nayati INTERNATIONAL

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Occupational
Health, Hygiene & Safety

OHHS NEWS

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About us

nayati International is a non-profit and tax exempt organization committed to making a difference in the quality of life of the communities around the world through research and education. Collaborating and working together with qualified experts, consultants and national and international organizations, institutions, we work with great commitment and in a participatory approach providing support and direction to communities.

nayati International is working in India building capacity in Occupational and Public Health through workshops and training activities. In collaboration with national organizations and international organizations like World Health Organization-Collaborating Centers, National Institute for Occupational Safety and Health – USA and several international experts, nayati has been conducting workshops of international caliber. For information on our past workshops and upcoming ones, please visit www.nayati.org.

Dear Colleagues

Dear Colleagues,

Hope you all had a wonderful year so far and as always, we at nayati wish you all a happy, healthy and safe future ahead. We are glad to be reaching out to you again this year after our annual workshop and bring to you OHHS magazine. As those of you who attended know, this year's workshop on "Assessment and Control of Worker Exposure to Potent Drugs and Chemicals" was designed specifically to meet the needs of the Pharmaceutical Industry. This industry is making great strides in India and Occupational health and hygiene has become an issue of great concern nationally and internationally. The excellent response and participation in the 4 day workshop is an encouraging indication of the importance the industry is giving to the health of its workforce and we reiterate our partnership in working for this cause.

We would like to use this magazine as an opportunity to share with you and those we missed at the workshop, a short pictorial of some of the events and about the event. It was no doubt a rigorous 3 days of control banding, hazard banding and calculations of exposure limits but the opportunity to learn from an international faculty that had years of expertise in the challenges of Occupational health issues of Pharmaceutical industry was very valuable. With 3M India participating, it was a great opportunity to practically learn the proper use of PPE – an important component for protecting worker health.

The discussions on the last day shed a lot of light on the challenges that the industry is facing. One important issue that came up which the industry is yet to tackle is the pollution of waters by hazardous pharmaceutical waste. Studies have shown extraordinary high levels of wide range of pharmaceuticals in treated effluents. That this alarming situation is seen in our own backyard, Hyderabad is a matter of grave public health concern. A problem as serious as this needs to be addressed before it reaches even greater proportions and all of us stakeholders would have to work together in mitigating this problem.

As some of you already know, we now have a wonderful resource in the OHLearning.com set up by the truly multinational project – the Occupational Hygiene Training Association (OHTA). We have the details of this project in the article in this magazine and nayati is glad to be approved by OHTA to provide training. The training modules and materials developed by experts are a great resource for every one interested in the subject and most importantly, they can all be downloaded and are available free of cost. Please visit OHLearning.com to know more about the program.

As always, we extend our gratitude and thanks to Dr. J.S. Yadav, Director and Indian Institute of Chemical Technology (IICT) for co-sponsoring the event and permitting the use of their facilities, to National Institute for Occupational Safety and Health (NIOSH), USA, Sizkorsky Aircraft, International Safety Systems and 3M India and the faculty who made this workshop valuable for the participants. Thanks to all of you participants without whose support this event would not have happened.

nayati has been interacting with you for the past three years trying to bring to you information on issues related to Occupational Health, Hygiene and Safety. Your support of these activities is actually your commitment to the health and well being of your workforce. Please let us know of ways we can assist you and your workforce in improving their health and well being.

As usual, this newsletter is also available on our website www.nayati.org, along with the archives. Please give us your feed back and help us serve you better.

Thank you and please keep in touch.

Lalitha Burra, Ph.D., CIH
Director, nayati International

WORKSHOP SERIES ON OCCUPATIONAL HEALTH, HYGIENE & SAFETY

ASSESSMENT AND CONTROL OF WORKER EXPOSURE TO POTENT DRUGS & CHEMICALS

At: INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY, HYDERABAD, ANDHRA PRADESH, INDIA
Wednesday, Feb. 10 – Saturday, Feb. 13, 2010

nayati INTERNATIONAL

Working For Better Quality Of Life
Through Research and Education

Indian Institute of Chemical Technology
Hyderabad, Andhra Pradesh

CSIR INDIA

Council of Scientific and Industrial Research
Human Resource Development Group

NIOSH

National Institute for Occupational
Safety & Health, USA

Sikorsky
A United Technologies Company

SKC

For additional information contact nayati at services@nayati.org
www.nayati.org

Faculty and Organizers

Ms. Donna Heidel, CIH, is currently the Research Industrial Hygienist and Coordinator for the Prevention through Design program at NIOSH, USA. Ms. Heidel has 25 years' experience in the health care industry, spending 15 years building a world-class, global, integrated occupational toxicology and industrial hygiene program at Johnson & Johnson, a decentralized company consisting of 230 operating companies in 57 countries; implemented their global health hazard and control banding programs. Internationally, she established effective industrial hygiene processes in 32 operating companies in Europe, the Middle East and Africa and supported capital projects throughout North America, Puerto Rico, Europe, China, Singapore, Japan, and Latin and South America. Ms. Heidel is an expert in hazard and risk assessment and exposure control of highly potent compounds with extremely low occupational exposure limits, including cancer chemotherapy drugs and nanoparticles.

David M. Eherts, Ph.D., CIH, is currently the Vice President, Environmental Health and Safety, Sikorsky Aircraft Corporation. Dr. Eherts has decades of experience in the Pharmaceutical industry: He was Merck's Global Occupational and Environmental Toxicologist after which he joined Rhone-Poulenc (later merged to become sanofi-aventis) as Site Director of EHS for a 2,000-person R&D site; as global head of EHS for R&D and as Worldwide Director of Occupational Health and Industrial Hygiene; he was the Global Director of Industrial Hygiene, Environment and Product Stewardship at the company's U.S. headquarters in New Jersey. He later joined Purdue Pharma as Executive Director of EHS at its corporate headquarters in Stamford. Outside Sikorsky, Dr. Eherts heads the Return-on-EHS-Investment (ROEHSI) Taskforce for the Organization Resources Counselors (ORC) group and is a frequent presenter at design and aviation safety conferences, occupational toxicology roundtables and other industry events.

Ms. Toral Mehta, CIH is a Certified Industrial Hygienist with Masters in Industrial Hygiene from Sardar Patel University, Gujarat. She is currently the Global Project Manager at the New York office of International Safety Systems Inc., a global consulting firm with offices in US, India, Brazil, China and Latin America. Toral has several years experience conducting workshops on API exposure assessments, Containment Verification with Surrogate at several Multinational Pharmaceutical companies in India, USA, UK, Singapore and Canada.

Viren Shah, MIH is currently the manager of Technical and Regulatory affairs at 3M, India. With his extensive pharmaceutical background including position at Aventis Pharma, Viren and his team at 3M have been active in creating Industrial Hygiene and safety awareness in the industry. As a team leader he has taken up the responsibilities of product training and technical know-how of the product line. With his in depth knowledge of Pharmaceutical Process and Personal Protective equipment selection, his involvement in product design and development for the Indian market, he has been a source of excellent support to the industry and his customers guiding them in appropriate product selection. Viren along with his 3M team have been a great support to the Health and Safety professionals in the community.

Workshop 2010

Ms. Lalitha Burra, Ph.D., CIH is a Certified Industrial Hygienist and the founder Director of nayati International (USA, India) a non-profit organization involved in promoting Occupational Health and safety in India. Dr. Burra obtained her doctoral degrees from University of Kanpur in India and also from Louisiana State University, Baton Rouge, USA.

She has almost 20 years of experience in laboratory and analytical aspects of Occupational Health and Hygiene exposures, sampling, monitoring and assessment of chemical and biological hazards and was the technical director of accredited Industrial Hygiene Laboratories in USA for several years. She has co-founded and directed a fully equipped, chemistry and microbiology accredited Industrial Hygiene Laboratory for almost a decade. After more than 20 years of successful professional and business career in US, Dr. Burra has recently relocated to India to share her knowledge and expertise and help promote Health and safety through education, training and research activities.

Assessment and Control of Worker Exposure to Potent Drugs & Chemicals (Feb 10-13, 2010)
IICT, Uppal Road, Secunderabad, A.P.

Wednesday, Feb 10, 2010

Morning Session:

9.00am – 9.15am Registration

9.15am – 1.30am **1.00am to 11.15am Coffee Break**

Introduction

Identification of Occupational Health Issues Associated with Active Pharmaceutical Ingredients

Pharmacology and toxicology of active pharmaceutical ingredients (APIs), including high-potency APIs and chemical process intermediates (CPIs)

Occupational routes of exposure

Interpretation of in-silico, in-vitro and animal testing and human clinical data and application to the derivation of safe worker exposures

Occupational toxicology testing and interpretation of data

1.30pm – 2.30pm Lunch **4.00pm – 4.15pm Coffee Break**

Afternoon session:

2.30pm – 5.30pm Developing Health Hazard Bands and Occupational Exposure Limits for APIs

Health Hazard Bands

"Default" health hazard bands for new molecular entities; Health hazard banding for investigational new drugs and APIs and CPIs with limited toxicology and/or human health data.

Workshop #1: Developing a health hazard band for an investigational new drug

Occupational exposure limits

Where to find OEL and communicate information for APIs (e.g., safety data sheets); Understanding the basis for OEL establishment, including assumptions; Developing OELs.

Workshop #2: Developing an occupational exposure limit for an API

Thursday, February 11,2010

Morning Session:

9.00am – 1.30pm **11.00am – 11.15am Coffee Break**

Qualitative Risk Assessment and Exposure Monitoring of Workers

Industrial hygiene sampling and analytical methods

Development and validation of new methods: Air sampling; Surface sampling

Industrial hygiene qualitative risk assessment

Workshop #3: Qualitative risk assessment of pharmaceutical processes

Conducting exposure monitoring surveys

Interpreting exposure monitoring results

Surrogate testing

Selection of appropriate surrogates

Interpretation of results

Workshop #4: Interpreting IH data sets

Communicating exposure monitoring results with Management; Workers; Occupational health (physicians, nurses)

Workshop 2010

Thursday, February 11, 2010 cont.....

1.30pm – 2.30pm **Lunch,** **4.00pm – 4.15pm** **Coffee Break**

Afternoon Session

2.30pm – 5.30pm

Controlling Worker Exposure Risks (A Control-Banding Approach)

Principles of control banding

History/successes in the pharmaceutical industry; 3, 4 and 5 band models; Development of control band technology based on exposure monitoring results, published data, and/or peer data

Appropriate task-based controls/containment for bands and range of expected exposure controls

Selecting the appropriate control band based on the health hazard band/OEL and determinates of exposure

Physical form; Task duration; Amount; Dilution with excipients; Process

Control band technology for low, moderate, high, to extremely high potency APIs

Workshop #5: Selecting the appropriate control band

Friday, Feb 12, 2010

Morning Session:

9.00am – 1.30 pm

11.00 am to 11.15am Coffee Break

Verifying controls

Use of work practice controls and PPE to supplement engineering controls

Workshop #6: PPE selection, donning, doffing

Application of Prevention through Design to the Pharmaceutical Drug Discovery, Drug Development and Drug Manufacturing Process, Facilities and Equipment

1.30pm – 2.30pm Lunch **4.00pm – 4.15pm** **Coffee Break**

Afternoon Session

2.30pm – 5.30pm

Prevention through Design applied to the drug development process

Laboratory, kilo lab, pilot plan, clinical supplies manufacturing and scale-up for manufacturing H&S activities to support each stage of development

Prevention through Design applied to drug synthesis and formulation processes

Synthesis and formulation process considerations for high potency APIs

Prevention through Design applied to facility design and equipment selection

Appropriate levels of containment and control during facility and process equipment design, specification, and commissioning

Developing effective business cases

Saturday, February 13,2010

Morning Session:

9.30 am – 1.30 am **11.00am – 11.15am** **Coffee Break**

Questions and Open discussion

Course Evaluation and Feed Back, Closing

1.30pm – 2.30pm **Lunch**

Workshop 2010

Panel of experts

Ms. Donna Heidel's lecture to the participants

Participants

3M and its technical staff helping demonstrate use of PPE

Workshop 2010

3M Technical staff helping Demonstration of Fit testing

Participants sharing experiences

Handing over certificate of participation

Thank you,

On behalf of nayati, we thank all of you for your support in making this workshop a success:

Indian Institute of Chemical Technology (IICT) Hyderabad, India

Council of Scientific and Industrial Research (CSIR) Human Resource Development Group (HRDG), New Delhi, India

National Institute for Occupational Safety & Health (NIOSH), USA

Sikorsky Aircraft, USA

SKC, Inc., USA.

3M India

Dr. J.S. Yadav, Director, Indian Institute of Chemical Technology, Hyderabad, India

Dr. Max Lum, EdD, MPA, Associate Director, Office of Health Communication and Global Collaboration (NIOSH) USA

Our panel of experts

Dave Eherts, PhD., CIH., Sikorsky Aircraft, USA
Donna Heidel, CIH, NIOSH-USA
Toral Mehta, CIH, International Safety Systems, India
Viren Shah, MIH, 3M India

Volunteers and Participants

And several of our colleagues and peers for their continued support in all our activities.

Control Banding And Nanotechnology

By David M. Zalk And Samuel Y. Paik

This article was originally published in the March 2010 issue of The Synergist, the magazine of the American Industrial Hygiene Association.

Industrial hygienists love challenges. Here's one with more than a few twists:

Let's say you're going through the basics of a risk assessment. You have some chemical agents, a few workers, and the makings of your basic exposure characterization. However, you have no occupational exposure limit (OEL), essentially no toxicological basis, and no epidemiology. You cannot use sampling pumps, cassettes, tubes, or any of the media in your toolbox, and the whole concept of mass-to-dose is out the window, even at high exposure levels.

Of course, by the title, you knew we were talking about nanomaterials. But did you know that nanomaterials turn everything you know about industrial hygiene upside down? The very foundations of the profession, which you worked so hard to master, are pulled out from under you. And nanomaterials make the gold standard of our profession, the quantitative science of exposure assessment, look pretty rusty.

Quantitative measurements of nanomaterials are possible, but the instruments are generally very expensive, and getting an appropriate workplace personal exposure measurement can be very difficult, if not impossible. The potential for worker exposures, however, is very real, as evidenced by a recent publication reporting worker exposures to polyacrylate nanoparticles in a Chinese factory (Song et al. 2009).

With something this complex and challenging, how does a concept as simple as control banding save the day? Many industrial hygienists know of control banding from its application in the COSHH (Control of Substances Hazardous to Health) Essentials toolkit from the British Health and Safety Executive. Considerable disagreement about COSHH Essentials and its value for risk assessments exists in the published research. But almost all the experts agree that control banding can be useful when no OELs are available (Zalk and Nelson 2008).

This aspect of control banding—its utility with uncertainty—led international experts to recommend it for nanomaterials. However, since this recommendation was only theoretical, we took on the challenge of developing a working toolkit, the control banding (CB) Nanotool (see Zalk et al. 2009 and Paik et al. 2008), as a means to perform a risk assessment and protect researchers at the Lawrence Livermore National Laboratory.

Dealing with Uncertainty

While engineered nanomaterials have potentially endless benefits for society, the very properties that make them so useful to industry could also make them dangerous to humans and the environment. The uncertainties and unknowns with nanomaterials include the contribution of their physical structure to their toxicity, significant differences in their deposition and clearance in the lungs when compared with their parent material, a lack of agreement on the appropriate indices for exposure to nanomaterials, and a dearth of background information on exposure scenarios or at-risk populations.

Our insufficient background knowledge of nanomaterials can be traced partly to the lack of risk assessments historically performed in the industry. A recent survey indicated that 65 percent of companies working with nanomaterials are not doing any nanomaterials-specific risk assessments; instead, companies are focusing on traditional parent material methods for industrial hygiene (Helland et al. 2009). The number of peer-reviewed publications that address environmental, health and safety aspects of nanomaterials has increased over the last few years, but the percentage of these that address practical methods to reduce exposure and protect workers is orders of magnitude lower.

Our intent in developing the CB Nanotool was to create a simplified approach that would protect workers while unraveling the mysteries of nanomaterials for experts and non-experts alike. Since a large part of the toxicological effects of both the physical and chemical properties of nanomaterials were not only unknown but changing logarithmically with the continued growth in nanomaterials research, we needed to account for this lack of information as part of the CB Nanotool's risk assessment.

We chose a standardized 4x4 risk matrix (see Figure 1) as our starting point, working with the severity parameters on one axis and the probability parameters on the other. The development of the severity axis was the hardest part of our effort. It required the dissection of nanomaterials and their physicochemical properties, which are often unknown; adding information on the parent material, which is far more available; and somehow scoring these input factors in a manner that appropriately weighted each factor.

We decided to give unknown input factors a score of 75 percent of the points corresponding to the highest rating for each category. Assigning maximum points for unknowns would have branded nearly every nanomaterial as extremely dangerous, necessitating the highest level of control. Balancing a conservative approach with a reasonable scientific estimate was the best way not to stifle research ingenuity, yet still protect workers. The probability axis, which fits well with traditional industrial hygiene knowledge, was much easier to develop and score. The details of the CB Nanotool go far beyond this, but we give the basics below.

Severity Factors

Based on the literature available prior to publication of the CB Nanotool, the factors below were considered to determine the overall severity of exposure to nanomaterials. The research and logic behind both the composition and scoring distribution of these factors can be found in our publications (see Zalk et al. 2009 and Paik et al. 2008). These factors influence the ability of particles to reach the respiratory tract, deposit in various regions of the respiratory tract, penetrate or be absorbed through skin, and systemically elicit biological responses. The division of severity factor points taken cumulatively is 70 percent for the nanomaterial and 30 percent for the parent material. Research to date does not contraindicate the potential for engineered nanomaterials to be more toxic than their parent materials.

The following factors contribute to nanomaterials severity. (NM stands for nanomaterial; PM for parent material.)

Surface chemistry NM: Surface chemistry is known to be a key factor influencing the toxicity of inhaled particles. Points are assigned based on knowledge of whether the surface activity of the nanoparticle is high, medium or low.

High	10
Medium	5
Low	0
Unknown	7.5

Particle shape NM: Points are assigned based on the shape of the particle. The highest rating is given to fibrous or tubular – shaped particles based on toxicological studies. Particles with irregular shapes (anisotropic) have higher surface areas than isotropic or spherical particles and therefore are given the next highest rating.

Tubular, fibrous.	10
Anisotropic	5
Compact/spherical . . .	0
Unknown	7.5

Particle diameter NM: Points are assigned based on the particles' deposition in the respiratory tract, regardless of the region in the respiratory tract.

1–10 nm	10
11–40 nm	5
41–100 nm	0
Unknown	7.5

Solubility NM: Poorly soluble, inhaled nanoparticles can cause oxidative stress, leading to inflammation, fibrosis or cancer. Soluble nanomaterials can also cause adverse effects through dissolution in the blood, but to a lesser degree.

Insoluble	10
Soluble	5
Unknown	7.5

Carcinogenicity NM: Points are assigned based on whether the nanomaterial is carcinogenic, regardless of whether the material is a human or animal carcinogen. Little information is available.

Yes	6
No	0
Unknown	4.5

Reproductive toxicity NM: Points are assigned based on whether the nanomaterial is a reproductive hazard or not. Little information on this factor is available.

Yes	6
No	0
Unknown	4.5

Mutagenicity NM: Points are assigned based on whether the nanomaterial is a mutagen or not. Little information on this factor is available.

Yes	6
No	0
Unknown	4.5

Dermal toxicity NM: Points are assigned based on whether the nanomaterial is a dermal hazard or not. Little information on this factor is available.

Yes	6
No	0
Unknown	4.5

Asthmagen NM: Points are assigned based on whether the nanomaterial is an asthmagen or not. Little information on this factor is available.

Yes	6
No	0
Unknown	4.5

Toxicity PM: Although research agrees that nanomaterials can be more toxic than parent materials, knowledge of the PM toxicity is a good starting point for understanding the NM toxicity. Points are assigned according to the OEL of the bulk material.

< 10 μg/m3	10
10–100 μg/m3	5
101 μg/m3–1 mg/m3	2.5
> 1 mg/m3	0
Unknown	7.5

Carcinogenicity PM: Points are assigned based on whether the PM is carcinogenic or not.

Yes	4
No	0
Unknown	3

Reproductive toxicity of PM: Points are assigned on whether the PM is a reproductive hazard or not.

Yes	4
No	0
Unknown	3

Mutagenicity of PM: Points are assigned on whether the PM is a mutagen or not.

Yes	4
No	0
Unknown	3

Dermal hazard potential of PM: Points are assigned on whether the PM is a dermal hazard or not.

Yes	4
No	0
Unknown	3

Asthmagen PM: Points are assigned based on whether the PM is an asthmagen or not.

Yes	4
No	0
Unknown	3

The overall severity score is determined based on the sum of all the points from the severity factors. The maximum score is 100. An overall severity score of 0–25 is co nsidered low severity; an overall severity score of 26–50 is considered medium severity; an overall severity score of 51–75 is considered high severity; and an overall severity score of 76–100 is considered very high severity.

Probability Factors

The probability scores are based on factors determining the extent to which employees may be potentially exposed to nanomaterials:

Estimated amount of NM used during operation: For nanomaterials embedded on substrates or suspended in liquid, the amount is based on the mass of the nanomaterial and not the substrate or liquid portion.

> 100 mg	25
11–100 mg	12.5
0–10 mg	6.25
Unknown	18.75

Dustiness/mistiness: Since employees are potentially exposed to nanoparticles in either dry or wet form, this factor encompasses dustiness and mistiness of the nanomaterial. Knowledge of the operation (e.g., handling dry powders versus liquid suspensions of nanoparticles) would be a means to estimate dustiness/ mistiness. A CB Nanotool design feature is that a rating of "none" for dustiness/mistiness level (and only for this factor) automatically results in an overall probability score to be "extremely unlikely" regardless of the other probability factors, since the other factors will not be relevant if no dust or mist is generated.

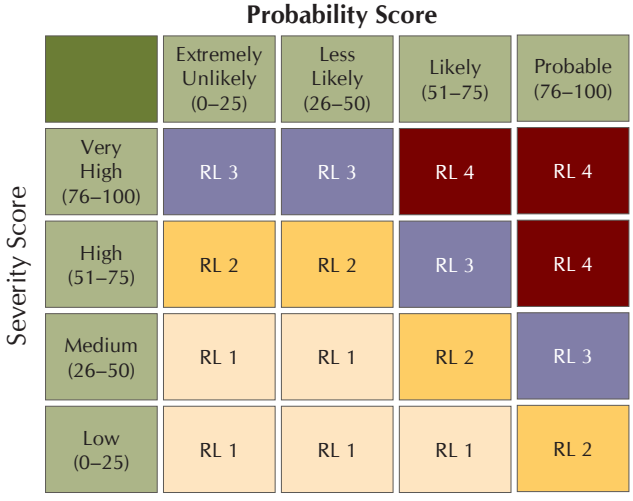
High	30
Medium	15
Low	7.5
Unknown	22.5

Number of employees with similar exposure: Points are assigned by the number of employees assigned to this activity. More employees means a higher probability of employees being exposed.

> 15	15
11–15	10
6–10	5
Unknown	11.25

Frequency of operation: Points are assigned based on the frequency of the operation. More frequent operations are more likely to result in employee exposures.

Figure 1. Risk level (RL) matrix as a function of severity and probability scores. Control bands are based on overall risk levels.



Control bands by risk level: RL 1: General ventilation; RL 2: Fume hoods or local exhaust ventilation; RL 3: Containment; RL 4: Seek specialist advice.

Daily	15
Weekly	10
Monthly	5
Less than monthly . .	0
Unknown	11.25

Duration of operation: Points are assigned based on the duration of the operation. Longer operations are more likely to result in employee exposures.

> 4 hours	15
1–4 hours	10
30–60 minutes	5
< 30 minutes	0
Unknown	11.25

The overall probability score is based on the sum of all the points from the probability factors. The maximum score is 100. An overall probability score of 0–25 is considered extremely unlikely; an overall probability score of 26–50 is considered less likely; an overall probability score of 51–75 is considered likely; and an overall probability score of 76–100 is considered probable. Based on the severity and probability scores for an operation, the overall level of risk and corresponding control band is determined by the matrix shown in Figure 1.

Nanotool 2.0

The outcome of taking on this challenge by developing the CB Nanotool can be found in our first published article (Paiket al. 2008). Much to our surprise, the CB Nanotool generated quite a large amount of interest, particularly among international organizations, including the International Labor Organization and the World Health Organization. The International Organization for Standardization is developing a control banding approach for nanomaterials (ISO/NP TS 12907-2).Control banding for work with nanomaterials is now recommended by many countries worldwide, including Canada, Australia, the Netherlands and South Korea.

Our co-author, Paul Swuste of the Delft University of Technology, was vital in obtaining high-profile European opportunities for presenting our work. Suddenly, experts were considering our qualitative CB approach to be as good as and—dare we say—possibly better than the current quantitative risk assessment approach. As more nanomaterials professionals became aware of the CB Nanotool, they raised additional questions and challenges. Our latest article (Zalk et al.2009) thoroughly evaluates the CB Nanotool to address these questions. The professional evaluation of our qualitative methods provided an opportunity to improve the tool—resulting in version 2 of the CB Nanotool, which is presented in this article—and shine a new, positive light on control banding.

Good things happen when industrial hygienists take on challenges.

Acknowledgement: This work was performed under the auspices of the U.S. Department of Energy by Lawrence Livermore National Laboratory under Contract DE-AC52-07NA27344, LLNL-JRNL-421516.

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References

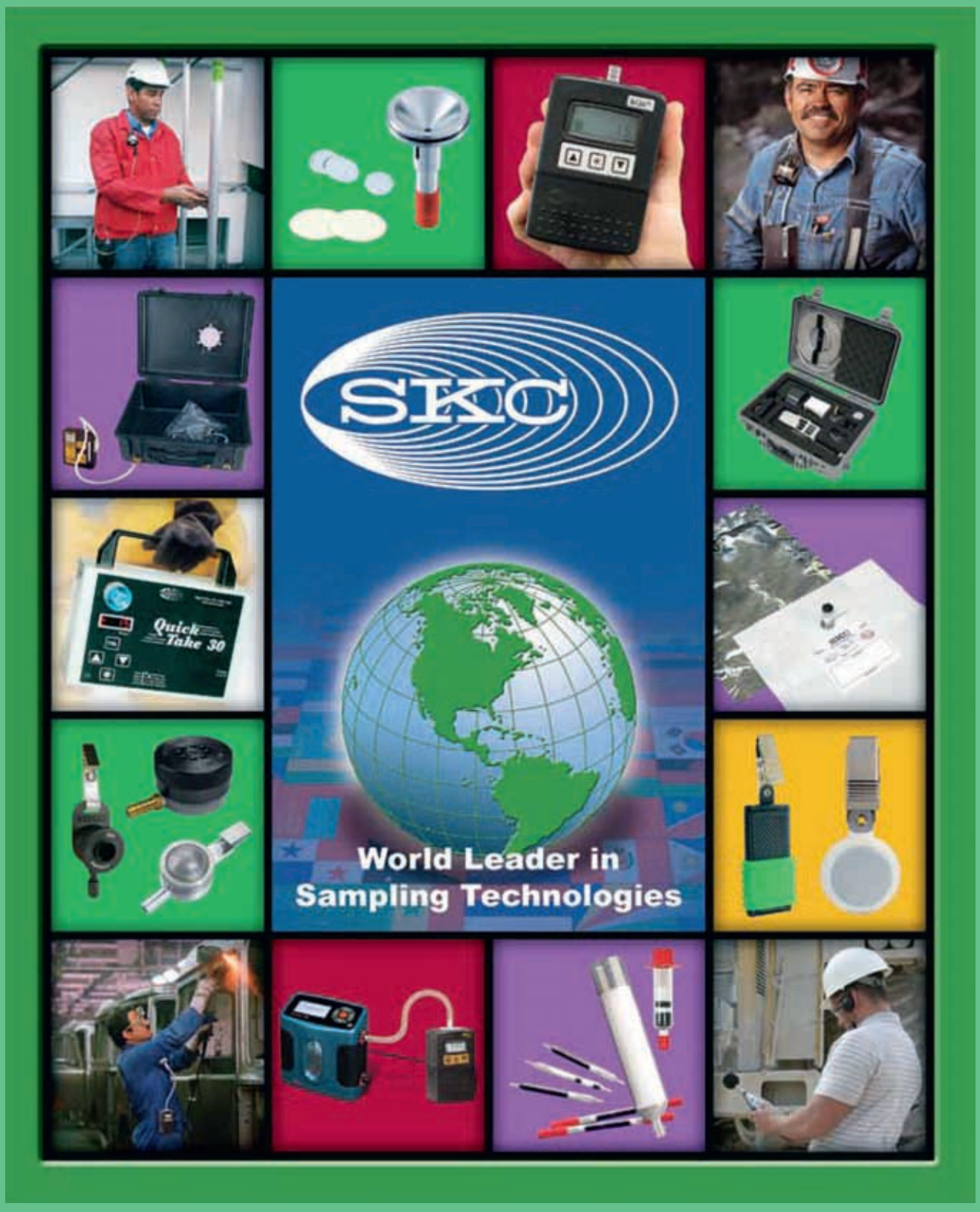
Helland, A., M. Scheringer, M. Siegrist, et zal.: "Risk Assessment of Engineered Nanomaterials: A Survey of Industrial Approaches." Environ. Sci. Technol. 42(2):640–646 (2008). Available at http://pubs.acs.org/doi/abs/10.1021/es0628071.

Paik, S.Y., D.M. Zalk, and P. Swuste: "Application of a Pilot Control Banding Tool for Risk Level Assessment and Control of Nanoparticle Exposures." Ann. of Occup. Hyg. 52(6):419-428 (2008). Available at http://annhyg.oxfordjournals.org/cgi/content/short/52/6/419.

Song, Y., X. Li, and X. Du: "Exposure to Nanoparticles Is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma." Eur. Respir. J. 34(3):559–67 (2009). Available at http://erj.ersjournals.com/cgi/content/abstract/34/3/559.

Zalk, D.M., and D.L. Nelson: "History and Evolution of Control Banding: A Review." J. Occup. Environ. Hyg. 5:330–46 (2008). Available at www.ncbi.nlm.nih.gov pubmed / 18350442.

Zalk, D.M., S.Y. Paik, and P. Swuste: "Evaluating the Control Banding Nanotool: A Qualitative Risk Assessment Method for Controlling Nanoparticle Exposures." Nanopart. Res. 11(7):1685–1704 (2009).Available at www.springerlink.com/content/4t3241552m176137/.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Global Impact

GHS and REACH Will Transform Worker Safety and Health Programs

By Robert Skoglund And Denese Deeds

This article was originally published in the September 2009 issue of The Synergist, the magazine of the American Industrial Hygiene Association.

In late 2002, the United Nations Economic and Social Council issued the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS) as a model regulation for hazard communication. Model regulations are intended to facilitate the harmonization of similar regulations across jurisdictions.

Now, seven years after GHS was first issued,it is finally being incorporated into hazard communication regulations around the world. In the United States, OSHA's proposed codification of GHS is expected in the third quarter of 2009. Canadian regulators are further along than the U.S. The European Union (EU) published its codification of GHS as the Classification, Labeling, and Packaging (CLP) Regulation in December 2008, and a number of Asian countries are in the final stages of codifying GHS.

In 2007, the European Commission issued its Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. REACH transfers the onus of demonstrating the safety of chemicals from regulators to manufacturer and importers. Chemicals produced or imported into the EU in quantities exceeding one metric ton must be registered with the European Chemicals Agency (ECHA). According to the "no data, no market" principle, REACH mandates a minimum set of hazard and exposure data; substances with insufficient data will be removed from the market. Although intended for the EU, REACH will have a global impact on worker safety and health programs. Its full effects will not be felt until after the first wave of registration dossiers is submitted to ECHA in late 2010.

Taken together, GHS and REACH will have far-reaching consequences for health and safety programs. This article examines some of the changes we can expect to see from the new regulations and suggests ways that industrial hygienists can manage these changes in the workplace.

New Hazard Data

The OSHA Hazard Communication Standard does not mandate the generation of new hazard data. Hazard classification and the resulting precautions are based on whatever data are available. Similarly, GHS does not mandate the generation of new data, though the lack of data for some endpoints must be noted in the labeling.

REACH, however, does require registrants to provide a minimum set of hazard data. These data requirements are a function of the tonnage of chemical that a registrant puts on the market annually. The threshold for registration is 1 metric ton per year. At this level, the health hazard data requirements include acute toxicity (one route), in vitro skin and eye irritation, skin sensitization and mutagenicity (the Ames test).

Registrants who put more than 10 metric tons of a chemical on the market each year are expected to provide data for in vivo skin and eye irritation, mutagenicity (additional in vitro data), acute toxicity (additional routes), 28-day repeat-dose toxicity, and screening level reproductive/ developmental toxicity. For more than 100 metric tons per year, registrants must provide additional repeat-dose and reproductive/ developmental toxicity data.At the highest threshold—1,000 metric tons per year—registrants are expected to provide carcinogenicity and further reproductive/ developmental data. REACH also requires data on physical properties and environmental hazards.

REACH also promises to increase the accessibility of hazard profiles. The details are yet to be worked out, but Article 119 of REACH requires ECHA to make hazard information provided by registrants available to the public free of charge over the Internet. This includes the results of each toxicological study in a registrant's dossier.

This generation of data will lead to changes in the hazard profile, and therefore the hazard classification, of many common workplace chemicals.

New and Expanded Hazard Endpoints

OSHA has clarified that environmental hazards are outside its jurisdiction. In contrast, GHS and REACH address physical, health and environmental hazards.

Because of their influence, material safety data sheets (MSDSs) may begin to include significantly more information in section 12 (for ecological information).

GHS includes 16 physical hazards and 10 health hazards. Furthermore, most of these endpoints are divided into multiple categories. While most of these endpoints are consistent with those in the OSHA Hazard Communication Standard, GHS introduces

some new endpoints and categories—for example, self-heating substances and substances which, in contact with water, emit flammable gases. New health hazards will include germ cell mutagenicity and effects on or via lactation, as well as the separation of target organ toxicity after single versus repeated exposures.

Existing endpoints with expanded categories include acute toxicity. For example, OSHA has two categories for acute oral toxicity: highly toxic (≤50 mg/kg) and toxic (>50 to 500 mg/kg). Under GHS, there may be as many as five categories for acute oral toxicity: ≤5 mg/kg; >5 to ≤50 mg/kg; >50 to ≤300 mg/kg; >300 to ≤2,000 mg/kg; and >2,000 to ≤5,000 mg/kg. As a result of these new and expanded endpoints, both the breadth and depth of the hazard information communicated in the workplace will increase.

Prescriptive Classification Criteria and Mixture Rules

Appendix A of the Hazard Communication Standard, which is approximately four pages long, defines the OSHA health hazards. Many of the criteria are descriptive rather than prescriptive. In contrast, GHS provides 150 pages of criteria and mixture rules for physical and health hazards, and much of this guidance is prescriptive. These rules will result in changes to the hazard classifications of many common workplace chemicals.

GHS criteria describe which tests and data should be used for classification as well as the manner in which hazard assessments should be conducted in order to minimize the use of animals in testing. For example, users are directed to classify skin corrosivity and serious eye damage based on pH rather than in vivo tests.

The adoption of GHS in the U.S. will result in significant changes in the classification of untested mixtures. Under the OSHA Hazard Communication Standard, the thresholds for extrapolating the hazards of components to the mixture are 1 percent for non-carcinogens and 0.1 percent for carcinogens. Under GHS, the hazards that need to be extrapolated at 0.1 percent are expanded to include germ cell mutagenicity, and reproductive/developmental toxicity (including effects on or via lactation). The thresholds for some of the other endpoints will be raised to greater than 1 percent.

In addition, GHS will add the European concepts of "additivity" and "step-down" of hazards to the mixture rules. Additivity is the practice of summing the concentrations of components with similar hazards; if the total exceeds the applicable threshold, the hazard—such as skin corrosion/irritation or eye damage/irritation—is extrapolated to the mixture. Step-down refers to the mitigation of a component's hazard at lower concentration in the mixture as opposed to OSHA's all-ornothing approach.

Fraction of Unknown Toxicity

While animal rights advocates and even toxicologists have questioned the role of acute toxicity data in health and safety programs, these data are a cornerstone of GHS. All chemicals and mixtures must have either a measured value, a bridged value or a calculated value for acute toxicity. The calculated value for acute toxicity is known as the Acute Toxicity Estimate (ATE); it is derived using acute toxicity data for each component and a formula based on the weighted average approach. An alternate formula can be used if data are not available on all components, but if this data gap is greater than 1 percent of the composition, the communication of the ATE must be accompanied by a statement that indicates which percentage of the mixture is of unknown toxicity. While the concept of "unknown toxicity" is understood by EHS professionals, it will be new to many workers.

> Some changes will be mere semantics, with little impact on safety and health programs; others may require changes in how chemicals are managed in the workplace.

Figure 1. The GHS pictogram for substances that are hazardous to human health.

Pictograms

For workers, the most apparent changes under GHS and REACH will be the incorporation of pictograms into workplace hazard communication. GHS requires these pictograms on labels and MSDSs. Many of the new pictograms are consistent with those used to communicate hazards in the transportation sector, such as the flame for flammables and the burning circle for oxidizers. Other pictograms have been incorporated from other systems, including the exclamation point to

highlight certain human hazards and the dead tree and dead fish for environmental hazards.

GHS does include a de novo health hazard pictogram that has been described as either a human form with a star or the exploding human (see Figure 1). This pictogram is used for respiratory sensitization, germ cell mutagenicity, carcinogenicity, reproductive/developmental toxicity, target organ toxicity (after single or repeated exposures), and aspiration. Workers will need to be trained to recognize, understand and respond appropriately to the new pictograms.

Derived No Effect Levels

The change associated with GHS and REACH that will cause the most confusion for workers will be the new "exposure limits" known as Derived No Effect Levels (DNELs). REACH defines a DNEL as the level above which humans should not be exposed. Registrants who annually put more than 10 metric tons of a chemical on the EU market will be required to calculate all applicable DNELs. The various DNELs for a substance are a function of the target populations (for example, workers or consumers), routes of exposure, duration of exposure (acute versus chronic), and whether the effect is local or systemic.

There is a potential for more than 20 types of DNELs for a chemical. The "worker-inhalation-chronic-systemic" DNEL is most similar to the traditional health-based occupational exposure limit (OEL). The guidance for the derivation of DNELs is prescriptive and rather conservative, so the worker-inhalation-chronic-systemic DNEL may be significantly lower than the corresponding healthbased OEL. Early attempts to calculate worker-inhalation-chronic-systemic DNELs have resulted in values ranging from roughly equal to less than 10 percent of the published OEL. Workers will need to be trained to recognize, understand and respond appropriately to these new REACH exposure limits.

The Role of Industrial Hygienists

GHS and REACH will cause a paradigm shift in workplace hazard assessment and communication. Industrial hygienists can play three vital roles in managing these changes:

Tracking: Keep track of changes to the hazard profile and hazard classification of chemicals that are important to your company. Discovering these changes when a new MSDS is received may be too late. Establish lines of communication with vendors and trade organizations that are involved in the chemistries important to your business.

Interpretation: Analyzing and determining the relevance of new hazard data, modified hazard classifications and new exposure limits will be critical. Some changes will be mere semantics, with little impact on safety and health programs; others may require changes in how chemicals are managed in the workplace. Extensive changes might cause your employer to stop using some chemicals. The ability to filter the tsunami of new information and focus limited resources on relevant issues will be invaluable.

Preparation: You will need to prepare management for possible changes in work practices, such as investments in new engineering and other exposure-reduction controls. This can be difficult, particularly when it involves chemicals your company has used for years. Employee training should address obvious changes, such as the new pictograms and hazard endpoints and categories, as well as the more subtle changes in the hazard profile and classification of existing chemicals and the addition of multiple DNELs to MSDSs.

You must also prepare yourself: Develop at least a working knowledge of GHS and REACH. GHS model regulation is approximately 450 pages and can be downloaded, at no cost, from the website of the United Nations Economic Commission for Europe (www.unece.org). The REACH regulation is approximately 300 pages, but understanding and applying the regulation requires thousands of additional pages of official guidance. Both the regulations and the guidance can be downloaded, at no cost, from the ECHA website (http://echa.europa.eu). Look for webinars and classroom sessions on the basics of GHS and REACH. By developing a network of people interested in GHS and REACH, you will have a mechanism for sharing expertise and tracking the regulations' impact on chemistries that are important to your business. This impact will grow considerably over the next several years. It is incumbent upon industrial hygienists, as key members of the EHS team, to play a leading role on this issue in the workplace.

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Basic Occupational Health Services

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The Constitution of India states that 'State shall make provisions for securing just and humane conditions of work'. This provides the basis for provision of occupational health services to all citizens of the country.

However, in reality, there is plenty of opportunity to provide occupational health services to all working population, not only in India, but even in the developed world. Occupational health services are available only to 10-15% of workers worldwide and to a miniscule of working population in developing countries. Even where services are available, the quality and relevance may be low. Though there is an intense economic pressure on cost of production all over the world, there cannot be a trade-off between health and productivity at work.

The Basic Occupational Health Services (BOHS) are an application of the primary health care principles in the occupational health sector. The BOHS seek to provide occupational health services for all working people in the world regardless of mode of employment, size of workplace or geographic location, that is, according to the principle of universal services provision. These services are most needed in countries and sectors which do not have services at all or which are seriously underserved. It lays stress on the importance of a national strategy and plan of action to incorporate occupational health in all policies.

The concept of BOHS has been developed jointly by the World Health Organization (WHO), International Labor Organization (ILO), and International Commission on Occupational Health (ICOH) and has its roots in the 'Alma Ata' declaration (1978) by the WHO. The BOHS principles were first discussed at the WHO/ILO Joint Committee of Occupational Health in 2003. The BOHS has become a central piece of global occupational health services development plans of the WHO and ILO. The WHO, with its collaborating centers in occupational health, the ILO, ICOH and other international organizations, work for the BOHS. The BOHS shot into limelight with outgoing ICOH President, Prof. Jorma Rantanen, championing the cause.

The BOHS concept envisages coverage of all workers, and has a strong focus on prevention. They are to be provided for SMEs as well as self employed persons through public services. There will have to be different modalities for the same. There has to be a strong primary health care approach, which needs strong coordination between health and labor ministries, in our country. The expert institutions on occupational health have an important role to play in BOHS and they need to support the provision of BOHS by developing low-cost solutions.

The BOHS aim at:

a) Protection of health at work,
b) Promotion of health, well being, work ability and
c) Prevention of occupational diseases and accidents.

Activities under BOHS encompass not only health surveillance, emergency preparedness and first aid services but also include surveillance of work environment, risk assessment and preventive and control measures. Health education and health promotion are also an integral part of BOHS.

The BOHS provide a practical tool in identifying priorities and pooling scarce resources to develop an integrated and effective occupational health system and services, tailored to suit the national conditions and needs of each country. Improved conditions of work will lead to a healthier work force and, in turn, improved productivity.

It is estimated that India has a working population of approximately 500 million. According to 2001 census, around 70% of the population resides in rural areas. Less than 10% of the workforce is organized, 60% selfemployed and 30% do not have regular jobs. The increasing proportion of females in the workforce adds to the traditional OSH issues. The changing face of service sector, in view of the exponential growth on account of globalization and increasing use of information technology, is expected to present new challenges.

Proper diagnosis and reporting of occupational diseases is necessary to achieve and implement BOHS. As all of us are aware, the statistics on accidents and

occupational illnesses are far from accurate. There are research reports that show the official estimates are vastly low. The organized sector, both private and public, has reasonably well developed OHS based on ILO conventions. However, this sector is miniscule. The OHS are almost non-existent in the unorganized sector.

Currently, there is no government agency or department which deals exclusively with occupational safety and health matters. The director general of the Factory Advisory Services and Labor Institutes deals with the safety and health of workers employed in factories and ports, whereas, the director general of Mines Safety deals with the safety and health of miners. While there are other departments under the Ministry of Labour, which deal with OSH issues in different sectors, e.g. the construction sector, no agency covers safety and health for workers in unorganized sectors.

In India, we face the twin challenges of integration of occupational health with general health services and delivery of occupational health from medical college hospitals. There is separate training on occupational safety and health for safety professionals and occupational health professionals. The training on occupational health is still at an early stage and there are still no Chairs on occupational health in Indian universities and there are hardly any postgraduate training facilities on OH.

The BOHS demands government leadership with tripartite or better still, quadripartite collaboration between government, employers, employees and non-governmental organizations (NGOs) like IAOH. We need development of appropriate OSH infrastructure and proper dissemination of health and safety information. Our institutions need to provide simple tools for practical health and safety work at workplaces. Needless to add, our focus needs to be on small and medium sized enterprises, self-employed persons and informal sector.

Recently, the national occupational health and safety policy has been finalized by the government and let us hope that it will take the country one step closer towards BOHS for all.

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SUGGESTED READING

1. *Rantanen J. Basic Occupational Health Services. A WHO/ILO/ICOH. 2nd ed. Helsinki: Finnish Institute of Occupational Health; 2005.*
2. *The Global Plan of Action on Workers' Health 2008-2017. Geneva: World Health Organisation, the 60th World Health Assembly; 2007.*
3. *A Global Strategy on Occupational Safety and Health. Geneva: International Labour Organisation, the 91st session of the International Labour Conference; 2003.*
4. *WHO Occupational Health. Available from: http:// www.who.int/occupational_health/en/.*

Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings

Source: website of National Institute for Occupational Safety and Health (NIOSH)
http:/// www.cdc.gov/niosh/docs/2004-165/

Health care workers who work with or near hazardous drugs may be exposed to these agents in the air or on work surfaces, clothing, medical equipment, or patient urine or feces. Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs (see Appendix A of NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings for a list of hazardous drugs). The health risk depends on how much exposure a worker has to these drugs and how toxic they are.

Health care workers should take the following steps to protect themselves from hazardous drugs:

- Read all information and material safety data sheets (MSDSs) your employer provides to you for the hazardous drugs you handle.
- Participate in any training your employer provides on the hazards of the drugs you handle and the equipment and procedures you should use to prevent exposure.
- Be familiar with and able to recognize sources of exposure to hazardous drugs. Sources of exposure include all procedures involving hazardous drugs including preparation, administration, and cleaning), and all materials that come into contact with hazardous drugs (including work surfaces, equipment, personal protective equipment [PPE], intravenous [IV] bags and tubing, patient waste, and soiled linens).
- Prepare hazardous drugs in an area that is devoted to that purpose alone and is restricted to authorized personnel.
- Prepare hazardous drugs inside a ventilated cabinet designed to protect workers and others from exposure and to protect all drugs that require sterile handling.
- Use two pairs of powder-free, disposable chemotherapy gloves, with the outer one covering the gown cuff whenever there is risk of exposure to hazardous drugs.
- Avoid skin contact by using a disposable gown made of polyethylene-coated polypropylene material (which is nonlinting and nonabsorbent). Make sure the gown has a closed front, long sleeves, and elastic or knit closed cuffs. Do not reuse gowns.
- Wear a face shield when splashes to the eyes, nose, or mouth may occur and when adequate engineering controls (such as the sash or window on a ventilated cabinet) are not available.

Warning!

Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

- Wash hands with soap and water immediately before using personal protective clothing (such as disposable gloves and gowns) and after removing it.
- Use syringes and IV sets with Luer-LokTM fittings for preparing and administering hazardous drugs.
- Place drug-contaminated syringes and needles in chemotherapy sharps containers for disposal.
- When supplemental protection is needed, use closed-system drug-transfer devices, glove bags, and needleless systems inside the ventilated cabinet.
- Handle hazardous wastes and contaminated materials separately from other trash.
- Clean and decontaminate work areas before and after each activity involving hazardous drugs and at the end of each shift.
- Clean up small spills of hazardous drugs immediately, using proper safety precautions and PPE.
- Clean up large spills of hazardous drugs with the help of an environmental services specialist.

Employers of health care workers should take the following steps to protect their workers from exposure to hazardous drugs:

- Make sure you have written policies about the medical surveillance of health care workers and all phases of hazardous drug handling— including receipt and storage, preparation, administration, housekeeping, decontamination and cleanup, and disposal of unused drugs, contaminated spills, and patient wastes.
- Seek input from workers who handle hazardous drugs when developing these policies and other programs to prevent exposures.
- Prepare a written inventory of all hazardous drugs used in the workplace, and establish a procedure for regular review and updating of this inventory.
- Train workers to recognize and evaluate hazardous drugs and to control exposure to them.
- Provide workers who handle or work near hazardous drugs with appropriate information and MSDSs.
- Provide a work area that is devoted solely to preparing hazardous drugs and is limited to authorized personnel.
- Do not permit workers to prepare hazardous drugs using laminar-flow work stations that move air from the drug toward the worker.
- Provide and maintain ventilated cabinets designed to protect workers and others from exposure to hazardous drugs and to protect all drugs that require sterile handling. Examples of ventilated cabinets include biological safety cabinets (BSCs) and containment isolators designed to prevent hazardous drugs from escaping into the work environment.
- Filter the exhaust from ventilated cabinets with high-efficiency particulate air filters (HEPA filters). Make sure these cabinets are exhausted to the outdoors wherever feasible—well away from windows, doors, and other air-intake locations.
- Consider providing supplemental equipment to protect workers further—for example, glove bags, needleless systems, and closed-system drug-transfer devices.
- Establish and oversee appropriate work practices for handling hazardous drugs, patient wastes, and contaminated materials.
- Provide workers with proper PPE on the basis of a risk assessment and train workers how to use it as required by the Occupational Safety and Health Administration (OSHA) PPE standard [29 CFR* 1910.132]. PPE may include chemotherapy gloves, nonlinting and nonabsorbent disposable gowns and sleeve covers, and eye and face protection. Ensure the proper use of PPE by workers.
- Use NIOSH-certified respirators [42 CFR 84].

  Note: Surgical masks do not provide adequate respiratory protection.
- Provide syringes and IV sets with Luer-LokTM fittings for preparing and administering hazardous drugs. Also provide containers for their disposal.
- Consider using closed-system drug-transfer devices and needleless systems to protect nursing personnel during drug administration.
- Periodically evaluate hazardous drugs, equipment, training effectiveness, policies, and procedures in your workplace to reduce exposures as much as possible.
- Comply with all relevant U.S. Environmental Protection Agency/Resource Conservation and Recovery Act (EPA/RCRA) regulations related to the handling, storage, and transportation of hazardous waste.

For additional information, see NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Health Care Settings [DHHS (NIOSH) Publication No. 2004–165]. Single copies of the Alert are available from the following:

NIOSH—Publications Dissemination
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Cincinnati, OH 45226–1998

Telephone: 1–800–35–NIOSH (1–800–356–4674)
Fax: 1–513–533–8573 E-mail: pubstaft@cdc.gov
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Pharmaceutical Industry Effluent Diluted 1:500 Affects Global Gene Expression, Cytochrome P4501A Activity and Plasma Phosphate in Fish.

Gunnarsson L, Kristiansson E, Rutgersson C, Sturve J, Fick J, Förlin L, Larsson DG.

Original article published in Environmental Toxicology and Chemistry, July 2009

Patancheru, near Hyderabad, India, is a major production site for the global bulk drug market. Approximately 90 manufacturers send their wastewater to a common treatment plant in Patancheru. Extraordinary high levels of a wide range of pharmaceuticals have recently been demonstrated in the treated effluent. As little as 0.2% of this effluent can strongly reduce the growth rate of tadpoles, but the underlying mechanisms of toxicity are not known. To begin addressing how the effluent affects aquatic vertebrates, rainbow trout (Oncorhynchus mykiss) were exposed to 0.2% effluent for five days. Several physiological endpoints, together with effects on global hepatic gene expression patterns, were analyzed. The exposed fish showed both an induction of hepatic cytochrome P450 1A (CYP1A) gene expression, as well as enzyme activity. Clinical blood chemistry analyses revealed an increase in plasma phosphate levels, which in humans indicates impaired kidney function. Several oxidative stress-related genes were induced in the livers; however, no significant changes in antioxidant enzyme activities or in the hepatic glutathione levels were found. Furthermore, estrogen-regulated genes were slightly up-regulated following exposure, and moderate levels of estriol were detected in the effluent. The present study identifies changes in gene expression triggered by exposure to a high dilution of the effluent, supporting the hypothesis that these fish are responding to chemical exposure. The pattern of regulated genes may contribute to the identification of mechanisms of sub-lethal toxicity, as well as illuminate possible causative agents.

Source: PubMed PMID: 19610678

Effluent from drug manufactures contains extremely high levels of pharmaceuticals.

Journal of Hazardous Materials, 148(3) p.751-755, Sep 2007

Larsson DG, de Pedro C, Paxeus N.

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It is generally accepted that the main route for human pharmaceuticals to the aquatic environment is via sewage treatment plants receiving wastewater from households and hospitals. We have analysed pharmaceuticals in the effluent from a wastewater treatment plant serving about 90 bulk drug manufacturers in Patancheru, near Hyderabad, India--a major production site of generic drugs for the world market. The samples contained by far the highest levels of pharmaceuticals reported in any effluent. The high levels of several broad-spectrum antibiotics raise concerns about resistance development. The concentration of the most abundant drug, ciprofloxacin (up to 31,000 microg/L) exceeds levels toxic to some bacteria by over 1000-fold. The results from the present study call for an increased focus on the potential release of active pharmaceutical ingredients from production facilities in different regions.

Source: PubMed PMID: 17706342

Prevention through Design

Source: *NIOSH Health and safety Topic : http://www.cdc.gov/niosh/topics/ptd/*

One of the best ways to prevent and control occupational injuries, illnesses, and fatalities is to "design out" or minimize hazards and risks early in the design process. NIOSH is leading a national initiative called Prevention through Design (PtD) to promote this concept and highlight its importance in all business decisions.

The concept of PtD can be defined as:

> *Addressing occupational safety and health needs in the design process to prevent or minimize the work-related hazards and risks associated with the construction, manufacture, use, maintenance, and disposal of facilities, materials, and equipment.*

A growing number of business leaders are recognizing PtD as a cost-effective means to enhance occupational safety and health. Many U.S. companies openly support PtD concepts and have developed management practices to implement them. Other countries are actively promoting PtD concepts as well. The United Kingdom began requiring construction companies, project owners, and architects to address safety and health during the design phase of projects in 1994, and companies there have responded with positive changes in management practices to comply with the regulations. Australia developed the Australian National OHS Strategy 2002–2012, which set "eliminating hazards at the design stage" as one of five national priorities. As a result, the Australian Safety and Compensation Council (ASCC) developed the Safe Design National Strategy and Action Plans for Australia encompassing a wide range of design areas including buildings and structures, work environments, materials, and plant (machinery and equipment).

Partnerships

NIOSH has partnered with the American Industrial Hygiene Association (AIHA), the American Society of Safety Engineers (ASSE), the Center to Protect Workers' Rights, Kaiser Permanente, Liberty Mutual, the National Safety Council (NSC), the Occupational Safety and Health Administration, ORC Worldwide, and the Regenstrief Center for Healthcare Engineering for the development of a National Initiative on Prevention through Design. Other partners may be joining this national initiative soon.

Approach to PtD

The approach that will be used to develop and implement the PtD National Initiative will be framed by industry sector and within four functional areas: Research, Education, Practice, and Policy. As the chart below indicates, this process encourages stakeholder input through a sector-based approach consistent with the one used under the National Occupational Research Agenda (NORA).

The ultimate goal of the PtD initiative is to prevent or reduce occupational injuries, illnesses, and fatalities through the inclusion of prevention considerations into all designs that impact workers. Along the way, intermediate goals will be identified to provide a path toward achieving the ultimate goal. NIOSH will serve as a catalyst to establish this Initiative, but in the end, the partners and stakeholders must actively participate in addressing these goals to make PtD business as usual in the 21st century.

International Occupational Hygiene Training and Qualifications

Now available through the Occupational Hygiene Training Association (OHTA) www.OHLearning.com

Recent decades have seen a major change in the pattern of industrialization across the world. With the expansion of the industrial base comes a change in geographical patterns of demand for occupational hygiene and occupational hygienists. In 2006, a number of senior occupational hygienists from multinational corporations produced a paper (Alesbury, Bailey, et al, 2006) with ideas for addressing this challenge. Their motivation was driven by a desire to reduce the burden of ill health caused by hazards in the working environment. From those early concepts, the idea has grown and evolved into the Occupational Hygiene Training Association (OHTA). This is a truly multinational project to improve worker health under the guidance of the International Occupational Hygiene Association (IOHA) and its member organisations.

The scheme delivers a means of growing occupational hygiene skills using a modular system of training and qualifications. The system has been developed through extensive consultation over the last four years and provides a system of standard training packages that can be accessed free of charge anywhere in the world from OHLearning.com. All materials have been peer reviewed and trialed before release. The concept is based on standardized, modular training and student assessment to a consistent format. It focuses initially on the development of basic and practical occupational hygiene skills at the technical level to identify, assess and control risk.

Training materials are developed through a rigorous process of authoring, peer review and testing. This quality approach and standardization facilitates translation into other languages. This enables use anywhere in the world while retaining the same core technical standards of teaching materials and student assessment processes. The outcome is a scheme that reduces costs, increases potential for local development, and provides a means to train large numbers of individuals in a cost effective way. The result is a standardized system of intermediate level qualifications that can be supplemented with higher level modules or other training to the standard required for professional qualification under the IOHA National Accreditation Recognition Scheme.

In addition to these intermediate level courses there is also a foundation level 'Principles' module. This provides a general introduction to occupational hygiene and is suitable as a starter course for those preparing to study the modules or for other individuals with an interest in occupational hygiene. Additional study at postgraduate level can be used to build the knowledge and skills required for professional accreditation under one of the IOHA national Accreditation Recognition (NAR) schemes. See Figure below.

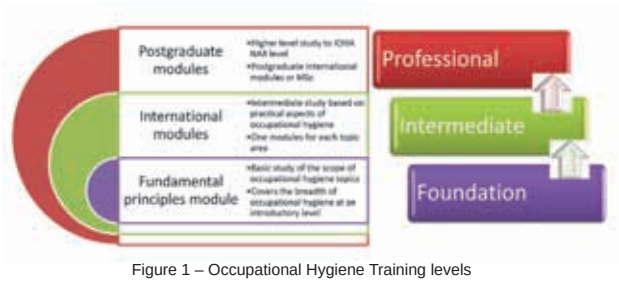

Figure 1 – Occupational Hygiene Training levels

The modular courses available so far are listed below. They cover a range of occupational hygiene topics. By using a package of courses, skills can be developed to suit the risk profile and priorities of the organization funding the training

Modules available	Level
W101 – Basic Principles in Occupational Hygiene	Foundation
W501 – Measurement of Hazardous Substances	Intermediate
W502 – Thermal Environment	Intermediate
W503 – Noise	Intermediate
W504 – Asbestos	Intermediate
W505 – Control	Intermediate
W506 – Ergonomics	Intermediate
W507 – Health Effects of Hazardous Substances	Intermediate

Although anyone can download materials free of charge, students are encouraged to attend training courses delivered by OHTA approved course providers. These are organisations with a proven track record in training and a qualified occupational hygienist as course director. These approved course providers and their courses are listed on OHLearning.com Approved course providers offer OHTA awards which bear the IOHA logo and phrase 'Supported by IOHA'.

OHTA would like to acknowledge the support of the many individuals and organisations across the world without whom the development of this scheme would not have been possible.

Roger Alesbury (roger@alesbury.net)

May 2010

Reference

Discussion Paper on Industry Needs for Occupational Hygiene, October 2006. Roger Alesbury, Steve Bailey, Alex Bianchi, Lindsay Booher, Lesley Burgess, John Dobbie, Richard Heron, Tom Kupferer, Alison Margary, Karen Niven, Martin Newell

Interested in becoming a Certified Industrial Hygienist (CIH)? visit www.abih.org for all the details

Certification and certification maintenance advance the profession. They also identify industrial hygiene professionals and distinguish them from others involved in industrial hygiene activities. Many employers see the CIH designation as important selection and promotion criteria. By participating in and supporting the ABIH program, qualified persons are helping to identify and maintain the professional stature of industrial hygiene. Reasons cited for pursuing certification include:

- Broadening the practitioners' knowledge base
- Increasing both confidence and credibility
- Peer recognition
- Securing employment
- Career advancement/higher pay
- Contracts requiring a specific certification
- Recognition

For more information on the procedures for taking the examination and obtaining certification, visit www.abih.org.

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