from the verification of proper installation and maintenance of controls prescribed by a CB strategy.

6

Specific Issues in Control Banding

Most CB strategies are limited to the inhalation route of exposure and to certain chemicals used in manufacturing (others being regulated in specific statutes). Work is ongoing to expand applications to other topics, including dermal hazards, process-generated hazards such as airborne crystalline silica, asthmagens, and asbestos.

6.1 Dermal Absorption

The challenge for application of CB for dermal hazards lies in the banding of dermal exposures. Much research has been devoted in recent years to developing methodologies for risk assessment of dermal contact with chemicals, with the focus on dermal exposure assessment. The Dermal Exposure Assessment Method (DREAM—a method for semi-quantitative dermal exposure assessment) [Van-Wendel-de-Joode et al. 2003] is a systematic and structured strategy for dermal exposure assessment; however, in its present form, it is highly complex. In DREAM, the model's 33 exposure determinants are mostly assigned by educated assumptions; it is time-consuming to conduct, and requires an occupational health professional to complete a questionnaire for model inputs. Garrod and Rajan-Sithamparanadarajah [2003] explored some of the issues involved in developing a dermal module in COSHH Essentials and proposed alterations to the control strategies (Bands 1–3). The current COSHH Essentials strategy does not differentiate between substances that affect the skin (e.g., corrosives) and those that are absorbed through the skin. This may be because the EU system classified many chemicals before extensive data were available to rank the risk of skin uptake. Other complicating factors include that some chemicals can act as carriers for poorly penetrating substances and that some R-phrases do not have exposure route indicators for systemic toxicity endpoints. Because of these limitations, Garrod and Rajan-Sithamparanadarajah [2003] suggest that most chemicals be considered as having the potential for skin uptake. In proposing three skin hazard bands (see Table 13), they considered the following questions:

1. Is there an identifiable dose threshold for the toxicologic endpoint?
2. How serious is the health effect?
3. At what exposure levels do health effects occur?

Most of the chemicals in COSHH Essentials Hazard Bands A, B, and C are considered in the lower skin hazard band. Compared with the inhalation hazard rankings of chemicals, those that cause burns (R34), severe burns (R35), and skin sensitizers (R43) are moved to higher hazard bands.

Table 13. Skin hazard bands

Skin hazard bands	Included risk phrases	Total daily skin burden of concern	Advice
1 – Lower skin hazard group	All risk phrases in COSHH* Essentials hazard groups A, B, and C except R34 = causes burns R35 = causes severe burns R37 = respiratory tract irritation R43 = may cause sensitization by skin contact	Dust: 500 mg Liquid: 10 mg	Process: process modification, substitution of physical form Procedure: segregation, cleaning routines, training, hygiene procedures, laundry, skin care programs, PPE† (disposable gloves), skin condition reporting
2 – Higher skin hazard group	All R-phrases in hazard group D, plus R34, R35	Dust: 50 mg Liquid: 1 mg	Process: full containment (except small amounts of certain substances) Procedure: as above, plus controls (e.g., biological monitoring, permits to breath containment) Advice: selecting gloves and other PPE, skin surveillance
3 – Highest skin hazard group	All R-phrases in hazard group E, plus R43	Any amount of particulate or liquid	Seek specialist advice.

*COSHH=Control of Substances Hazardous to Health
†PPE=personal protective equipment
Adapted from Garrod et al. 2004

Regarding dermal exposure, Garrod et al. [2004] present a strong case against considering duration of exposure as a factor influencing uptake. Their argument is that skin can act as a reservoir, and thus contribute to uptake of contaminants even after exposure has ceased. Additional arguments for this position include documented penetration and retention of contaminants by gloves, contamination of the inside of gloves when contaminated hands are put in them, and inevitable dermal contamination when working outside containment. They allowed for the possibility of two durations when considering exposure banding: a single splash that is immediately removed and all other scenarios. These authors conclude that dermal exposure cannot currently be banded in the way that inhalation exposures are banded and offer recommendations for altering COSHH Essentials to account for dermal exposures:

- Providing guidance for actions to take if containment is breached
- Raising the control strategy in certain cases
- Disallowing any reductions in control strategy based on short-term usage
- Using skin surveillance when skin sensitizers are used more often than once per month
- Taking into consideration the concentration of liquid mixtures and the specific body area in contact with chemicals.

Protecting skin from exposure to occupational hazards is a pervasive challenge in many industries. Because the level of control cannot be quantified as increasing levels of 10-fold protection (as can be done with inhalation exposure control), Garrod et al. [2004] recommend biological monitoring to assess adequacy of control. They conclude that ". . . hazard banding is feasible, exposure banding is not, and control banding for skin cannot at present be done with any rigour [sic], but it is feasible to provide suitable control guidance sheets for dermal exposure control."

RISKOFDERM is an EU-funded project formed with the aim of providing a validated predictive model for occupational dermal exposure assessment that could be adapted into a practical dermal exposure toolkit for SMEs [EC 2004; van Hemmen et al. 2003; Marquart et al. 2003; Goede et al. 2003; Warren et al. 2003; Oppl et al. 2003; Schuhmacher-Wolz et al. 2003]. In March 2004, the RISKOFDERM Toolkit became available on the Internet. RISKOFDERM was intended to raise awareness, estimate exposures, identify control actions, recognize hazard potential, and recommend control actions in hierarchical order [van Hemmen et al. 2003]. The Toolkit was evaluated by a panel of international industrial hygienists and revised according to findings of then ongoing RISKOFDERM research. Both paper and electronic formats are available online, which are now available for use by educated nonexperts, who would ask fairly simple questions and be guided to qualitative scales for dermal exposure, resulting risk, and possible control measures. As this project includes several key persons from HSE, the outcome of RISKOFDERM may very well support a relatively simple dermal exposure banding concept that could be incorporated into COSHH Essentials or other toolkits that are in the development process.

6.2 Silica (HSE)

HSE has developed CGSs for silica—Silica Essentials—which can be accessed through the individual industry sectors at www.hse.gov.uk/pubns/guidance. These sheets are part of a new phase of COSHH Essentials where the guidance is task-specific and targeted to specific industry sectors, such as foundries, construction, quarries, brick making, and ceramics. The Web page was launched in 2006 and provides practical standards that industry can apply to reduce exposure to silica. Silica Essentials is a good example of a CB strategy where, based on good control-practice recommendations, users access direct advice from industry experts. They require no detailed data input from the user and do not rely on R-phrases. The appropriate CGS can be determined by identifying the appropriate activity for which guidance is sought, such as rock drilling, fettling castings, tile pressing, or abrasive blasting. The work to develop the CGSs is complementary to other initiatives from HSE to raise awareness of industry hazards and the importance of adequate control to reduce ill health. Such initiatives on silica include the silica information sheets and a strategy to control exposure to silica dust in small potteries.

6.3 Asthmagens (HSE, NIOSH, OSHA)

In the United Kingdom, an estimated 1,500–3,000 new cases of occupational asthma occur each year. This increases to 7,000 cases a year if asthma-made-worse-by-work (work-related asthma) is included. In the United States, it is estimated that occupational asthma incidences range from 6.3–44.1 per 100,000 [Henneberger et al. 1999], and task-related exposures associated with occupational asthma are considered to be an appropriate focus for preventive strategies [Wagner and Wegman 1998]. HSE and NIOSH are working collaboratively to include asthmagens in CB strategies. In 2003, HSE included in their Strategic Outlook the intention to build collaborations with international technical and scientific organizations such as NIOSH. This collaborative HSE and NIOSH work includes a focus on asthmagens in relation to their inclusion within CB strategies. Although no conclusive CGSs are currently available relating to this cooperative research, this strategy is an example of international organizations' belief that occupational exposures in the workplace are worthy of consideration in a CB strategy.

6.4 Asbestos Essentials (HSE)

The guidance manual *Asbestos Essentials: Task guidance sheets for the building maintenance and allied trades* [HSE 2001] includes eight "Equipment and Method Guidance Sheets" on topics such as training, building enclosures, use of a Type H vacuum cleaner, and wet methods. R-phrases are not included; rather, the guidance is presented by task. The 25 Task Guidance Sheets cover tasks such as painting insulation boards and removing gaskets and floor tiles. Each Task Guidance Sheet is structured according to description of task, PPE, preparing the work area, repair, cleaning, personal decontamination, and clearance procedures.

7

Special Events Surrounding Control Banding

CB is currently the subject of much interest, both nationally and internationally. International workshops have been held in London (2002), Cincinnati (2004), concurrently in Pilanesburg, South Africa and Orlando (2005), and South Korea (2008). International collaborative agreements have been forged to coordinate the work of international agencies and their partners, and a global implementation strategy has been developed.

7.1 First International Control Banding Workshop (ICBW1)

The first International Control Banding Workshop (ICBW1) was held in London on November 4 and 5, 2002, with the sponsorship of BOHS, the British Institute of Occupational Hygienists, HSE, IOHA, the World Health Organization (WHO), and the ILO. In addition to providing a clear description of the CB process, significant outcomes of the workshop include—

- HSE, IOHA, and ILO collaborated to produce the ICCT, which was based on the HSE COSHH Essentials, adapted for use internationally. This version incorporates the GHS.
- Participants agreed that any version of the CB strategy must be simple to use and compatible with existing work methods.
- Adapted versions range from the sophisticated strategies pioneered by the pharmaceutical industry, to the holistic GTZ strategy (Chemical Management Guide) [Adelmann 2001]. The GTZ strategy has been implemented by employers in Indonesia, on the premise that the control of chemicals reduces waste and loss in addition to protecting worker health and environmental quality.
- Valuable in a large variety of workplaces, the wide range in versions of CB is necessary for broad application. In particular SMEs in mostly developed countries and SMEs in developing countries may require separate strategies.
- The role of the International Programme on Chemical Safety (IPCS) International Chemical Safety Cards in providing relevant information was acknowledged, with the possibility of these cards being updated to include the necessary data (e.g., GHS, to support CB being considered) [Jackson 2002; Jackson and Vickers 2003].

During the workshop representatives of national and international organizations attended a strategic planning meeting.

It was agreed that a (now named) International Technical Group (ITG) on CB would be organized, with the IPCS serving as secretariat. The major purposes of the ITG are to share the knowledge gained from trials and demonstration projects, maintain the integrity of the ICCT, and ensure that the technical aspects of the system are maintained and updated (e.g., to reflect changing national legislation and implementation of the GHS). (See Appendix C for the ITG's Global Implementation Strategy. Also, see Zalk 2002b.)

All the presentations from ICBW1 can be viewed at www.bohs.org/mod.php?mod=fileman&op=view_cat&id=14.

7.2 Second International CB Workshop (ICBW2)

The ICBW2, subtitled Validation and Effectiveness of Control Banding was held March 1 and 2, 2004, in Cincinnati, OH. Attendees from 13 countries shared their views regarding challenges currently facing CB. Presenters from Europe, the United States, Asia, and South America spoke of their specific research and experiences.

During breakout sessions priority issues emerged, including cost-effectiveness and efficiency to expand the reach of CB concepts while minding the largely volunteer effort bringing this forward. Presentations and discussions of CB topics covered the multiple tools and CB strategies for consideration. Most of the presentations from the ICBW2 can be viewed at www.acgih.org/events/course/controlbandwkshp.htm.

Significant outcomes of ICBW2 were the framework for a research agenda for developed and developing countries and the creation of a National Control Banding Workshop Organizing Committee. Also at ICBW2 was formed a consensus Global Implementation Strategy from the ITG on CB.

The ITG on CB, led by WHO, IPCS, and ILO, had the opportunity to meet before, during, and after ICBW2 to finalize the Global Implementation Strategy for release after the event. The complete implementation plan is contained in Appendix C of this document. The National Control Banding Workshop convened in March 2005 in Washington D.C. to review an early draft, which became the foundation of this document, and to discuss proposed U.S. strategies to employ CB concepts.

7.3 Third International Control Banding Workshop (ICBW3)

The Third International CB Workshop (ICBW3) was held in September 2005 at the Pilanesberg National Park in South Africa in conjunction with the 6th International Scientific Conference of Occupational Hygiene. For the first time an ICBW convened outside the developed nations, solidifying the inextricable involvement of developing countries. The three focus topics for ICBW3 included Global Trends in CB Collaborations, a Silica Workshop, and CB's Expansion of Range beyond chemicals. The last two highlighted the future context of the ICBWs: to further develop specific professional areas of practical prevention needs. Areas considered for expanding CB applications included psychosocial factors and safety management, and specifically, the possibility of creating an ergonomic toolkit, an effort initially presented at ICBW2, which has increased to involve additional partners and activities [Zalk 2003].

7.4 Fourth International Control Banding Workshop (ICBW4)

ICBW4 was held in Seoul, South Korea at the XVIII World Congress on Safety and Health at Work in July 2008. At that venue, the CB discussions emphasized safety applications and exploration into the latest national programs (India, South Korea, and Japan).

7.5 International Agreements

ILO and WHO agreed to work together under the auspices of the IPCS on January 23, 2003. The roles of each organization were spelled out in the agreement [Vickers and Fingerhut 2002].

The Global Implementation Strategy for the Occupational Risk Management Toolbox was outlined by the ITG at ICBW2 and approved on May 28, 2004. This strategy, which discusses partners, stakeholders, the ICCT, key elements, terms of reference, and the international research agenda, can be found in Appendix C.

8

Critical Analysis of Control Banding Strategies

The core of this review is a discussion of the strengths and weaknesses of CB strategies. Much of the literature on these characteristics describes concepts and misperceptions about CB and its potential applications, similarities to other occupational safety and health interventions, potential conflict with OEL development, and the need for environmental sampling and IH expertise. This section also contains a critical analysis of the barriers and catalysts for implementing CB in the United States. In addition, consideration is given to the areas where expansion of CB concepts or development of new control-focused solutions and guidance might be explored.

In the broadest scope, the CB strategies and related guidance for addressing occupational hazards are recognized for their potential to facilitate occupational safety and health knowledge management. Knowledge management is an emerging field focusing on assessing the creation, transfer, and use of knowledge to address specific challenges [Schulte et al. 2004]. Effective knowledge management can be accomplished through the development of guidance materials for hazard control and the application of CB strategies.

8.1 A Discussion of Weaknesses and Strengths of CB Efforts

In evaluating the weaknesses and strengths of the CB strategy, it is useful to refer to an outline of common issues, as shown in Table 14.

8.1.1 General Control Banding v. COSHH Essentials

COSHH Essentials has met criticism in the literature for its generic nature that does not adequately or accurately take into account the environment and parameters within which the exposure occurs [Swuste et al. 2003; Harrison and Sepai 2000]. And, because presenters of the CB concept have highlighted COSHH Essentials, some mistakenly believe that the two are the same. Confusion stems from the misunderstanding that the nature of COSHH Essentials is to use refined parameters to offer a best estimate of personal exposures; however, predicting exposure is not the primary aim of COSHH Essentials or CB. Rather, CB is qualitative and is an overarching strategy for managing hazards in the workplace. A benefit of the comparison is that critiques of COSHH Essentials have led to improved revisions of the CB concept.

Table 14. Issues relating to the strengths and weaknesses of the CB* strategy

CB Strategy Issues	Weakness summary	Strength summary
General CB vs. COSHH† Essentials	Highlighting COSHH Essentials within CB presentations led to misunderstanding that the two are the same. Research critical of COSHH is therefore critical of CB.	Current CB publications and events are clarifying that CB is an overarching strategy and not a single toolkit. COSHH Essentials critique led to improved revisions.
Estimated controls vs. specific science	IH‡ practice in the United States is based on solid scientific protocols, so why replace them with potentially underprotective CB outcomes?	Traditional IH practice is expensive, and options are necessary so all U.S. workers are protected. CB strategies reduce costs and promote IH expertise as needed.
CB strategies vs. full-time IH professionals	Implementation of CB strategies will reduce the need for IH consultants and move profession toward ES&H§ generalists.	CB strategy indicates thresholds that require IH expertise. With CB implementation employers will be educated about IH concepts and practices.
CB vs. reliance on OELs¶	Some professionals believe that moving CB forward in the absence of OELs will strengthen the argument to eliminate them.	CB strategies will not serve as a replacement for OELs in the United States. CB validation protocol will include personal monitoring for OEL use.
Not monitoring vs. monitoring	Traditional exposure assessment relies heavily on personal IH monitoring. Some perceive CB as eliminating this crucial step.	CB requires IH personal monitoring for validation and maintenance. Task-based control solutions are appropriate given sufficient historical data.
Qualitative output vs. quantitative input	COSHH Essential's interim step of predicting exposures is an area estimate, offering controls in the absence of workplace variations.	COSHH Essentials criticisms are assisting in perfecting the strategy. Task-based point source models do not require exposure prediction.
Static controls vs. dynamic controls	Current CB strategies implement static controls. Validation needs to include dynamic aspects of initial accuracy, process change, and control degradation.	CB validation protocol will include evaluating dynamic implementation strategies. The database resulting from this process will offer a useful task-based CB solutions database.

*CB=control banding
†COSHH=Control of Substances Hazardous to Health
‡IH=industrial hygiene
§ES&H=Environmental Safety and Health
¶OEL=occupational exposure limit.

8.1.2 Estimated Controls v. Specific Science

Because the known and scientifically founded parameters of a perfect system may not be economically viable or available at small companies, managers offer CB as a means of achieving the best exposure reduction process affordable. Research indicates that in some cases the guidance from CB models will likely either underprotect the worker or prescribe overprotective controls [Jones and Nicas 2004, 2006b]. Some believe these potentially underprotective recommendations will replace the solid scientific protocols of IH practice, that is, the introduction of qualitative strategies could lead management to consider replacing Environmental Safety and Health (ES&H) staff with CB strategies and tools, justifying the latter as being more economically efficient. The resulting control guidance obtained using the CB strategy could be less useful and protective than that recommended by a professional. Most IH experts admit that many workers are left unprotected, despite available controls [Kalisz 2000]. Although introducing a CB system might seem relatively easy in theory, ensuring controls are properly implemented and evaluated for their effectiveness is a difficult and economically challenging endeavor. Therefore, CB strategies benefit industry because they reduce costs and promote IH expertise as needed. In workplaces where IH support may never extend, alternative strategies and mechanisms for providing control-focused guidance hold great promise for reducing occupational disease and illness.

8.1.3 Control Banding Strategies v. Full-time Industrial Hygiene Professionals

The above paragraph mentions that management may decide to eliminate the need for full-time IH staff in favor of qualitative strategies; however, the CB strategy indicates thresholds that require IH expertise. With CB implementation, employers will be educated about IH concepts and practices. The CB strategy, should it reach a point that it is viable for the nation's industries, may provide an opportunity to strengthen and promote the IH profession. Specifically, IH professionals can use CB as a tool to improve hazard awareness and promote hazard communication and control [Money 2003].

8.1.4 Control Banding v. Reliance on OELs

Some professionals believe that moving CB forward in the absence of OELs will strengthen the argument to eliminate them. To those with the scientific understanding of the processes at work to derive appropriate exposure limits to protect the health of the workforce, the possibility of eliminating the OELs is unconscionable. However, in the United States, CB strategies will not serve as a replacement for OELs. CB validation protocol will include personal monitoring for OEL use. The value of the CB strategy to the OEL-setting systems is two-tiered: (1) supplemental to the concept of OELs, a successful CB strategy will give a newly educated (by the IH professional as described above), broad-spectrum audience a better understanding and respect for exposure prevention [Guest

1998; Russell et al. 1998] and (2) the CB strategy will assist users in managing the increasing numbers of chemicals [Balsat et al. 2003; Swuste et al. 2003; Money 2001; EC 2001; Vincent and Bonthoux 2000; UIC 1999].

8.1.5 Not Monitoring v. Monitoring

Exposure assessment and risk assessment rely on personal exposure measurements as a link to establish the probability of illness related to work or the environment. The CB strategy recommends a minimal level of protection for the worker performing a common task, but this may be at the risk of ignoring the variability between workers. Monitoring results are essential for the prioritization and organization of occupational and public health budgets and deriving which strategies are most effective and economically viable [Kromhout 2002b].

Though CB does not require personal monitoring for implementation, validation and maintenance of the strategies do. IH personal monitoring is a necessary part of the validation of toolkits to ensure controls are appropriate [Tischer and Scholaen 2003; Money 2003; Swuste et al. 2003]. Developing a particular toolkit requires established emissions assessments for specific point sources. And, since further exposure assessment will be required for CB validation, it can be argued that this process will contribute to the number of completed task-related exposure assessments available for reference [Jones and Nicas 2004, 2006a; Kromhout 2002a; Maidment 1998].

8.1.6 Qualitative Output v. Quantitative Input

The emphasis of the CB concept on simplicity and transparency may result in reliability and accuracy being sacrificed. The majority of toolkits currently in development do not account for work-area exposure. Yet, a work-area exposure estimate has been technically and scientifically proven to be a poor surrogate for an actual personal monitoring result obtained within a worker's breathing zone [Kolanz et al. 2001]. In addition, such estimates may not account for the dimensions of the work space; whether the chemical will be sprayed, rolled on, or poured in; how much time is required for transfer; how much is applied at each manufacturing step over time; and, whether there is an extraneous step such as welding or treating of the chemical after its application [Tischer and Scholaen 2003].

For point source exposures, toolkits will either use exposure prediction for the task-related controls they suggest or show that implemented controls are effective for reducing exposure regardless of predicted exposure. The parameters of a particular task performed by a single person are important, but more important is the reduction of exposure even if the end result may be above established OELs [Jones and Nicas 2004, 2006a; Kromhout 2002b]. To validate the CB, further exposure assessment will be an essential confirmation and will also serve to improve the given toolkit's information basis to be applied in its subsequent toolkit revisions [Oldershaw 2003]. Exposure assessment would then not only benefit the individual worker but would also provide scientific and technical information to practicing IH professionals. The lack of data for validation may cause problems with toolkits aimed at estimating qualitative exposures for bulk chemical processors [Money 2003]. The validation protocol within the CB strategy may then provide more professional judgment for SMEs than already exists.

8.1.7 Static Controls v. Dynamic

If businesses do not have full-time IH professionals on staff, the recommended controls that result from CB strategies may not be implemented for the long-term and may not be periodically assessed for effectiveness. The dynamic nature of industry and manufacturing does not quite fit with brief managerial consideration of safety and health in the absence of onsite consultation. How is the IH profession to oversee that PPE recommendations are implemented appropriately? If the wrong glove material is recommended or an inappropriate respirator type is chosen, protection may be insufficient, and the toolkit would not detect the error [Guest 1998]. The consequence of such scenarios is to render a false level of safety [Jones and Nicas 2004, 2006a]. In such a case, workers assume that they are protected from hazardous exposures while at work though current NIOSH research shows that is not the case for a portion of them. To protect themselves, workers in facilities managed with a strategy other than CB, who are unsure of exposure levels, must rely on their own knowledge and awareness of hazards to protect themselves. Relying on personal knowledge may seem a better alternative than being incorrectly informed that their workplace is safe based on CB determinations. The overall CB concept relies on the goodwill of nontechnical overseers, who are likely to be undertrained and ill-equipped with appropriate information to validate and maintain the best controls [Tischer and Scholaen 2003; Maidment 1998].

A limitation of the current CB strategy is that it is static, whereas a system that is reviewed and updated periodically would ensure that the controls implemented and the managerial oversight are maintained over time. Consequently, part of validation is comparison among the possible methods of implementing controls and the construct within which these methods are introduced—to employers and workers. The validation effort supports development of task-specific guidance that integrally involves CB strategies in effective control solutions.

8.2 Determine the Barriers to, and Considerations for, Implementing Control Banding to Address Safety and Health Hazards in U.S. Workplaces

Among potential barriers to the implementation of CB strategies in the United States are legal implications, concerns about devaluation of worker protection, and application of R-phrases. The creation of a dynamic process to ensure quality of implementation over time and the use of CB strategies within U.S. regulatory and management schemes could facilitate the implementation of CB.

It is impossible to discuss any new system that seeks to protect workers in the United States without addressing legal considerations. One challenge relates to implementing a generic CB system that may provide practical tools for managing and reducing hazardous exposures, yet may not be applicable or provide appropriate protection in all cases [Jones and Nicas 2004, 2006b; Money 2003; Kromhout 2002b]. It is essential to recognize these limitations and to address information gaps to ensure that use of CB strategies achieve the appropriate levels of workplace protection, rather than contribute to occupational illness and injury, as well as to employer liability.

8.2.1 Use of Standardized Hazard Statements in Control Banding

Under the CB strategy used in COSHH Essentials, the hazard and degree of severity of hazard are obtained from the R-phrases given on EU labels and MSDSs. The U.S. classification and labeling system in the workplace is the OSHA Hazard Communication Standard (HCS). The HCS requires classification of chemicals according to the hazard criteria in the standard and also requires the label preparer to include appropriate "hazard warnings" on the chemical label. It does not specify the language to be used to convey the hazard information since it is a performance-oriented standard. It also does not require that the label phrases appear on the MSDS for the chemical. The U.S. definitions of hazard are similar to the EU's but not identical. Thus the R-phrases assigned to particular chemicals may or may not accurately reflect the hazard of the chemical under U.S. law. Therefore, one cannot simply use the R-phrases for a chemical to apply CB in a U.S. workplace.

In order for CB to work, the use of standard hazard statements linked to specific criteria is necessary for consistency and the determination of the proper level of control. Many companies in the United States have developed their own databases of standard phrases that they use to convey hazards for their products. Some companies in the United States have used the hazard information on U.S. MSDSs and applied their professional interpretation of the data to link it to an EU R-phrase and then used the phrase to apply CB. Doing this successfully would require a level of professional expertise and judgment in toxicology and other disciplines that would be limited to larger North American companies in most situations. The lack of this piece of information—the standard hazard statement—for the CB equation is a significant impediment to successful implementation of CB in the United States. Ready availability of standardized phrases linked to U.S. hazard criteria is necessary to ensure the possibility of widespread application of CB, particularly in small businesses.

The GHS is intended to resolve some of the challenges associated with hazard classification, labeling, and communication. The GHS is a common and coherent strategy to classifying the health, physical, and environmental hazards of chemicals and to communicating the hazards through labels and MSDSs. GHS includes a core set of label elements and has harmonized hazard statements for each category and class of chemicals covered. It also has a harmonized strategy for classifying mixtures of these chemicals. The United Nations adopted the GHS strategy in 2003. The United States, the European Union, Canada, and many other countries are now considering its use. In the United States, four agencies have primary responsibility for its implementation—Consumer Product Safety Commission (CPSC), Department of Transportation (DOT), Environmental Protection Agency (EPA), and Occupational Safety and Health Administration (OSHA). OSHA has proposed rulemaking activity (first published as a draft in 2005, with an update expected in 2009) for revising its hazard communication standard to incorporate the GHS elements. The revised hazard communication standard will require use of standard hazard statements on U.S. labels as well as on MSDSs.

Global implementation of the GHS would provide an international system upon which to base CB. In recognition of this, the ILO has included the GHS hazard categories in its ICCT. Action is also being taken to modify the roughly 1,600 International Chemical Safety Cards prepared under the IPCS to follow the GHS criteria for classification and the harmonized hazard statements for the most commonly used chemicals.

8.2.2 Considerations for Implementing Control Banding

Current efforts for creating a CB strategy have focused almost entirely on evaluating and perfecting existing toolkits. Yet, NIOSH research shows that this focus may be flawed for national implementation at this time because it is a static strategy without consideration for the multiple factors that consistently affect change in U.S. manufacturing and other industrial sectors. Therefore, a parallel effort is necessary to create a dynamic system for the CB strategy that seeks to incorporate changing factors over time for both the controls implemented and the managerial oversight to ensure CB does not fall into misuse, improper application, or lack of implementation entirely. Essential to the utility of a dynamic system is the protocol for validation to ensure that assessments and resulting control recommendations are appropriate and effective and the ability to identify exceptions and areas requiring further evaluation and improvement [Guest 1998; Yap 2004; Tischer and Scholaen 2003; Jones and Nicas 2004, 2006a,b; Brooke 1998; Loughney and Harrison 1998; Palmer and Freegard 1996].

Under the current static CB strategy, it is anticipated that some employers will recognize the benefits of CB without being in a position to implement or enforce its use. An alternative dynamic CB strategy should incorporate management considerations that would facilitate putting the CB strategy into practice. This strategy should be accompanied by a method of measurement for the extent of institutional implementation, for its ability to adapt to changes over time, and for determination of the level of successes and reduction of exposure potentials. This dynamic strategy should be developed with a theoretical strategy that involves consideration of costs and benefits. It should ensure that all tasks, chemicals, and exposures involved are considered so the properties, toxicity, application, and conditions during

Table 15. Current documented input to the ANSI* Z10 review committee for pertinent sections

- 3.2 Employee participation (Identify tasks, risks, and possible controls)
  — no mention of evaluating exposures
- 5.4 Document and Record Control Process
  — if CB† in an OHSAS,‡ it becomes part of the process
- 6.1 Monitoring and Measurement: F. "Other methods"
  — does not rule out semi-quantitative/qualitative
- 6.3 "System" Audits: evaluating activities and corrective actions—recordable CB process fits audits
- 6.4 Track actions for effective implementation
  — possible weak point with CB, needs strengthening

*ANSI=American National Standards Institute
†CB=control banding
‡OHSAS= Occupational Health and Safety Assessment Series

applications are part of the decision matrix. Creating this system with a task force of safety and health professionals working in concert with managerial oversight and workplace employee representatives will facilitate the best use of CB to maximize its effectiveness, consistent application, and economic efficiency. An example of a vehicle for this strategy is the American National Standards Institute (ANSI) Z10 committee (Table 15). A major premise on which a dynamic strategy should rely is the understanding that industry specific, worker-influenced solutions have the best possibility of being applied, achieving success, remaining in place over time, and having a mechanism for ensuring commensurate controls are in place regardless of changes in tasks, processes, products, and the inevitable workplace rotation of affected worker populations.

8.2.3 OSHA and Its Voluntary Consultative Services

The U.S. OSHA Consultation Program to Small Businesses was first promulgated more than 30 years ago and has since served as an effective mechanism for promoting safety and health guidance and solutions for the small business audience since. However, fear of government intervention and penalties prevents many small businesses from using this service [Kalisz 2000]. As a means to overcome this reluctance among small businesses, introducing practical, qualitative risk assessment and management tools, such as a CB strategy, may provide opportunity for OSHA to form strategic partnerships, possibly recognizing and rewarding successful control implementations in the process. Results of effective partnerships might contribute to a solutions database and provide effective advertising of services focusing on worker safety and health education [Topping 2001]. OSHA could assist in accomplishing compliance by helping businesses develop guidelines. This could create a larger demand and respect for these consultative services, emphasizing the assistance to businesses and working toward cooperative solutions [Money 2003]. In building support for the partnerships and exploration of CB applications, the involvement of organized labor representatives is paramount.

This envisioned CB strategy for implementation synchronizes well with the existing OSHA Consultation Program offering free consultation services.This program offers employers the opportunity to find out about potential hazards at their worksites, improve their occupational safety and health management systems, and even qualify for a 1-year exemption from routine OSHA inspections. In the year 2000, 20 CFR* Part 1908 was amended to reflect many of the underlying tenets of the CB strategy: (*1*) provide for greater worker involvement in site visits, (*2*) require that workers be informed of the results of these visits, (*3*) provide for the confidential treatment of information concerning workplace consultation visits, and (*4*) update the procedures for conducting consultation visits. Specific task-based hazard guidance concepts associated with CB might also have utility for the OSHA Consultation Program for providing guidance to target smaller businesses. This can be accomplished while communicating the distinction between OSHA safety and health consultation services and enforcement efforts.

**Code of Federal Regulations*. See CFR in references.

8.3 Implementation of a Risk Management System in the United States that Includes CB Strategies

The implementation of CB strategies in the United States for qualitative risk assessment and management requires additional research and development. Topic areas for further exploration include the provision of national-level guidance and coordination, pilot projects at the state level, and expansion of the ORM (Occupational Risk Management) Toolbox to include more chemicals and ergonomic, safety, and environmental concerns. Cooperation with international efforts to implement CB can strengthen efforts in the United States through bilateral sharing of research and experience. Linking CB strategies with Occupational Safety and Health Management Systems and the GHS will add value.

8.3.1 Can Toolkits and Toolboxes Reduce Occupational Exposures to Protect the Health of Workers on a National Basis?

At present, data are not available to allow appropriate validation of CB toolkit models [Jones and Nicas 2004, 2006a,b; Money 2003; Tischer et al. 2003; Kromhout 2002b; Maidment 1998]. Yet, such a task could be addressed through priorities established by the appropriate task force or working group. Such a National Control Banding Working Group would be charged with creating a validation process for evaluating the existing toolkits, focusing on strategies within selected industrial sectors and specific trades. One objective of the validation process would be to emphasize field IH input for identifying needs for improving toolkits and determining the scope of their implementation. This working group will decide which measurable parameters for ranking hazards to consider in choosing the appropriate CB, the prioritization of controls, and the effectiveness of their application. Because personal sampling requirements are essential to validation of the CB strategy, the validation strategy should be developed using statistically supported bases and be coordinated with research that focuses on prospective and retrospective epidemiologic studies. Validation efforts should simultaneously compare and contrast the success rates of different methods of implementing a given CB strategy.

8.3.2 Implementation in Small Businesses

During development of a validation process, toolkits can still provide hazard guidance in small business trades and industrial sectors. A practical validation effort could involve comparison of existing toolkits and the type of system within which it is implemented [Oldershaw 2003]. The different state OSHA plan systems may provide opportunities to apply a toolkit through demonstration or pilot programs. If a state OSHA strategy can integrate partnerships with trade organizations, organized labor groups, educational institutions, and government agencies, then a pathway would exist to build this model with a participatory strategy by including both workers and employers in its development [Money 2003]. This strategy fits well with the intent of the OSHA Alliance Program created in 2002 to enable organizations committed to safety and health to work cooperatively with OSHA to prevent illnesses, injuries, and fatalities in the workplace. Seeking and providing end-user input as part of this focus on the workforce will help improve the final CB product and determine when its use is most practical and how best to implement it.

8.3.3 Expanding to an ORM Toolbox for Chemical Control

This effort should begin by including point source emissions that do not involve the use of bulk chemicals, such as silica exposures relating to construction work. Construction work is an important example for showing how an application moving directly to exposure controls based on the task performed is the best use of the CB strategy. Stoffenmanager (discussed earlier in Section 3.3.4) has evolved to include a Construction Stoffenmanager, developed by Arbouw, under commission from the Dutch Association of Employers in the Finishing Sector of the Construction Industry and the Association of Contractors of Tiling Work in the Netherlands. The demonstration modules for this instrument are intended to help employers of plasterers and tilers to assess and control the risks of hazardous substances. Using the construction industry as an important emphasis area would allow expansion of IH aspects to include other chemical and physical exposures and perhaps to address biological exposures such as mold initially. Validation of controls tied to specific construction tasks that have an established exposure assessment would be linked to achieving target reductions in exposure on a task-by-task basis. The development of a complete ORM Toolbox will enable applications for addressing hazards that cut across industry barriers. For example, silica dust exposures in construction have some similarity to conditions and activities in some mining processes. Experience with exposure characteristics, processes, and controls in both industries may be transferable and could contribute to development of a solutions database with established toolkit and toolbox controls [Jones and Nicas 2004, 2006a,b; Guest 1998; Brooke 1998].

8.3.4 Develop Ergonomics Toolkits Based on Existing National Models

One potential application of the CB strategy in the early stages of exploration is the reduction of musculoskeletal disorders resulting from ergonomic exposures. The more traditional applications for chemical toolkits seek to address an extremely large and growing inventory of chemical substances. Chemical production involves the introduction of new constituents that may never be fully researched or adequately characterized with regard to exposures, toxicity, and control options. In contrast, ergonomics has a finite group of well-researched and defined risk factors and effective programs [Stewart et al. 2005; Zalk 2003]. In theory, a comprehensive collection of ergonomics toolkits could be developed, validated, and implemented prior to creation of a parallel chemical-agents strategy. For applications in this arena, the CB strategy could promote the use of practical tools for assessing and reducing risk based on recent advances in participatory ergonomics. Compiling a repository of well-researched, validated, existing work practices in the United States could lead to a solutions database for musculoskeletal hazards and ergonomic control options. Initial discussions of expanding CB strategies to include ergonomics were first raised at the ICBW2, and subsequently the International Ergonomics Association has become involved through participation at both the ICBW3 and ICBW4.

8.3.5 Investigate Expansion to Safety and Environmental Parameters

Expansion of the ORM Toolbox could also encompass the ES&H multidisciplinary concepts that affect U.S. business establishments. The example of creating a construction ORM Toolbox could serve as an appropriate initiation for a system that would incorporate occupational safety and health requirements at a given worksite and include an additional focus on traumatic injuries. In this system an appropriate context for a safety-related toolkit would probably emphasize integrated training that offers a simplified strategy to lessons learned by accumulated tasks within a given trade. As an additional application, an environmental toolkit could be developed to assist employers and educate workers on the benefits of waste management for improving the air, soil, wastewater, and waste disposal streams. It is essential to involve stakeholders to define minimum performance standards, and to include this input in the creation of simplified training programs. For implementation in the United States and other countries, it would be progressive to incorporate pictorial training consistent with the GHS symbology to reduce the need for multiple translations. A challenge facing industrial hygienists in communicating exposure reduction successes is the dearth of appropriate yardsticks for measuring program benefits of a disease prevented. Possible solutions to address this challenge include better surveillance and use of appropriate metrics to track the effectiveness of hazard control interventions.

8.3.6 Investigate Expansion to Psychosocial Toolkits

The development of the Psychosocial Risk Management toolkit (PRIMAT) started with the definition of key principles and a framework of best practice for psychosocial risk management [Leka 2005]. Risk-reduction interventions and evaluation of those interventions will be developed for organizations as part of the framework guidelines on risk assessment. The framework also considers key indicators and aspects of corporate social responsibility, identification of key stakeholders, cost effectiveness, and societal learning. It goes a step further to consider policy level and its link to practice, both at the enterprise level and the national context. The next steps of the project will include the development of toolkits for the enterprise and the national levels as well as training materials. More information on the status of PRIMAT and associated products can be found at www.prima-ef.org.

8.3.7 Implementing a National Control Banding Strategy

To coordinate multiple activities supporting a control-focused risk management initiative, each requiring field research, validation, feedback, and improvement, would require coordination to oversee the process and track progress. Participation in this effort by stakeholders, labor organizations, and the ES&H organizations would be integral to its success. Part of this strategy would involve education for national ES&H and labor organizations to provide them with the foundation for a CB strategy and their role in its development, validation, and implementation. Insurance companies, workers' compensation agencies, and multinational companies could also contribute by sharing expertise, resources, and communication networks to prioritize efforts and promote the application of control-focused solutions to occupational hazards.

The scope of such a strategy requires linking with other similar committees and CB strategy entities internationally. A coordinated, consistent effort could maximize utility of limited resources and encourage harmonization in an increasingly global economy. As part of this strategy, exploring the twinning and regional partnering of developed countries with developing countries for trial implementation, with a focus on communicating and sharing of successes, may also assist in limiting the need for translating programs that are developed in native languages.

8.4 How Can International Cooperation Assist in the Creation of Toolkits and ORM Toolboxes?

8.4.1 Twinning Developed Countries with Developing Countries

An effort to investigate twinning concepts was begun at the Control Banding Practical Applications Workshop, held June 13–16, 2004, in Utrecht, The Netherlands. This meeting was coordinated as part of the WHO Collaborating Centers (WHOCC) Occupational Health Network 2001–2005 Work Plan's Task Force 10 on Preventive Technologies. This event resulted in planning to create and implement twinning strategies for pilot projects with CB for South Africa, Benin, and India. Developing and overseeing these twinning strategies and training protocols would be coordinated with and economically assisted by more established programs in developed countries, such as those in the United Kingdom, the United States, and The Netherlands. Attendees included leadership and representatives from the International Technical Group on CB and attendees from The Netherlands, Switzerland, India, Benin, South Africa, Brazil, Central America, Canada, Great Britain, and the United States. This cooperative effort is a model for future cooperative work between developed and for developing countries. International collaboration can appreciably strengthen national capabilities for the protection of workers' health and the environment. Sharing knowledge and experiences will also limit duplication of efforts and instead will build capacity by combining resources. It can also serve as the best method to test and improve existing toolkits, to identify the steps necessary to successfully build new toolkits, and eventually to create the blueprint for developing complete ORM Toolboxes.

8.4.2 Americas Silica Control Banding Effort

Since 2005, NIOSH has been exploring the utility of CB in its response to a request for assistance to address silica exposures in South American countries. Specifically, a multidisciplinary, interdivisional NIOSH team of researchers has traveled to Santiago, Chile to provide training and technical assistance to the Occupational Health Department, Instituto de Salud Publica de Chile (Chile Public Health Institute) and the Ministerio del Salud de Chile (Chile Ministry of Health) as part of the Multinational Program for Elimination of Silicosis in the Americas. These technical assistance visits to Chile have involved meetings with public health officials and training on occupational safety and health issues, including several intensive courses focusing on CB tools and applications. Courses have included live translation during classroom sessions and field visits to quartz quarries and rock crushing plants. Chilean participants received training on strategies for assessing and controlling exposures to silica-containing dust in mines and other high-risk workplaces. In conjunction with the visits, NIOSH researchers participated in joint field site visits to a large underground and surface copper mine in the Andes and a rock crushing small enterprise in the Santiago region. The purpose of the field visits was to observe work activities and tasks associated with potentially high exposures to crystalline silica dust and whether control-focused, task-specific hazard guidance sheets (such as Silica Essentials and NIOSH mining engineering reports) might provide relevant information to reduce hazards. This cooperative effort has been formalized through a letter of agreement with NIOSH, the Chile Public Health Institute, the Chilean Ministry of Health, and the Pan-American Health Organization (PAHO) in September 2006. Plans are also being made for continued collaboration and expansion to include additional South American countries of Brazil and Peru.

8.4.3 Expanding to an ORM Toolbox

For cooperative efforts internationally, eventually a focus on large scale industries or sectors in developing countries will be necessary to link ORM Toolbox needs in developed countries. Selection of appropriate industries will help determine the effectiveness of exposure prediction related to some existing toolkit applications. For practical purposes, activities and progress-implementing elements of CB should consider the guidance presented in the International Technical Group's Implementation Plan (Appendix C). Such efforts would be consistent with the activities of the WHOCC in their 2006–2010 Work Plan, which includes 25 risk management (CB) projects (www.who.int/occupational_health). The initial draft of the 2006–2010 Work Plan was drafted as part of the IOHA 6th International Scientific Conference on Occupational Hygiene, which was held in September 2005, in South Africa.

8.4.4 Fitting Control Banding into Occupational Safety and Health Management Systems

The International Organization for Standardization (ISO) is an existing network of the national standards institutes in 147 countries which could facilitate further development of an appropriate CB strategy with international relevance. With the success of ISO 9000 for working with quality management and ISO 14000 for working with environmental management, a natural extension of this concept would be to include safety and health. The Occupational Health and Safety Assessment Series (OHSAS), the OHSAS 18001–2, is a management system that seeks to help organizations control occupational safety and health risks. Similar to the objectives of the CB strategy, OHSAS 18000 series is a method of assuring conformance with an occupational safety and health policy. IOHA performed a critique of the OHSAS 18001 for the ILO. (The resulting report can be accessed at the IOHA Online Library for WHO and ILO documents at www.ioha.net.) Strengths identified within the critique include long-term employer savings by using risk assessments for cost avoidance, reducing workers compensation and medical costs, focusing on proactive prevention to reduce safety and health liabilities, and setting safety and health dedication apart from other traditional areas of business and trade. Linking the CB strategy within an existing system like OHSAS could provide a mechanism for toolkit and toolbox implementation to ensure it is maintained and improved within a management system that can be assessed at appropriate intervals.

Part of integrating CB into a business model is overcoming the difficulties safety and health professionals have in communicating the value of their services. The collective professions of environmental and occupational safety and health generally have limited understanding of the language of businesses, which converts issues directly into financial terms [Schulte et al. 2004]. One possible exception is the pharmaceutical industry, where this strategy has been successful and, consequently, could serve as a model to be followed as a formal means of communication in other industrial sectors. In addition, further benefit could be derived if workers' compensation and insurance organizations could promote and lead the education efforts for learning how best to speak the language of business [Schulte et al. 2004; Ennals 2002]. Self-insured multinational organizations have already learned the value of this process by investing in research in improving return-to-work rates [ILO 1998]. Therefore, harmonizing CB strategies with the development of the American National Standards Institute (ANSI) Z10 version of OHSAS in the United States could potentially improve the effectiveness of both efforts.

8.4.5 Control Banding Compatibility with the Globally Harmonized System for Classification and Labeling of Chemicals

The GHS was developed as the result of an international mandate adopted at the United Nations Conference on Environment and Development in 1992. The goal was to have such a system developed by the year 2000, including criteria for the classification of hazards, labels, and MSDSs. The work was to build on existing systems in the United States, Europe, Canada, and the United Nations transport systems. Classification and labeling laws are based on countries recognizing that the quantity of chemicals in commerce is so extensive that no country can effectively regulate each one individually. Having laws that require information to be transmitted to users regarding these chemicals is one way to ensure that steps can be taken to provide protection from their hazards. Although similarities exist among international hazard classification systems, the national, regional, and international requirements are different enough to require multiple classifications and multiple labels and MSDSs of a chemical to be shipped to different countries. Therefore, the mandate from the United Nations Conference on Environment and Development was to encourage countries to work together to eliminate these differences by harmonizing their requirements, maintaining or enhancing protections in the process, and eventually providing the opportunity to eliminate technical barriers to trade in this area.

Development of the GHS involved 10 years of effort by multiple countries and international organizations. Completed in 2002, the maintenance, updating, and implementation of the GHS are assigned to a new United Nations Subcommittee of Experts on the GHS. The United States was an active participant in the development of the GHS, through contributions from both the government and relevant stakeholders, and is a member of the United Nations Subcommittee. An international goal to have as many countries as possible implement the GHS by 2008 was established by both the Intergovernmental Forum of Chemical Safety and the World Summit on Sustainable Development. Some countries have been successful in meeting this goal, while the United States and other countries are still involved in efforts (described below) to implement GHS requirements.

The United States lacks a system of standardization, analogous to that used in the European Union, for hazard statements on labels and MSDSs. As emphasized earlier, the United States cannot move forward with the GHS because of this obstacle. Nevertheless, the availability of an internationally approved system to classify chemicals and prepare harmonized labels and MSDSs provides a strong impetus for adoption. The additional impetus to adopt the GHS is provided by the potential widespread applications for CB in the United States.

Despite the barriers to adapting concepts of the GHS in the United States, there is considerable interest in the system and some activities related to its implementation. The four regulatory agencies potentially affected by the GHS are all actively engaged in considering adoption (EPA, DOT, OSHA, and CPSC). OSHA has prepared an analysis comparing the GHS to its HCS requirements, and in September 2006 the Administration published an advanced notice of proposed rulemaking to incorporate elements of the GHS into the HCS. Both the OSHA analysis and advanced notice are available on the OSHA Web site with links to the official text of the GHS as well. GHS implementation has also been a subject of discussion in OSHA meetings with its North American Free Trade Agreement partners on handling of hazardous substances, and the three countries (Canada, Mexico, United States) have exchanged information about implementation activities on a regular basis. There is also an existing U.S./EU pilot project to link the GHS with CB in order to implement the GHS seamlessly across the Atlantic, with CB as an integral part of this process that seeks to control exposures related to the international distribution of chemical inventory. Information relating to this pilot project is at www.useuosh.org with many useful discussions and subtopics linked to the concepts presented. By 2006, the Asia-Pacific Economic Cooperation established a goal of implementation. The United States also participates in this trade-related organization.

The GHS is seen by international organizations as a significant tool to ensure the sound management of chemicals worldwide. The GHS provides the informational framework upon which comprehensive programs to address chemical safety and health can be based in countries that do not have the infrastructure to create such a system. The additional benefit of having the system updated and maintained by an international body rather than by each individual country is significant in the context of global chemical safety and health. Thus, WHO, ILO, IPCS, Organization of Economic Cooperation and Development, and other international organizations continue to promote its adoption and implementation worldwide. The United Nations Institute for Training and Research is also working with ILO to promote implementation through pilot projects in various countries as well as other capacity-building activities. The United States is a partner in this work, having provided some funding to the United Nations Institute for Training and Research to promote implementation of the GHS. The ability to use CB in countries that have adopted the GHS has already been recognized as a potentially powerful tool to achieve chemical control in economies in transition.

On a grander scale, efforts to implement the GHS also provide opportunities to work with and cultivate multinational cooperation with private enterprises. Partnerships are established by investing time, experts, and financing for the necessary field implementation, validation, and development of long-term occupational safety and health management systems essential for CB strategies. It should be emphasized that the best CB product, including toolkits and toolboxes, will be one that is transcendent of borders for implementation yet adaptable to the specific legal and sociocultural features of the countries in which it will be applied.

8.5 Recognition of Specific Industries or Activities Where CB May Be Adopted

Small chemical manufacturing facilities and trades that use chemicals within their processes and procedures are the primary focus of existing toolkits. This focused effort should be structured to allow comparisons based on utility for medium and large chemical industries. This effort has already begun with the testing of COSHH Essentials against existing personal monitoring exposure assessments in India. Beyond risk assessments per COSHH Essentials and the ICCT, work could begin by focusing on point source emissions with known solutions databases such as the inclusion of attributable portions of the Silica Essentials within a Construction Toolbox that seeks to incorporate silica dust, wood particulate, noise, safety, traumatic injuries, and other well-documented control solutions. NIOSH has initiated projects that account for a strategy of qualitative risk assessment and management (CB) and the development of task-specific hazard control guidance. Because rates of illness and injury for specific industries are higher than for general industry, they are already being targeted: pallet manufacturing; concrete products industries; roofing, siding, and sheetmetal; plumbing, heating, and air conditioning; auto and home supply stores; eating establishments; and medical offices and clinics. Additional systems are in place to evaluate CB use with glutaraldehyde in healthcare facilities, metal working fluids, and silica exposure potential across all trades.

Multidisciplinary CB models for work-related risk reduction in construction could address the variety of hazards (chemical, ergonomic, safety, and environmental) in that industry. Thus, the incorporation of individual toolkits into a Construction Toolbox is an appropriate next step. The ICBWs have facilitated toolkit strategies for ergonomics, silica, and safety in a manner that includes the provision of national-level guidance and coordination of pilot projects at the state level. An ORM Toolbox concept has become a byproduct of this coordination, which has broadened the CB model to include a more comprehensive exposure control basis for universal industries such as construction and agriculture. Working to further develop this multidisciplinary effort is an international, informal working group that includes the United States, United Kingdom, and the Netherlands that is seeking occupational health and safety professional input toward the development of a task-specific Construction Toolbox framework [Zalk 2008; van Thienen and Spee 2008].

8.6 Additional Applications of CB in Ergonomics, Noise, and Traumatic Injuries

Ergonomics is a promising area for adaptation and adoption of CB strategies. Additional research and development is required before the utility of CB strategies in noise, traumatic injuries, and nanotechnology can be evaluated.

8.6.1 Control Banding for Ergonomics

Ergonomics hazards are an area where a CB strategy could provide practical solutions to physical agents that may cause musculoskeletal disorders in the workplace. Whereas chemical inventories and applications continue to expand, with many substances lacking data on toxicity, exposure characteristics, and potential adverse health impacts, ergonomics has a finite group of well-researched and defined risk factors and effective programs. For applications in this arena the CB strategy could promote the use of practical tools for assessing and reducing local risks, some of which have been derived from recent achievements in participatory ergonomics in developing countries. Participatory-based programs in developing countries support low cost improvements in small enterprises, such as Work Improvement in Neighborhood Development, which focuses on agriculture, Work Improvement in Small Enterprises [Muchiri 1995], and Participation-Oriented Safety Improvement by Trade union Initiative. To tie these concepts together, an intercountry network has been formed to exchange positive experiences and collaborate in educating trainers and developing training tools, which, in Asia, are called Work Improvement Network. These can be accessed at www.win-asia.org.

A reduction in work-related musculoskeletal disorders is essential to the improvement of occupational health in both industrialized and developing countries. Currently 40% of the world's occupational and work-related health costs are attributed to musculoskeletal diseases [ILO 1999]. With industrialization taking root in developing countries, ergonomic interventions need to be adaptable in order to span several industries and work sectors. Ultimately, this will require a programmatic process that is low cost, easy to understand, and sensitive and adaptable to the social, cultural, and political considerations of each targeted industry. One part of this process is putting in place a permanent ergonomic infrastructure to train and disseminate information to the internal groups and organizations in need. Within the process of training, a combination of ergonomic hazard assessment tools should be presented. These tools, or toolkits in development, could include a brief manual that leads to checklists for direct use by managers and workers of small enterprises in a manner that puts into practice the ILO Ergonomic Checkpoints document published in 1996 and currently being revised and updated. Initial toolkit versions could be implemented and assessed according to the usefulness of the strategies recommended. Examples of industry- and task-specific guidance that could be developed include an agricultural ergonomics toolkit, a construction ergonomics toolkit, and a human/computer interaction toolkit [Zalk 2003]. Essential in this toolkit development strategy will be a follow-up mechanism to ensure that the newly trained individuals (infrastructure) receive some expert guidance when employing their new skills. Finally, an economic evaluation of expected improvements should become an integral part of the process. This would help facilitate management's acceptance of the proposed ergonomic interventions, providing justification for control development to eliminate or mitigate the hazards with supporting business case models and simple cost/benefit analyses [Zalk 2003; Stewart et al. 2005].

8.6.2 Control Banding for Noise

An example of the difficulties in applying the CB strategy to physical agents is in controlling exposures to noise. Unlike the above strategies for chemical risks and ergonomics, an appropriate delineation for control needs and effectiveness would require precise exposure measuring equipment. There are too many factors, almost all specific to workplace and worker, beyond the current concept for simple toolkit-related strategies that render simplification impractical. The key field guideline that can be used is the distance required for understandable, normal conversation. This guideline, common in field practice, is approximately 2–3 feet from the speaker. If a person's voice needs to be raised for communication, then the noise exposure level is most likely at or above a key 85 dBA threshold. Above this threshold, the use of hearing protection for affected workers is advised. Any further recommendations above this level are directly tied to 3 dB (ACGIH TLV) or 5 dB (OSHA permissible exposure limit) exchange rates that halve the time of exposure with each elevation of exchange rate. This precision would be difficult at best, and truly impractical in concept, to offer appropriate worker exposure times.

8.6.3 Control Banding for Traumatic Injuries

In the year 2005, the U.S. Bureau of Labor Statistics reported almost 5,734 fatal occupational injuries (http://stats.bls.gov/iifwc/cfoi/cfoi_revised05.htm). Within these injury statistics are specific industries and activities associated with higher rates of injuries (both fatal and nonfatal). An example of this is in the manufactured wood pallet industry, which has an overall increase of 245% in injury rates compared with general industry, including more than a 1,300% increase in amputations and more than an 800% increase in cuts and punctures. Many industrial sectors (e.g., agriculture, construction) with hazards (e.g., confined spaces, electrical hazards, fall hazards) that contribute to occupational injuries could benefit from control-focused solutions and guidance. Traumatic injuries can be addressed within a Construction Toolbox through task-specific hazard guidance provided in training and included as control solutions. In addition, control solutions and guidance developed for one industry sector (e.g., construction) often have relevance to other industries, such as agriculture and mining, and can be applied to address similar hazards.

Similar to the banding of chemicals by toxicity, classifications already exist for different variables of accident causation. Banding safety risks for selection of appropriate barriers for injury prevention is similar to selecting appropriate engineering controls based on chemical hazard bands in CB. Barriers to injury, including management factors, are strongly related to the quality of safety management systems and are important parameters for risk prevention [Swuste and Zalk (in press); Swuste 2007; Zalk 2006].

8.6.4 Control Banding for Nanotechnology

Also being considered is the potential for applying CB strategies for the qualitative risk assessment and management of exposures to nanomaterials. Researchers have explored the concepts of a "Nanotool" with simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicologic and exposure data [Paik et al. 2008]. These strategies may be particularly useful in nanotechnology applications, considering—

- The overwhelming level of uncertainty concerning which nanomaterials and nanotechnologies present as potential work-related health risks
- Characteristics of these materials that might lead to adverse toxicologic activity
- Possible strategies for assessing related risk
- Management of these issues in the absence of this information

A pilot CB tool, or CB Nanotool, was developed specifically for characterizing the health aspects of working with engineered nanoparticles and determining the level of risk and associated controls for five ongoing nanotechnology-related operations being conducted at two Department of Energy research laboratories. Four of the five operations evaluated in the study were found to have implemented controls consistent with what was recommended by the CB Nanotool, with one operation even exceeding the required controls for that activity. The one remaining operation was determined to require an upgrade in controls. The authors conclude that application of CB appears to be a useful strategy for assessing the risk of nanomaterial operations, providing recommendations for appropriate engineering controls, and facilitating the allocation of resources to the activities that most need them.

8.7 Current Collaborations to Explore CB

Collaboration with multiple stakeholders, including national and international agencies, organized labor, trade groups, academic institutions, and professional societies can build capacity and maximize resources, contributing to improved toolkits to protect worker health globally. The interest in CB strategies has grown and led to improvements based on partnerships to explore its utility for multiple applications and a variety of workplace settings. One organization instrumental in bringing forth the modern incarnation of CB is the IOHA, which is comprised of established IH organizations worldwide. The concept is currently housed within the WHOCC Occupational Health Network Work Plan 2006–2010 (www.who.int/occupational_health). The WHOCC is a collective effort that also maximizes partnerships with 65 Collaborating Centres around the globe, working in concert with the ILO and the major occupational health Non-Governmental Organizations of IOHA, the International Commission on Occupational Health, and the International Ergonomics Association. With the CB strategy having strong support within the development and dissemination protocol of the GHS discussed in this document, it is also intricately tied to the WHO/ILO IPCS office. Under the auspices of the IPCS, an ITG has been established to facilitate the further development and implementation of the greater encompassing ORM Toolbox. ITG has developed a Global Implementation Strategy (see Appendix C) to ensure that national CB Work Plans are developed and implemented by relevant stakeholders. In addition to the multiple organizations discussed above, ITG is also partnering with HSE, NIOSH, and the GTZ.

Building upon international coordination efforts of the ITG and its Global Implementation Plan, NIOSH and other organizations within the United States have initiated activities to explore CB options, research needs, and potential applications. The first effort to create greater awareness of this concept involved planning and coordinating the ICBW2. Although international in concept, this workshop was supported by an essential U.S. partnership matrix including ACGIH, AIHA, OSHA, NIOSH, and the U.S. National Safety Council, in addition to the above global organizations of ILO, IOHA, and WHO. In fact, the current ITG Global Implementation Plan was initially drafted at this workshop. An outcome of this event was the need to consider U.S.-specific parameters for developing a national CB effort. This led to the National Control Banding Working Group meeting in March 2005, in Washington, D.C. For this event, the U.S. partnership matrix was expanded to include representatives from the EPA, trade unions, corporations, and academia. These partnerships have allowed for continued discussion and consideration of CB strategies, in cooperative efforts to address research needs, barriers to implementation, validation concerns, and creation of awareness of control-focused solutions and guidance.

9

Discussion and Conclusions

CB strategies can be used effectively for performing workplace risk assessments and implementing control solutions for many, but not all, occupational hazards. COSHH Essentials is a popular toolkit model that has been well researched—although further validation is important—with narrowed applications in the larger scale of CB. CB strategies will not eliminate the need for personal monitoring and should lead to an increased appreciation for the role of the IH professional and useful solutions-based databases.

A review of the literature and the brief history of CB evolution, applications, and evaluation indicates that CB strategies cannot provide appropriate solutions for the assessment and management of all occupational hazards. There are situations in which CB cannot provide the precision and accuracy necessary to protect worker health; alternatively, there are undoubtedly situations in which CB will provide a higher level of control than is necessary. Despite these concerns, CB strategies have the potential to be entry-level tools for occupational risk management. They can be an integral part of a tiered strategy for risk assessment, in which simpler tools are used at a screening level, followed by a more complex strategy as needed or as indicated by the particular situation [Nelson et al. 2003; Mulhausen et al. 2004].

The COSHH Essentials strategy from HSE was designed to help SMEs perform risk assessments for all chemicals and mixtures of chemicals indicated under the COSHH regulations. The United States does not have any similar regulation that requires risk assessments for all chemicals in use. However, the basic premise is of value to industries in the United States—thousands of chemicals are in use and only a few levels of risk management (i.e., CB strategies) are available to control worker exposures to these chemicals. As an underlying principle, the COSHH Essentials toolkit is valuable for CB strategies because it meets all six of Money's [2003] core principles (understandability, availability, practicality, user-friendliness, confidence on the part of users, and transparent, consistent output). The COSHH Essentials model must be viewed as a supplemental tool in a comprehensive program that also accounts for personal protection, training, health surveillance, hazard communication, and worker participation, and not as an unconditional replacement for a comprehensive risk management program [Oldershaw 2003].

In addition, the process of applying R-phrases to hazard bands is a useful practice but is not intended to replace OELs [Brooke 1998]. With regard to applications of the CB strategy, Russell et al. [1998] point out that when performing risk assessments, employers should still consider other factors such as the need for health surveillance and the need to monitor exposure to ensure adequacy of control. Similarly, employers will want to consider recommending controls appropriate for the processes within their particular workplace. CB strategies ideally have utility in providing guidance for performing risk assessments and in selecting appropriate control measures; CB strategies are not a replacement for traditional exposure monitoring and use of OELS.

As described previously, the validity of the exposure assessment component is essential to the effectiveness of the CB strategy. An additional critical component is the establishment of a uniform and standardized toxicologic characterization for a chemical by the supplier, using either R-phrases or similarly recognized categorical designations. It is the R-phrases that are applied to a substance or chemical mixture that determine its allocation to a hazard band and thus the intended target airborne concentration range. A continuing concern with most CB strategies, including COSHH Essentials, is the fact that they are primarily focused on the inhalation route of exposure. Consideration of other potential routes of exposure and anticipated toxicologic endpoints could strengthen the utility of CB strategies and broaden the scope for recommending control options [Brooke 1998]. Further refinement of CB strategies should include consideration of procedures for ensuring adequate margins of safety and a schedule for frequent updates of information as it becomes available.

One potential benefit of CB implementation could be increased use of exposure-assessment applications for field practice, providing additional information for surveillance of exposures and control effectiveness. As a consequence, the CB strategy could also have the effect of raising the profile of the industrial hygienist while maximizing public health resources for the benefit of the profession and the population at large. As part of the CB validation plan, increased practice of exposure assessment will serve as the basis for evaluation of implemented controls and will provide the feedback to improve hazard control guidance for subsequent revisions of the given toolkit.

10

Recommendations to Facilitate the Implementation of CB Strategies in the United States

Based on the potential utility of CB and the fact that most chemical substances do not have established OELs, it seems appropriate to explore applications and implementation of CB strategies in the United States. These recommendations are made under the categories of improving awareness of concepts, validation considerations, expansion of the CB model, dissemination, coordination, and collaboration. From the review of the literature and of recent workshops (including the U.S. National Control Banding Workshop in 2005), symposia, and conferences exploring the utility and potential applications of qualitative risk assessment and management (i.e., CB) strategies, the following recommendations have been identified with potential activities and programs to facilitate the implementation of CB in the United States.

10.1 Recommendations for Improving Awareness and Standardization of Concepts

1. Coordinate terminology to ensure a singular CB vocabulary is established, adopted, understood, and communicated for practical purposes such as training, professional discussions, and application of concepts.
2. Following application of CB strategies, carefully consider the exposure scenarios under which personal monitoring should be required, using specific R-phrases or other appropriate communication language.
3. Adopt the GHS to work toward ensuring standardized hazard statements are available on U.S. chemical labels and MSDSs to promote widespread CB applications. Include a procedure for frequent updates of information. Educate the wider occupational and ES&H community on this change.
4. Develop a resource so that SMEs can obtain additional assistance on implementing control measures that are more protective. Perhaps the CGSs could include a link to professional associations (e.g., AIHA, ACGIH), accredited labs and services, or provide a link to companies that provide technical services (e.g., accredited labs, consultants).
5. Continue to develop and offer training for professionals and for SME operators on the implementation

of CB strategies and the toolbox and toolkits available. Emphasize the role of CB in the context of tiered risk assessment (i.e., selection of the appropriate tool for a specific risk scenario).

6. Develop an incentive system based on input from broader groups of stakeholders, including insurance, financial, trade, and legal interests.
7. Incorporate economic analyses into the process of selecting exposure control methods, with the goal of developing a more complete understanding of the relationship between the hierarchy of controls and their cost effectiveness. A key assumption underlying CB appears to be that a higher degree of control (e.g., containment, followed by engineering control) is generally expensive and may be "overprotective" against exposure to substances in the lower risk categories. This assumption has driven the idea that CBs should be rigidly tied to specific risk levels. This assumption may be inaccurate in many cases and may complicate the CB strategy unnecessarily. In addition, for many substances there is less than complete information concerning their long-term human health effects, making R-phrases inadequate to fully describe the risk persons in the workplace face if they are exposed. In such situations, a higher level of control would be prudent rather than overprotective.
8. Conduct research on the utility of CB to SMEs and the barriers to using it.

10.2 Recommendations for Validation

1. Make sure that a validation protocol accounts for the effectiveness of a given toolkit and its controls.
2. Use validation protocols to validate and compare various implementation methods and the construct in which they are introduced with both employers and workers.
3. Validate each step of the CB strategy independently: exposure prediction, hazard prediction, control recommendations, training, and control implementation.
4. Assess errors associated with CB hazard classification, exposure assessment, and control recommendations to determine the accuracy of the model.

10.3 Recommendations for Expanding the Control Banding Model

1. Develop a comprehensive, easy-to-use set of ergonomic hazard- and risk-assessment tools. These ergonomics toolkits should begin with a brief manual leading to checklists for use by SME employers and workers.
2. Consider dermal absorption as a factor that might make an impact on hazard classification, exposure assessment, and control solutions in a CB risk management model.
3. Include guidance and control-focused solutions for additional

substances, specifically those that were excluded by HSE because they were regulated under other codes (e.g., pesticides, lead, asbestos).

4. Include processes that address combined chemicals use, mixtures, and compounds of variable composition that can have additive or synergistic safety and health consequences.
5. Convert existing guides and solutions documents to toolkits by beginning the documents with instructions on how to do a qualitative risk assessment of the workplace.
6. Develop sector specific toolkits (e.g., construction, healthcare, and manufacturing).

10.4 Recommendations for Disseminating Control Banding

1. Develop public sector (governmental) and private sector (trade association, industry, organized labor, academic consortia) strategies to coordinate efforts for developing, implementing, and evaluating qualitative risk assessment and risk management strategies and task-specific, hazard-control guidance.
2. Create awareness, implementation, and dissemination strategies among the regulatory, consultative, professional, and trade associations consistent with research to practice concepts.
3. Identify strategies for promoting the value and utility of CB using business case models and examples of broader workplace protections despite limited resources.

10.5 Recommendations for Coordination and Collaboration

National Coordination and Collaboration

1. Encourage NIOSH and OSHA cooperation in focusing on CB utility for special emphasis areas, such as hazard communication and guidance for small businesses. The State OSHA plans, fitting within the OSHA Alliance, may provide mechanisms to implement CB strategies and demonstration projects for control-focused solutions and guidance.
2. Develop task-based CB toolkits that focus on point-source exposures related to specific tasks and controls that have been validated. Guidance can be developed and provided in a practical, applicable format when historical data exist to characterize exposure for a particular task (e.g., silica in mining or construction).
3. Include worker involvement as part of a tripartite strategy within a participatory process for any implemented CB strategy. Provide for assessment and feedback for this process using medical surveillance, with risk assessment based on health measures.

4. Coordinate resources and curricula for training professionals and SME audiences on the implementation of CB strategies and models available.

International Coordination and Collaborations

1. Coordinate the development and creation of an integrated system for both national and international databases. This database system should also include a component that tracks voluntary submission of data for the validation of various toolkits.
2. Adopt the ITG implementation strategy to coordinate occupational risk management concepts with international collaborative efforts, such as those within the WHOCC, in order to harmonize efforts and build capacity.
3. Link the CB strategies to an existing system of Occupational Safety and Health Management Systems for implementation. This will help to ensure it is maintained and improved within a management system that can be assessed at appropriate intervals and modified as necessary.

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Appendix A | Related Publications with Selected Annotations

Falconer K [2002]. Pesticide environmental indicators and environmental policy. J Environ Manage 65:285–300.

Falconer assesses the feasibility of developing environmental banding for more effective pesticide policy, specifically, developing pesticide groupings. Groupings would be formed on the basis of broad similarities and differences rather than of precise individual ordering. However, because of the complexity of pesticides, their usage, and impacts, no single ecotoxicological parameter can be used to define and quantify policy issues. Rather than using impact assessments, which must be conducted for each site, to define the grouping, Falconer suggests using hazard-based indicators. Enhanced pesticide labeling could be useful in decision-making by users. He concludes that pesticide groupings would be more feasible and useful than ranking of individual products.

Kirkwood P, Trenchard PJ, Uzel AR, Colby PJ [1991]. SARAH (System for Advising on the Regulations for Assessing Hazards): an expert system for training non-hygienists in carrying out occupational hygiene assessments. Ann Occup Hyg 35:233–237.

Similar to COSHH Essentials, the SARAH expert system can ease the workload of occupational hygienists by providing nonexperts with the tools to solve simpler occupational safety and health problems. It was designed for use by British Gas to assist in meeting COSHH requirements.

Money CD [2002]. European chemical regulation and occupational hygiene. Ann Occup Hyg 46:275–277.

This source describes the drivers for risk assessment of chemicals in the EU:

- In 1998, the third largest manufacturing industry was chemical manufacturing, employing 1.7 million people directly.
- Several leading multinationals and 36,000 SMEs were involved.
- Known adverse human health effects of many chemicals, and lack of knowledge about the impacts of many chemicals.

The number and volume of chemicals are also driving chemical risk assessment in the EU:

- 400 million tons of chemicals produced globally in 2001
- 100,000 substances registered in the EU
- 10,000 chemicals marketed in volumes >10 tons and 20,000 marketed at 1–10 tons

The article describes the REACH system, which is a regulatory system for chemical control. The REACH system uses a tiered approach to registration, triggered by production volumes. The proposed system would result in critical information about most chemicals being registered in a central database. Higher anticipated risks would trigger higher levels of required information.

Northage C, Marquart H [2001]. Occupational exposure information needs for regulatory risk assessment of existing chemicals. Appl Occup Environ Hyg *16*:315–318.

The authors describe the information required to conduct a risk assessment per EU Regulation 1488/99, which requires risk assessments be conducted on existing priority chemicals. Assessments should include human health and environmental concerns and are carried out at the national level. Data requirements for exposure assessment include the following:

- Description of work activities
- Percentage of substance in product and amounts used
- Distinction between different exposure scenarios
- Measurement methods
- Raw sampling data and statistical descriptors
- Task information
- Controls information
- Number of sites to which data apply
- Year
- Explanation of outliers
- Explanation of changes in exposures

Oldershaw P, Fairhurst S [2001]. Sharing toxicological information on industrial chemicals. Ann Occup Hyg *45*:291–294.

Sound risk management relies on regulatory standards, and development of a chemical's standard requires its complete toxicological profile. Some of the barriers to global access to robust toxicological profiles are the shortage of data, conflicting positions on data interpretation, poor transfer of toxicological information, inefficiencies in the use of available resources, and inadequate understanding of the science. Indications of progress include increasing quantities of data (e.g., the International Council of Chemical Associations commitment to baseline data on the High Production Volume substances, harmonizing positions on data interpretation, better transfer of toxicological data to those exposed, more efficient use of available resources, and improved understanding of the science). Oldershaw and Fairhurst called for several elements to improve data quality:

- More international collaboration
- Assessment with an eye to international needs
- Better understanding on the part of users
- Clear establishment of the state of available knowledge
- A pragmatic approach
- Agreement/codification/expression of scientific terminology
- Clear descriptions of extrapolation procedures

Tischer M [2001a]. What does *low exposure* mean? Exposure considerations in the testing of notified new substances. Appl Occup Environ Hyg *16*:228–232.

Tischer suggests that, when notifying the EU of new substances, risk assessors use R-phrases and the hazard banding model developed by the U.K. HSE to aid in decision-making on chemicals with no NOAEL.

Zalk DM [2001]. Grassroots ergonomics: initiating an ergonomics program utilizing participatory techniques. Ann Occup Hyg *45*:283–289.

Zalk emphasizes the important role of worker participation in developing effective ergonomics programs, in both industrialized and newly industrializing nations. Such an approach could be very valuable in worldwide application of CB techniques.

Appendix B | Allocation of Hazard Bands for Vapors

A substance's identifiable dose threshold influences its classification into Hazard Bands A–E, as used in the COSHH Essentials. Classification also depends on relative exposure level at which toxic effects occur and on seriousness of the health effect resulting from exposure. The governing R-phrase, for substance with more than one, is the R-phrase leading to the highest level of control. Along with that explanation, the R-phrase assignments were compared to health-based OELs for a selection of chemical substances. Each hazard band, which is based on toxicological considerations, covers a log (10-fold) concentration range[Brooke 1998].

Because the relationship between the ppm concentration and the mg/m3 concentration of a vapor is a function of its molecular weight (and also temperature and pressure, though not discussed in this article), the working group that oversaw development of this chemical classification decided to align the exposure bands. However, because of this alignment, if vapors and particulates are in the same hazard band, the concentration range for vapors, in mg/m3, is substantially higher than that for particulates.

Because of concern about this alignment procedure, R-phrases for vapors are allocated based on additional considerations. For example, the classification of R48 indicates danger of serious damage to health by prolonged exposure. If severe effects occur in animal-inhalation toxicological studies at 0.025–0.25 mg/L for 6 hours/day of exposure for 90 days, the substance is rated R48/20—Harmful. (0.025 mg/L represents the lower cut-off value; severe effects at a lower concentration would result in a rating of R23—Toxic.) Adjusting to a time period of 8 hours (and converting units) results in an equivalent 8-hour TWA of 19–190 mg/m3. For three hypothetical vapors with molecular weights of 50, 100, and 150, the equivalent 8-hour airborne concentrations are converted from mg/m3 to ppm, for the lower (<19 mg/m3), mid (19–190 mg/m3), and upper (>190 mg/m3) concentrations from the R48 range, resulting in a range of concentrations from 3–90 ppm. The resulting ppm concentrations are compared with the concentrations that would be experienced in Hazard Band B (>5–50 ppm). These comparisons showed in safety margins well below a value of 1.0 in the worst cases (generally involving high molecular weight compounds). Best-case comparisons, e.g., higher R48 cut-off values compared with the lower airborne concentrations for Hazard Band B (associated with lower molecular weight compounds), resulted in safety margins ranging up to 18.

R48/20 was allocated to Hazard Band C because the results of this analysis indicated that allocating Hazard Band B for vapors could result in significant concern for potential health effects under worst-case scenarios.

A similar analysis for particulates indicated higher margins of safety for them than for vapors. The analysis resulted in an even greater safety factor for particulates than for vapors. This logic was extended to toxic substances based on repeated exposures, assigning them to Hazard Band D. Similar logic resulted in the assignment of compounds to hazard bands based on effects resulting from single exposures (Harmful to Hazard Band B, Toxic to C, and Very Toxic to D).

For compounds with no identifiable dose threshold and potentially serious health effects, e.g., R40 Muta. Category 3, R46 Muta. Category 1 or 2, and R42 (respiratory sensitization), the appropriate allocation was Hazard Band E, which is always referred to expert advice. R-phrases for reproductive toxicity and carcinogens with nongenotoxic mechanisms and identifiable thresholds were allocated to Hazard Band D. Category 3 carcinogens with genotoxic mechanisms were assigned to Hazard Band E, as were Category 1 or 2 carcinogens, based on the EU Carcinogens Directive. Substances with skin sensitizers and corrosive or severe irritant effects were assigned to Hazard Band C based on their identifiable threshold. Moderate eye and skin irritants were assigned to Hazard Band A.

Note: Only after a substance's toxicological data are completely considered is it assigned to a hazard band. A substance should not be assigned to Hazard Band A simply because of lacking data.

Appendix C | Global Implementation Strategy Occupational Risk Management Toolbox

(Agreed by the IPCS International Technical Group on May 28, 2004)

This Global Implementation Strategy aims to build and implement an Occupational Risk Management Toolbox (Toolbox), containing toolkits to manage different workplace hazards. The first such toolkit, the International Chemical Control Toolkit (Chemical Toolkit), is based on an approach to risk assessment and management called control banding (CB). This approach groups workplace risks into control bands based on combinations of hazard and exposure information. It can also be applied to non-chemical workplace hazards. As this banding technique is semi-quantitative or qualitative depending on the application, it is particularly relevant for use in small and medium-sized enterprises, developing nations, and, in the case of chemicals, where no occupational exposure standard has been set. It may also be useful for environmental risk assessment and management, as health and environment controls are complementary, and often inseparable, at the workplace level.

Aim of the Global Implementation Strategy and Implementation Partners

Under the auspices of the International Programme on Chemical Safety (IPCS), an International Technical Group (ITG) has been established to facilitate the further development and implementation of the Toolbox. This Global Implementation Strategy provides key high-level approaches to achieve this aim. It is intended that work plans, focusing on particular applications, countries or regions, would be developed and implemented by relevant stakeholders. A particular focus of this Strategy is implementation of the Chemical Toolkit.

Partners in this international effort include: IPCS (International Labour Organization and World Health Organization); International Occupational Hygiene Association (IOHA); The Health and Safety Executive (HSE) in Great Britain; US National Institute for Occupational Safety and Health (NIOSH); and the German Gesellschaft für Technische Zusammenarbeit (GTZ). As this Strategy is implemented, new partnerships will be encouraged. The ITG Terms of Reference and Membership List are provided in Annex 1, which will be updated as needed.

Stakeholders

Stakeholders include implementers (including employers), researchers and workers/users of chemicals. Bodies that may be involved in the implementation of this Strategy include: intergovernmental and international non-governmental organizations (such as IOHA); government agencies; industry, including associations of chemical producers and suppliers; employer and employee associations; industrial hygienists; labour unions; labour inspectors; researchers; and training professionals.

The International Chemical Control Toolkit

The Chemical Toolkit (adapted from the HSE's COSHH Essentials) is available on the internet through the ILO SafeWork Website. It is undergoing further development, which will include technical improvement and additions. This process will also include translation and piloting in selected countries. The hazard information employed by the Toolkit is either the European Union (EU) label Risk (R) phrases, or the hazard statements of the Globally Harmonized System for Classification and Labeling (GHS). The target for global implementation of the GHS was 2008, individual country implementation dates could vary. Hence implementation of the Chemical Toolkit will need to be phased, initially focusing on building the necessary skills, knowledge and mechanisms for implementation, development and testing of guidance sheets, translation into other languages, and application of more generic approaches, such as the GTZ Chemical Management Guide (which is based on a simplified control banding technique). Implementation of the full Chemical Toolkit will be dependent on that country's use of EU risk phrases and/or GHS hazard statements.

Key Elements of the Implementation Strategy

Key elements are listed below, with lead bodies in parenthesis where relevant. At the work plan level, detailed actions taken must take into account the different needs of developing countries, economies in transition and developed countries. However harmonized approaches should be used where possible to avoid unnecessary duplication of effort.

1. Further develop the Chemical Toolkit, including the following:
    - Development of new control guidance sheets based on experience, to meet the needs of developing countries in particular (ILO with the input of others including GTZ; IOHA). This includes piloting, testing, evaluating, and revising. The need for country-specific sheets will be explored. However, unnecessary differences in the technical materials should be avoided. Some guidance sheets should be trade and/or task specific.
    - As guidance sheets begin to be developed by implementers (e.g. country-specific sheets), a mechanism for peer review, including peer review criteria. will be developed and the guidance sheets shared through an international Clearing House (see key strategy) (ILO, WHO).
    - Development of sheets for workplace processes that generate chemical exposures (ILO, IOHA).

- Addition of the skin route of exposure (the Chemical Toolkit currently focuses on inhalation exposure) (ILO with the input of HSE).
- Translation in local languages (WHOCC [Collaborating Centers], ILO, others).

2. Enhance links between the GHS, the Chemical Toolkit and other workplace tools.
3. Include GHS phrases in the IPCS International Chemical Safety Cards (WHO-IPCS, ILO).
4. Build and promote the Occupational Risk Management Toolbox, through the following:
   - Development of toolkits for workplace hazards other than chemicals (lead group ILO, WHO, IOHA, NIOSH, linking to an expanded network of other international and national bodies).
   - Integration of other toolkits in WHO CC Workplan (WHO CC [Collaborating Centers] Task Force on Preventive Technology).
   - Adaptation of existing participatory processes that have effectively engaged local communities (e.g., WISE, WIND programme) (ILO).
5. Explore new partnerships for implementation, including the following:
   - International bodies involved in implementation of the GHS, for example to tap into GHS implementation and training workshops (ILO).
   - The International Association of Labour Inspectors (IALI) (ILO to lead).
   - Identify potential donors and granting bodies.
   - Use country to country partnerships (twinning), for example between a developed and developing country.
6. Foster the development of work plans in support of this Strategy, focusing on specific applications, industry/occupation situations, countries or regions and maintain links with national and other working groups established to implement work plans. Work plans will aim to influence local decision-makers and effect local implementation. Information about work plans will be included in the Clearing House (see key below strategy).

   Identify ways to influence national decision-makers, including through:

   - WHO CC network activities
   - ILO-CIS Network
   - ILO and WHO offices
   - The EU
   - Agenda of inter-governmental meetings, e.g. on EU-US Cooperation.
   - Promotion at international and national Occupational Safety and Health/Industrial Hygiene Conferences.
   - Holding annual or biannual international CB workshops (1st workshop held November 2002; 2nd workshop held

March 2004). The 3rd workshop was held in September 2005 at the IOHA 6th International Scientific Conference (South Africa) and concurrently the XVII World Congress on Safety and Health (Orlando, FL). IOHA meeting was conducted back-to-back with WHO CC meeting.

- WHO CC Network meeting (Milan, June 2006) back-to-back with ICOH meeting provides an option for CB planning meeting and training.

7. Develop and publish a research agenda (lead: University of Oklahoma, working with other leading agencies, for the ITG), including sector-specific research (construction, agriculture, mining). This would include the areas listed below and would be updated regularly based on technical progress. A current research agenda will be maintained on the Web site (refer below), and at Annex 2. Research agenda will need to include application of the CB technique to different hazards, e.g., chemical, biological, physical, ergonomic exposures, etc.; different industry situations, e.g., SMEs, large industries, multi-nationals; developing countries; developed countries.
8. Collect and communicate research and information, including the following:
   - Maintenance of the Web site, hosted by ILO, with links to other relevant websites (lead: ILO).
   - Augment the Web site with a Clearing House including a web-based directory of research and validation studies (researchers list their ongoing studies and references for completed work).
   - Include other activities in the Clearing House, such as work plans developed by countries, etc.
   - Include a repository of guidance sheets in the Clearing House. Centers could be identified (regional, language-based) to maintain these (e.g., NIOSH), linked to the ILO Web site.
   - Publish regular update/topical articles in newsletters by email/net. Use existing vehicles and meetings to distribute (IOHA, NIOSH, Global Occupational Health Network Newsletter, etc).
9. Develop and maintain a capacity building and training plan, focusing on developing countries (WHO-OEH [Occupational and Environmental Health]). This will be needed for piloting work, then during the full-scale implementation. It would include the following:
   - Explore use of the GTZ Chemical Management Guide to build capacities and prepare countries for implementation of the Chemical Toolkit.
   - Cultivate regional train-the-trainer core groups.
   - Conduct train-the-trainer workshops in conjunction

with other international/regional events.

- Provide generic, translatable training materials.

10. Maintain an ITG to oversee the Global Implementation Strategy (quarterly telephone conferences, with face-to-face meetings occurring back-to-back with other events where possible) (WHO-IPCS).

International Technical Group (ITG) Terms of Reference and Membership

Terms of Reference

1. The functions of the ITG are:
    - To facilitate the further development and implementation of an Occupational Risk Management Toolbox, in particular the International Chemical Control Toolkit.
    - To maintain a Global Implementation Strategy, including identifying lead bodies for key actions.
    - To provide guidance to the relevant lead body/bodies concerning the collection and dissemination of information on activities.
    - To coordinate other activities undertaken in support of the Global Implementation Strategy, in particular, those of its members.
    - To measure and communicate progress against the Strategy.
2. The ITG makes its recommendations and decisions by consensus of those members present at a meeting.
3. The roles of Chair and Rapporteur alternate between the IPCS partners, i.e. ILO and WHO.
4. The ITG normally meets quarterly by teleconference. The ITG may agree to hold face-to-face meetings from time to time, and in these circumstances, participants make their own arrangements for bearing the cost of attendance.

Membership

The members of the ITG are experts from the following organizations:

American Industrial Hygiene Association (AIHA)

GTZ Convention Project on Chemical Safety, Germany

International Labour Organization (ILO)

International Occupational Hygiene Association (IOHA)

Health and Safety Executive (HSE), Great Britain

National Institute for Occupational Safety and Health (NIOSH), United States

World Health Organization ((OEH) and(PCS))

International Research Agenda

An international research agenda will be developed and published (see key strategy element 7). Proposals that have come forward to date are listed below.

1. Chemical Toolkit Applications in Developing Countries
   - Investigate applications within large enterprises.
   - Develop tools for SMEs.
   - Effectiveness of predicting exposures.
   - Validation of controlling exposures.
   - Field test of current product.
   - Translation of concepts and common phrases.
2. Other Applications in Developing Countries
   - Focus on large scale industries, select appropriate industries and hazards.
   - Develop other toolkits for the Occupational Risk Management Toolbox.
   - Adapt existing approaches (e.g., WIND Program), build on successes.
   - Develop an ergonomics toolkit based on existing models.
3. Chemical Control Toolkit Applications in Developed Countries—
   - Further validation studies.
   - Validate controlling exposures in selected small business trades.
   - Field industrial hygiene input on expanding, ranking hazards, prioritizing controls.
   - Focus on small business trades and define success.
4. Other Applications in Developed Countries—
   - Develop Ergonomics Toolkit based on existing national models.
   - Expand industrial hygiene aspects to include physical and biological exposures.
   - Investigate Occupational Risk Management Toolbox concept for SMEs.
5. Research to Fill Gaps in the Chemical Toolkit—
   - Investigate applications to the skin route of exposure.
   - Integration of skin and inhalation routes of exposure.
   - Integration of useful elements from comparable tools, e.g. the German Column Model.

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