

# Beyond Risk Assessment

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# Technology and Instant Access to Information

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Topics > Cameras >

DIGITAL PHOTOGRAPHY

# Digital Camera Sales Dropped 84% Since 2010

by Felix Richter, May 27, 2019

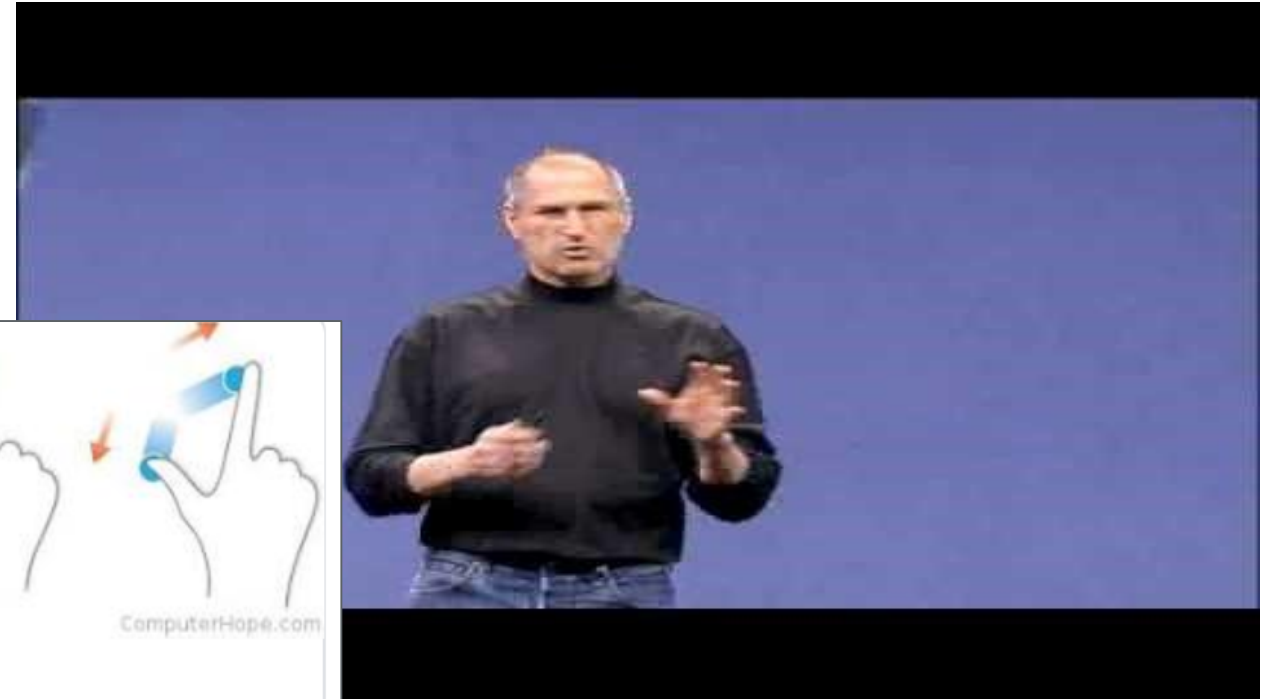
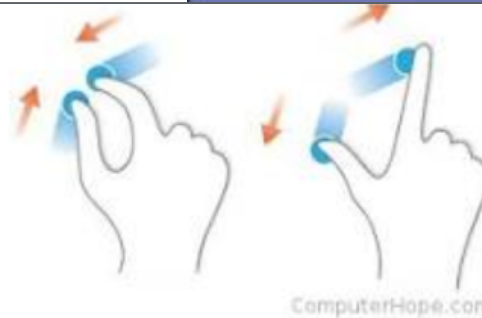


# Pinch-To-Zoom

**Pinch-to-zoom** refers to the multi-touch gesture that zooms in or out of the displayed content on a device with a touch screen. These devices include a smartphones and tablets. To use **pinch-to-zoom**, touch two fingers on the touch screen, and move them apart to **zoom** out, or together to **zoom** in. Jul 10, 2019

 [www.computerhope.com](http://www.computerhope.com) > jargon > pinch-to-zoom

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## > We have heard about:

- Robots
- Talc
- Psychosocial health factors
- Linear non-threshold
- Climate change
- Cannabinoids
- Microbiome
- Health metrics



## > Different topics, but one common theme



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HEALTH AND SCIENCE

# **CDC confirms second US case of coronavirus and is monitoring dozens of other potential cases**

PUBLISHED FRI, JAN 24 2020 10:14 AM EST | UPDATED 8 MIN AGO

# RISK

## ASSESSMENT PRINCIPLES

### FOR THE INDUSTRIAL HYGIENIST



Protecting Worker Health

MA. Wilson • J.B. Lewis • D.L. Wilson

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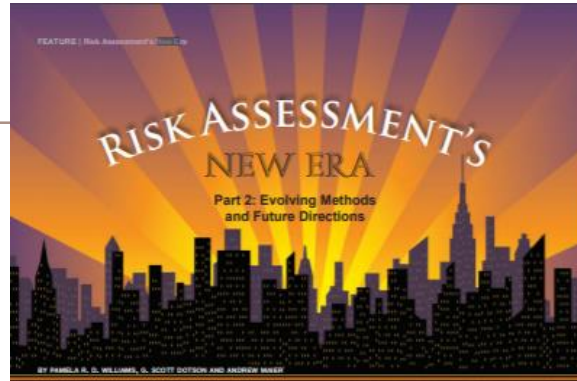
# Key Question

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- >How do we,
  - Define risk?
  - Assess, measure, or characterize risk?
  - Communicate risk?
  - Manage risk?
  - Address perceptions of risk?
  - Develop risk-based policies?







Editor's note: This article is the second in a series sponsored by the AIHA Risk Assessment Committee highlighting research and policy initiatives that are shaping the future of risk assessment in industrial hygiene. Part 1 appeared in the April 2012 issue, and Part 2 appeared in the May 2012 issue.

For more than three decades, health practitioners and regulatory agencies have used risk assessment methods to characterize health risks.

In the process of likelihood, risk to an individual from physical or other agents and opportunities for occupational exposure to occupational

**Cumulative Risk Assessment (CRA)** broader in scope than traditional chemical risk assessments, CRAs determine which chemicals, stressors or other risk factors are affecting certain populations. They address multiple chemical and non-chemical stressors, aggregate exposures and risks that is, exposure to a single stressor by multiple routes, and combined risks for common health end points by chemical or stressor groupings.<sup>14</sup>

The EPA framework for conducting CRAs involves planning, scoping and problem formulation; analysis, and integration and risk characterization.<sup>14</sup> This framework has been applied to CRAs of chemicals, such as organophosphate pesticides and phthalates. In

addition, EPA has developed various models and web-based tools to assess aggregate and cumulative exposures and risks.<sup>14</sup>

The greatest strength of CRAs is their emphasis on multiple exposures (occupational and non-occupational) and health effects in varied populations. But it's challenging to identify common groups and develop metrics to evaluate dissimilar risks, because of gaps in data and methodological limitations. CRAs have yet to include non-chemical stressors or to be used in occupational exposures.

**Biomonitoring** Biomonitoring assesses human exposure by measuring chemicals or their metabolites in human tissues



Editor's note: This article concludes a four-part series sponsored by the AIHA Risk Assessment Committee highlighting research and policy initiatives that are shaping the future of risk assessment in industrial hygiene. Previous articles in the series appeared in the April, May and June/July 2012 issues.

Assessing risk in the aggregate, cumulatively, and comparatively has entered a new era in which innovative technologies and methods are allowing health science professionals to explore and solve ever more complex problems.<sup>1,2,3</sup> Increasingly, risk assessments either support or are mandated by regulatory, management, business, and public policy decision making. They also support technical and lay educational efforts and behavior-based safety programs. Since the inception of our profession, industrial hygienists have been front and center in characterizing hazards and assessing exposures, which predates the four-step risk assessment paradigm articulated by the National Academy of Sciences (NAS) in its 1983 "Red Book": hazard assessment, exposure assessment, dose-response assessment, and risk

characterization. Many industrial hygienists have also participated in more recent initiatives, such as resource allocation, enterprise risk management, sustainability, and cost-benefit analysis.

In 2008, NAS updated its recommendations for improving the risk assessment process. According to these recommendations, a risk assessment should have a clear scope and defined metrics for judging the information discovered during the assessment. Essentially, data should be gathered only after criteria are established for determining whether a risk is acceptable. Industrial hygienists have followed this approach by utilizing the scientific method, validating sampling and analytical methods, and establishing occupational exposure limits (OELs) to help us develop strategies and judge significance in our practice of Exposure Risk Assessment Management (ERAM).

But our world continues to evolve, requiring us to evolve with it. What if



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Although industrial hygienists have used risk assessment for many years, some practitioners might not recognize it as a core element of the profession. Industrial hygienists routinely evaluate risk by assessing the hazard and exposure to chemical and physical agents, characterizing the subsequent risk and developing control strategies to reduce the risk. However, the process can go much deeper. This article presents the vision of the AIHA Risk Assessment

(WIO)—have used risk assessment to set standards and guidelines, the risk assessment process has been criticized for its long duration and variability between different organizations. The typical industrial hygienist is not involved in standard-setting risk assessment, but often interprets a standard's implications for worker and community exposure and subsequent controls. Therefore, understanding the details of risk assessment and risk management, as well as the tools and techniques used to characterize risk, is critical to our profession.

Many new risk analysis techniques are being used primarily to assess environmental and community health risks. The application of these techniques in occupational settings has received less attention. If occupational health concerns are overlooked or addressed only afterthoughts, the result could be a loss of risk analysis tools ill-suited for assessing and managing occupational environmental hazards and risks. As with professionals, industrial hygienists need to take a proactive stance to ensure that new tools in the risk sciences address the challenges posed by the occupational environment.

The details of environmental and occupational risk assessments differ, but key steps are equivalent, and they

share the same goal of reducing the overall risk of an activity. We define risk as the probability of an adverse event, and risk assessment as the process of characterizing the risk of the event. Industrial hygienists often consider this risk characterization to encompass exposure and toxicity. It is important to recognize that risk assessment is a tool used in many settings, including standards development, process evaluation, hazardous waste cleanup and location-specific assessments.

The industrial hygienist's multidisciplinary background incorporates aspects of the physical and biological sciences, public health, engineering and management. This diversity gives industrial hygienists a unique perspective not shared by other, more specialized health professionals. Our skills and experiences can focus attention on the development of techniques and tools capable of assessing the health risks found within the workplace, which in turn will promote the value of our profession and help us meet the needs of the communities we serve.

**Vision and Value**  
The vision of the RAC is to integrate risk sciences as a core competency within industrial hygiene. Whether we're focused on a specific hazardous agent (chemicals,

there is no OEL? What if there is a net-zero benefit for the feasible control? By what means will we make decisions regarding multiple independent stressors? How do we incorporate non-occupational sources into decisions regarding occupational health? How do we mitigate high-risk personal decisions that overshadow low-risk occupational activities? Industrial hygienists are well positioned to ensure that occupational, non-occupational, personal, business, global, engineering, and economic factors are integrated in risk-based decision making.

This article, which concludes a four-part series, presents a multistep roadmap for integrating risk and decision making (i.e., risk assessment, risk management, and risk communication) into the profession of industrial hygiene as a core competency. The key components of this roadmap are:

- development of a model for BE: risk and decision making
- development of risk-based decision metrics and tools



# Our Vision...

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1. Occupational risk assessment will not focus on OELs
2. New challenges will require “new” solutions
3. Shift from risk assessment to a broader view of risk and associated disciplines
4. Greater focus on scientific and technical .
5. Integration of risk-based decision making
6. Focus beyond the workplace



12  
SPECIAL SECTION  
Pole to Pole

20  
RISK ASSESSMENT  
Integrating Risk  
Sciences into IH

26  
FEATURE  
IH in Central America  
and Panama

30  
FEATURE  
Think Global,  
Act Local

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September 2018



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## Beyond Risk Assessment

Integrating the Risk Sciences into the Profession of Industrial Hygiene

BY G. SCOTT DOTSON

**R**isk: it is that four-letter word used extensively in today's society to discuss everything from the dangers of operating a vehicle to uncertainty in the economy to the perils of certain lifestyle choices. Risk is inherently personal in nature and varies greatly between individuals, organizations, and businesses. For this reason, risk can be a divisive topic. What one person or group deems as an acceptable or "safe" behavior, another will judge as "dangerous" or too risky. The one thing that most of us can agree on is that risks are all around us, regardless of the setting.

into new areas of expertise, and we are becoming more reliant on increasing our understanding of risk to meet these new challenges.

### RISK BEYOND THE WORK ENVIRONMENT

Health professionals in allied fields, such as environmental health and public health, are expanding the knowledge and application of the risk sciences. Through their efforts, we are gaining an increased awareness of the scientific basis of, and novel approaches to, risk assessment. Over the last forty years, the field of risk science, which includes risk analysis, assessment, and management, has grown dramatically and is recognized as a critical tool for addressing complex public and environmental health issues. Numerous organizations, such as the National Academy of Sciences, EPA, and the World Health Organization, have developed different components of the risk sciences. Some of the publications that have shaped our understanding of the risk sciences are listed on page 21.

For example, the NAS "Red Book" published in 1984 first outlined the risk assessment and management paradigm that serves as the basis for other approaches, such as those from EPA and WHO. The NAS "Silver Book" expands on the original paradigm and incorporates new elements intended to improve the risk analysis process such as problem formulation and scoping, risk-based decision making, and cumulative risk assessment. Although these efforts may have been created for public and environmental

The modern work environment is no different. The American economy has shifted since the mid-20th century from a focus on manufacturing to one based on the service industry. In response, a substantially greater number of workers can be found in office buildings compared to factories.

New technologies, such as nanomaterial-enabled products and processes, are found in every industrial sector alongside traditional hazards, such as noise and lead. As the work environment continues to change, are we prepared to address the challenges that these potential risk factors represent for both workers and their employers?

### RISK AND INDUSTRIAL HYGIENE

Analyzing and controlling risk in the work environment have long been recognized as core competencies for industrial hygienists. Whether we are discussing a specific hazard (chemical, noise, radiation) or topic (product stewardship, cumulative risk assessment, hazard banding), risk is at the center of the conversation. During these discussions, we often ask:

- Is there a universal definition of risk that we should be applying? If so, what is it?
- Should occupational risk assess-

ments focus on characterizing exposures or managing hazards?

- How do we communicate risks to our intended stakeholders?
- As industrial hygienists, are we exposure assessors or risk assessors?

The responses to these questions are often diverse, separating us into different camps based on our experiences, areas of focus, and opinions. Regardless of how you personally answer these questions, the importance of risk to the profession of industrial hygiene cannot be denied.

AIHA is actively engaged in integrating the topic of risk into our profession. Several risk-based initiatives are currently underway, such as the Risk Body of Knowledge and efforts to demonstrate the value of industrial hygiene as a component of enterprise risk management. These initiatives demonstrate not only that our understanding of risk is expanding beyond traditional risk assessment approaches but that the roles of industrial hygiene professionals are changing. Risk in the workplace is no longer being defined by occupational exposure limits or the application of the hierarchy of controls as the standard for risk management. Instead, our profession is expanding

**Risk in the workplace is no longer being defined by occupational exposure limits or the application of the hierarchy of controls as the standard for risk management.**

# The Five “Buckets”

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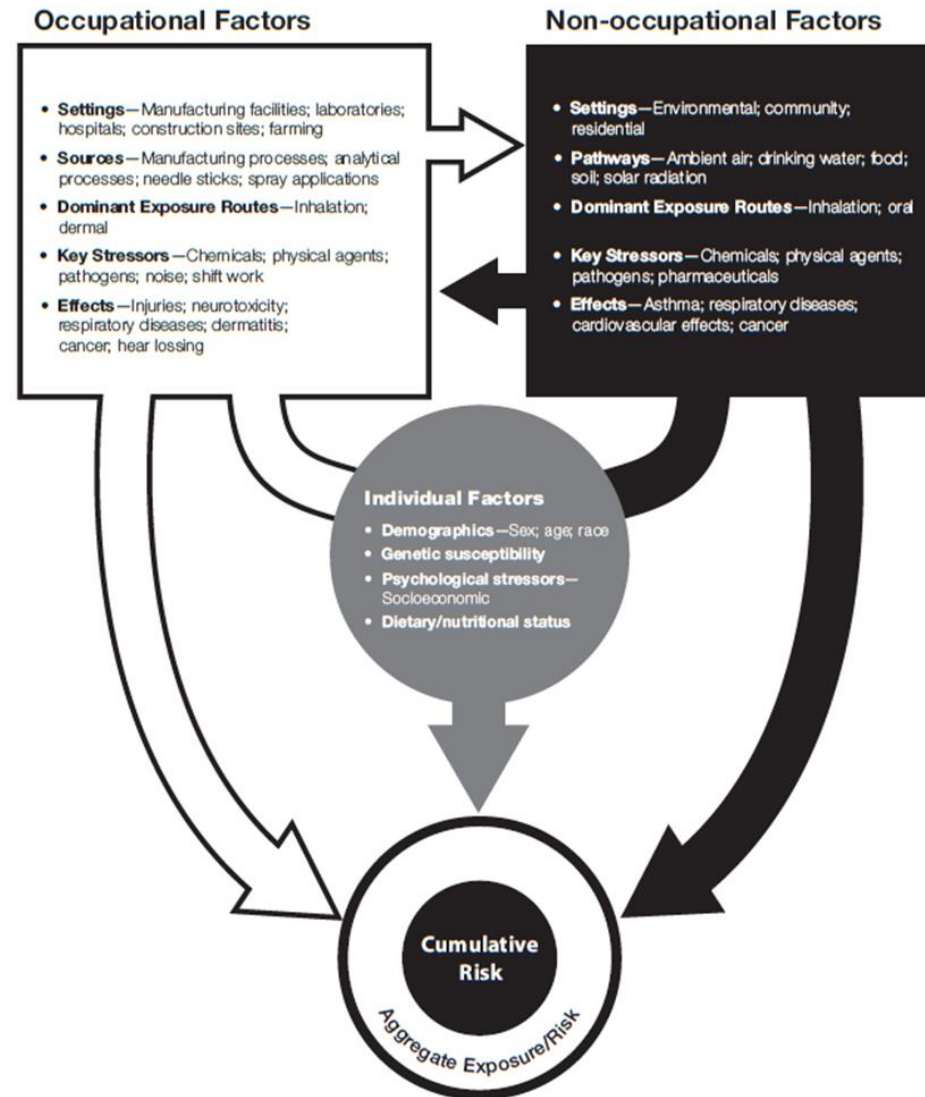


Table 1. Methods and Tools for Risk-Based Decision Making

| Method/Tool                                      | Description  |
|--|--|
| Decision analysis                                | Systematic approach for making decisions under uncertainty, which accounts for underlying beliefs and preferences. Steps involve identifying a problem and viable actions, establishing a decision tree that provides for choices and accounts for chance events, and assigning probabilities to each chance event and utility values to the consequences associated with each choice. |
| Cost-benefit analysis (or benefit-cost analysis) | Systematic process of enumerating all tangible and intangible societal costs and benefits associated with an option or alternative options. Costs and benefits are valued in a common unit (typically monetary) and net benefits are calculated as the difference between total benefits and costs.  |
| Cost-effectiveness analysis                      | Systematic approach for finding the lowest-cost means of achieving an objective or comparing the relative costs and effects of multiple options. Costs are measured in monetary terms, while effectiveness is expressed as some unit of output or outcome (e.g., number of lives saved).   |
| Comparative risk analysis                        | Method of comparing multiple risks using a common metric. This procedure is often used to rank environmental hazards by their relative risk for purposes of setting priorities.  |
| Value-of-information analysis                    | Method of evaluating the benefit of collecting additional information to reduce or eliminate uncertainty in a specific decision-making context. The newly acquired information should affect a behavior, decision, or outcome (or it is not worth obtaining).  |



# Boundaries Are Being Crossed: Cumulative Risk



# Complex Public/Occupational Health Issue?

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# Advancements and Challenges

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> Complex Suite of Real Time Monitoring  
(aka IH in a Box)

– 1 second above an IDLH?

> Big Data

– How do we analysis?

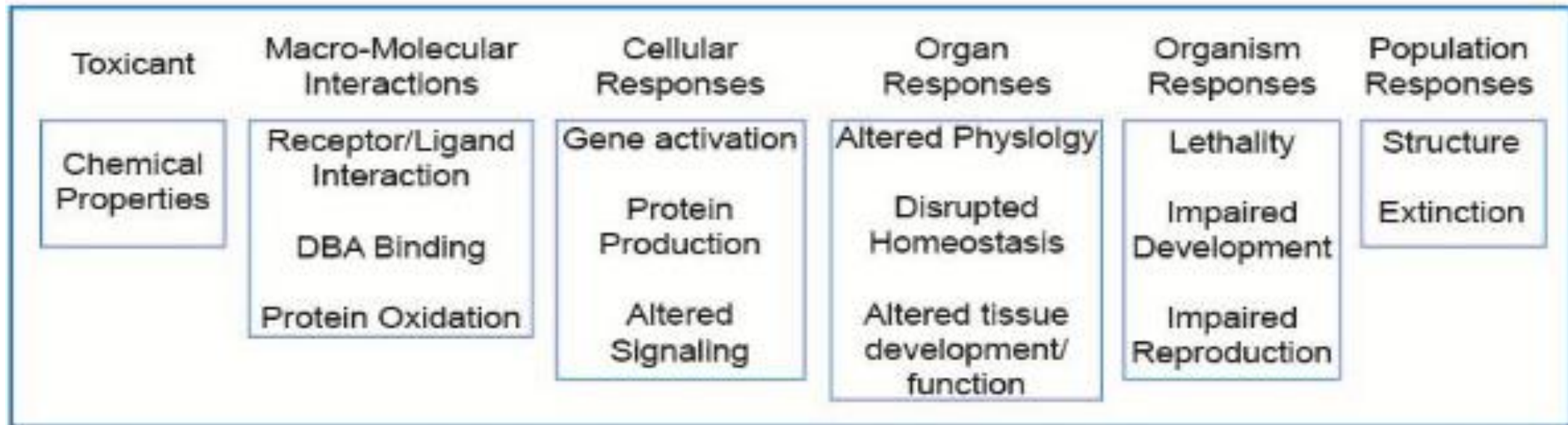


# More Advancements and Challenges

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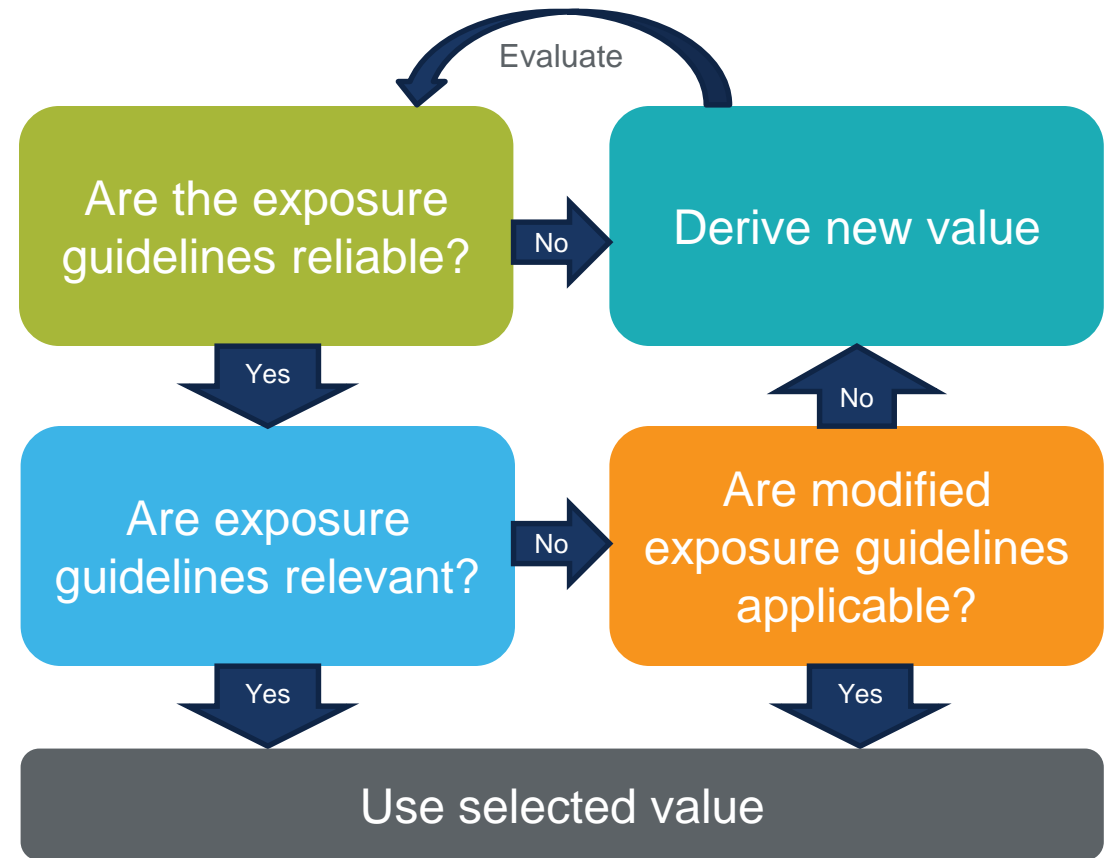
## > High-throughput toxicological studies

- What do the results mean?
- Is a subclinical change sufficient to be the basis of a risk assessment?



# OEL Selection

- > Systematic approach needed.
- > Two key aspects include:
  - Reliability
    - Uses latest health effects data
    - Consistent with current methods
  - Relevance
    - The basis matches scenario of interest in terms of population, temporal pattern, route of exposure, chemical form, etc.



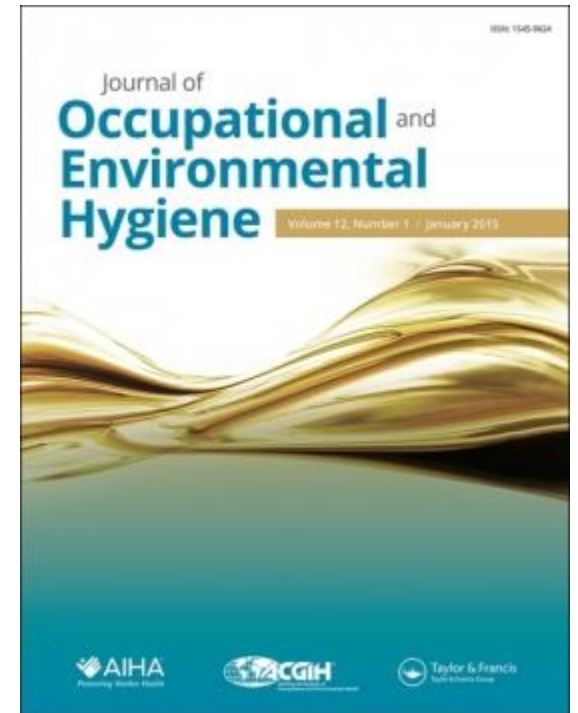


# NIOSH OEL Development

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Journal of Occupational and Environmental Hygiene Volume 12, 2015 – Issue Supplement 1: State of the Science of Occupational Exposure Limit Methods and Guidance.

- > Review of current methods and resources
- > Point of departure estimation
- > Uncertainty factor application
- > Dosimetry adjustments
- > Use of new high throughput data and biomarkers
- > Implementation in exposure and risk management context
- > Aggregate and cumulative risks
- > Setting OELs for allergens
- > OEL selection



# Revealing Hidden Risks

BY JEANNE FALLON-CARINE AND GRETCHEN N. HANCOCK

Over the past ten years the public has become all too familiar with events where companies either failed to anticipate, or didn't properly manage, enterprise risk. Companies in industries as diverse as oil and gas (Macondo), banking (Wells Fargo), automotive (Volkswagen), technology (Facebook), and tourism (Duck Boats) have experienced very public failures to identify and manage risk. The reputational ramifications that result from these failures have included, in some cases, investor pressure or stock price constriction. In the case of Macondo, an investigation revealed the highly embarrassing fact that BP leaders were present on the Deepwater Horizon rig on the day of the oil spill as part of a safety celebration related to conventional injury and accident metrics. As health and safety practitioners, it is critical for our profession to understand these failures of enterprise risk management as well as traditional accident metrics. This knowledge allows us to implement tools and processes to identify and manage risk with the goal of mitigating adverse outcomes for our employees, companies, and investors.



JULIE ROTH, CH, is a health, safety, and environmental manager with Baker Hughes, a GE Company based in Minden, Nev. She is currently the secretary of the AHA Risk Committee.

Send feedback to [synergist@aha.org](mailto:synergist@aha.org)

## A Holistic Approach to Risk

BY JULIE ROTH

This article is the first in a series to understand risk through their overall business strategies. Each installment will group similar industries together and highlight a few key themes.

The first installment contains content from three separate interviews with risk leaders from three industrial manufacturing companies. Because they wish to remain anonymous, the article refers to them by initials only. J.J. works in the food and beverage industry, G.H. in industrial cooling and household hardware, and L.B. in the appliance industry. Their responses have been edited.

**QUESTIONS AND ANSWERS**  
What is your company's overall approach to risk management?

J.J.: Our company's strategy is to increase environmental health and safety performance across every operation and facility. Our strategy is based on an ISO 45001/14001-compliant EHS management system, a digital system, cultural elements that increase leadership involvement and employee engagement, and a Tollgate process to split the strategy in manageable pieces over the next three to five years. (Editor's note: "Tollgate" is a term from the Six Sigma management technique. The intent of Tollgates is to keep managers from moving to a new phase of Six Sigma until the proj-

the synergist | May 2019

"We are looking at employees as industrial athletes, where we focus on the overall health of the individual."



JULIE ROTH, CH, is a health, safety, and environmental manager with Baker Hughes, a GE Company based in Minden, Nev. She is currently the secretary of the AHA Risk Committee.

Send feedback to [synergist@aha.org](mailto:synergist@aha.org)

Editor's note: In next part I of this series in the May Synergist, visit <http://bit.ly/synergistrisk2>.

## A Holistic Approach to Risk, Part 2

Interviews with Leaders in the Pharmaceutical Industry

BY JULIE ROTH

This article is the second in a series that focuses on the concept of risk throughout various industries. The purpose of this series is to understand how different industries are addressing risk through their overall business strategies. Each installment will group similar industries together and highlight a few key themes.

The content in this article stems from separate interviews with risk leaders from the pharmaceutical industry. To preserve their anonymity, the article refers to these leaders by initials only. Their responses have been edited.

**QUESTIONS AND ANSWERS**  
What is your company's overall approach to risk management?

J.D.: Our company can be broken into two parts, with significant differences in risk. The first business unit is our finished dose sites, which essentially bring all the components together. The components are mixed together to form granules and then the finished form (for example, tablets, capsules, or powders in a bottle). The second business unit comprises the chemical plants. The plants create an active pharmaceutical ingredient, or API, which provides the therapeutic effect. This API is what goes into the finished dose to form the finished product, which the patient receives.

For finished dose sites, our risk management across the organization is a bit siloed. The EHS department manages our overall risks. Our Quality department manages risks related to patients, and our Engineering department looks at fire and environmental risks associated with geographic regions or major disasters. In some

cases, our departments will interact with each other when we assess risk; however, risk assessment is largely done independently.

Within the EHS department we utilize a risk matrix to prioritize the greatest risks and find ways to reduce these risks. The use of the risk matrix was largely driven by our European sites, which have regulatory requirements for implementing risk assessments.

Risk assessments are conducted for each new project that we work on. Assessments address ingredients that are going into the process; the categorization of the API using a banding system; any flammable liquids being used; combustible dust properties; changes or modifications needed to existing equipment; containment at source of pharmaceutical powders to meet any containment requirements; personal protective equipment; air emissions; wastewater discharge; waste disposal requirements; and any changes that might be needed to existing training requirements.

For our chemical plants, the API group utilizes a similar risk matrix approach. The assessment is much more detailed for new projects at the chemical plants than for the finished dose sites. Examples include:

- Testing conducted on thermal properties of various chemical reactions
- The calculation for pressure relief valves is evaluated for new and existing equipment
- Evaluations of the potential for runaway reactions and systems to stop those reactions
- Hazard and operability studies or similar techniques are used to identify hazards. Risk assessments address air discharge, waste generation, wastewater discharges, handling of the contents of residual tanks or reactors, and cleaning of equipment.

**B.N.:** Pharma companies take a holistic approach to risk. Occupational toxicologists focus on understanding the dataset for the API and impurities. Industrial hygienists and engineers determine how best to effectively implement the results of the hazard characterization and risk assessment. We have the benefit of human data, which allow us to develop assessments tailored toward the end user. Occupational exposure bands are developed first and are followed by numerical occupational exposure limits. Controls are implemented using parameters that are developed for design of new facilities or processes. Exposure monitoring is conducted to verify that controls are working as designed. Risk communication is critical. Occupational health risk assessments are completed by toxicologists and occupational physicians to put potential exposures into perspective.

the synergist | June/July 2019

## In Closing...

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- > Risk is an inherent part of industrial hygiene
- > Shift from traditional risk assessment approach to more holistic approaches
- > New stressor, populations, scenarios, and analytics
- > Need for new skills (pinch-to-zoom for IHs)
- > Evolving technology



# Thank you

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