



# Overview of Current NIOSH Risk Assessment and Management Activities for Chemicals

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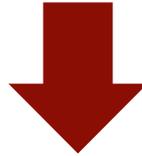
# Scope

- NIOSH's efforts in chemical risk assessment and management have been reviewed individually but not considered in their **entirety**.
- This presentation provides an overview of all of these efforts and solicits feedback on them.

# Chemicals are one of the most significant occupational hazards

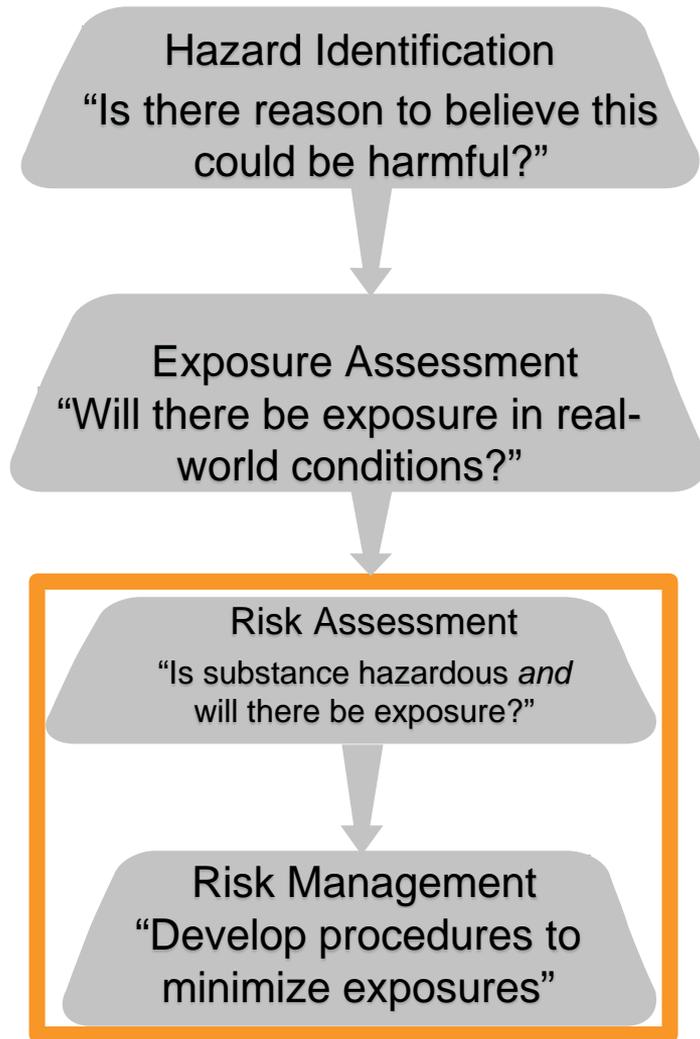
- 52.1 Million workers estimated exposed to chemicals in their work  
(Calvert et al 2013)
- From 2011-2015
  - 71,140 illnesses or injuries associated with chemical exposures (BLS 2011-2015)
  - 4,836 chemical-related fatalities (BLS 2011-2015)
- Difficult to estimate number of chronic diseases: cancer, pulmonary, cardiovascular, neurologic related to chemicals
  - 2–8% of cancers attributed to occupational exposures (Purdue et al 2015)
  - Severe underestimation has been identified

**NIOSH conducts extensive research on chemical hazards and exposure in most every Division, Laboratory, and Office.**



**The focus of this presentation is on risk assessment and risk management.**

# Focus of the presentation: Risk Assessment and Management of Chemicals



# Current NIOSH Risk Assessment and Management Activities for Chemicals

- Current Recommended Exposure Limit (REL) Development Efforts
  - Chemical Carcinogen Policy
  - Risk Assessment Practices
  - Nanoparticles/Advanced Manufacturing
  - Development of IDLH values and Skin Notation Profiles
  - NIOSH Pocket Guide/Manual of Analytic Methods
  - Respiratory Protective Devices
  - Occupational Exposure Banding
  - Prevention through Design/Green Chemistry
  - Exposome/Cumulative Risk Assessment
  - Collaboration on TSCA
  - Hazardous Drugs List
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# Direction and Authority

NIOSH is mandated by the *OSH Act (1970)*

*“...to develop criteria dealing with toxic materials and harmful physical agents and substances which will **describe exposure levels that are safe for various periods of employment**, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experiences.”*

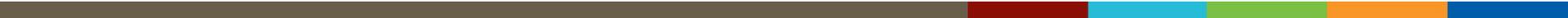
[OSH Act, 20 USC 22 (a)(3)]



# Current Recommended Exposure Limits (REL) under Development

- Glutaraldehyde—widely used
- 1-Bromopropane—replacement for ‘ozone depleters’
- Manganese—neurobehavioral effects
- Diethanolamine—widely used
- Lead—neurobehavioral effects
- Toluene diisocyanate—sensitizer
- Silver nanoparticles—high volume nanomaterials

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# History of NIOSH Chemical Carcinogen Policy

- Prior to 2016 NIOSH labeled known carcinogens “as potential occupational carcinogens”
- Went from recommending exposure limits based on 1/1000 lifetime risk to a new approach

**CURRENT INTELLIGENCE BULLETIN 68**

# NIOSH Chemical Carcinogen Policy

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



(2016)

# Cancer Policy: Three Key Components



Carcinogen Classification



Carcinogen Risk Management Limit



Analytical feasibility

# Summary

## Classification

Relies on **NTP, EPA, and IARC** for carcinogen classification

## Risk Management Limit

Changes NIOSH policy on target risk to **1/10,000** as a starting point

## Risk Management Limit

Sets new terminology (**occupational carcinogen and RML-CA**)

## Analytic Feasibility

When the LOQ or RQL > 1/10,000 risk level, **LOQ or RQL = RML-CA**

NTP: National Toxicology Program

EPA: Environmental Protection Agency

IARC: International Agency for Research on Cancer

RML-CA: Risk management limit for carcinogens

LOQ: Limit of quantitation

RQL: Reliable quantitation limit

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# Selected History of NIOSH Quantitative Risk Assessment

Agent	Adverse Effect <sup>1</sup>	Dose-response assessment <sup>2</sup>	Risk Characterization	Reference
1,3-butadiene	leukemia	toxicologic, Weibull time-to-tumor regression model, animal to human extrapolation  epidemiologic and toxicologic, literature review	extrapolation, excess lifetime risk, target risk unspecified	[Dankovic et al. 1993]
asbestos	lung cancer, asbestosis	epidemiologic, Poisson regression, additive relative rate function (cancer), power function (asbestosis)	extrapolation, excess lifetime risk, target risk unspecified	[Stayner et al. 1997]
cadmium	lung cancer	epidemiologic, Poisson and Cox PH regression, additive relative rate function	extrapolation, excess lifetime risk, target risk unspecified	[Stayner et al. 1992a; Stayner et al. 1992b]
carbon nanotubes and nanofibers	non-malignant adverse lung effects	toxicologic, NOAEL and BMD assessments	PoD/UF	[NIOSH 2013b]
coal mine dust	coal workers' pneumoconiosis, progressive massive fibrosis, pulmonary dysfunction	epidemiologic, logistic and multiple linear regression	extrapolation, excess lifetime risk, target risk unspecified	[Kuempel et al. 1997]
diacetyl and 2,3-pentanedione	pulmonary dysfunction	epidemiologic, linear extrapolation, multiple regression	extrapolation, excess lifetime risk, 10 <sup>3</sup> target risk	[NIOSH 2016a]
diesel exhaust	lung cancer	toxicologic and epidemiologic (review)	extrapolation, excess lifetime risk, target risk unspecified	[Stayner et al. 1998]

# History of NIOSH Quantitative Risk Assessment Continued

Agent	Adverse Effect <sup>1</sup>	Dose-response assessment <sup>2</sup>	Risk Characterization	Reference
EGME, EGEE, EGMEA, EGEE	reproduction developmental, hematotoxic effects	toxicologic, NOAEL and LOAEL assessments	PoD/UF	[NIOSH 1991]
hexavalent chromium	lung cancer	epidemiologic, Poisson regression linear ERR model	extrapolation, excess lifetime risk, $10^3$ target risk	[NIOSH 2013a; Park et al. 2004]
noise	material hearing impairment	epidemiologic, logistic regression	extrapolation, excess lifetime risk with no target risk level specified	[NIOSH 1998; Prince et al. 2003]
radon	lung cancer	epidemiologic, Cox proportional hazards regression	extrapolation, excess lifetime risk, target risk unspecified	[Hornung and Meinhardt 1987; NIOSH 1987]
silica	lung cancer	epidemiologic, Poisson regression, additive relative rate function	extrapolation, excess lifetime risk, target risk unspecified	[Rice et al. 2001]
silica	non-malignant lung disease	epidemiologic, Poisson regression, additive relative rate function	extrapolation, excess lifetime risk, target risk unspecified	[Park et al. 2002]
titanium dioxide	lung cancer	toxicologic, nonlinear extrapolation, BMD model averaging quantal endpoint	extrapolation, excess lifetime risk, $10^3$ target risk	[NIOSH,2011]

1. Analysis may have considered multiple adverse effects. The adverse effect shown in the table was selected as the primary effect in the risk assessment.

2. The doseresponse assessment refers to the primary source supporting final models and/or recommendations on risk-based exposure limits.

Abbreviations: BMD, benchmark dose; EGEE, ethylene glycol monoethyl ether; EGEEA, ethylene glycol monoethyl ether acetate; EGME, ethylene glycol monomethyl ether; EGME, ethylene glycol monomethyl ether acetate; ERR, excess relative rate; LOAEL, lowest observable adverse effect level; NOAEL, lowest observable adverse effect level; PH, proportional hazards; PoD, point of departure, UF, uncertainty factor.

# **(DRAFT) NIOSH Practices in Occupational Risk Assessment**

National Institute for Occupational Safety and Health

June 6, 2018

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Posted for public comment

<https://www.regulations.gov>

Enter CDC 2018-0060 in search field

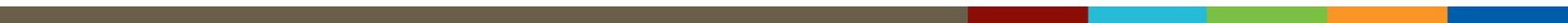
# NIOSH Practices In Occupational Risk Assessment

## Contents

- Problem Formulation
- Hazard Identification
- Dose-response assessment
- Dosimetry Adjustments for Human Equivalent Concentrations
- Risk Characterization
- Appendices
  - Sources of Errors
  - Emerging Practices

May serve as a major resource for the field

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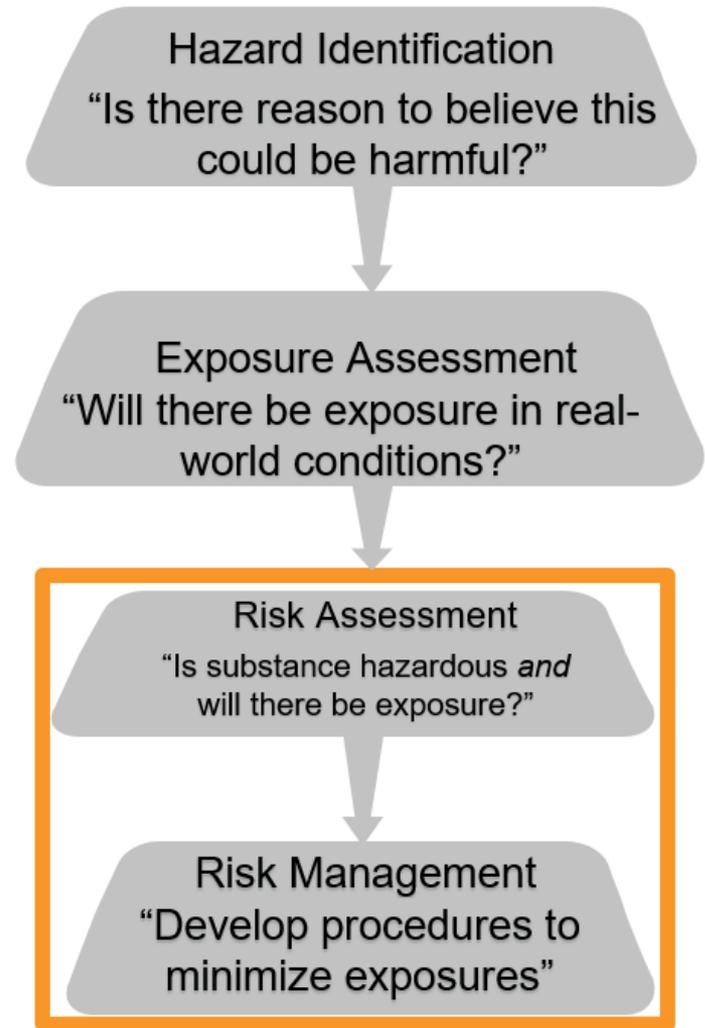
# Concerns about Nanoparticles

- Small particles may be more toxic than large particles
- Vast explosion of the technology in early 2000s
- Wide use of nanomaterials in high volumes in commerce
- Many organizations worldwide issued cautionary reports
- Critical need for guidance



## Key NanOEH Questions

- Are they hazardous?
- Is there exposure?
- What is the risk?
- Can they be controlled?



# Approaches to Safe Nanotechnology

Managing the Health and Safety Concerns  
Associated with Engineered Nanomaterials



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



CDC  
Workplace  
Safety and Health

**NIOSH**

CURRENT STRATEGIES FOR ENGINEERING CONTROLS IN

# Nanomaterial Production and Downstream Handling Processes



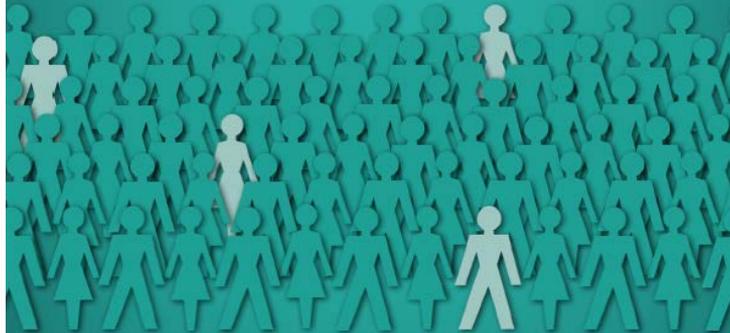
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Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health





## *Current Intelligence Bulletin 60*

Interim Guidance for Medical Screening and  
Hazard Surveillance for Workers Potentially  
Exposed to Engineered Nanoparticles

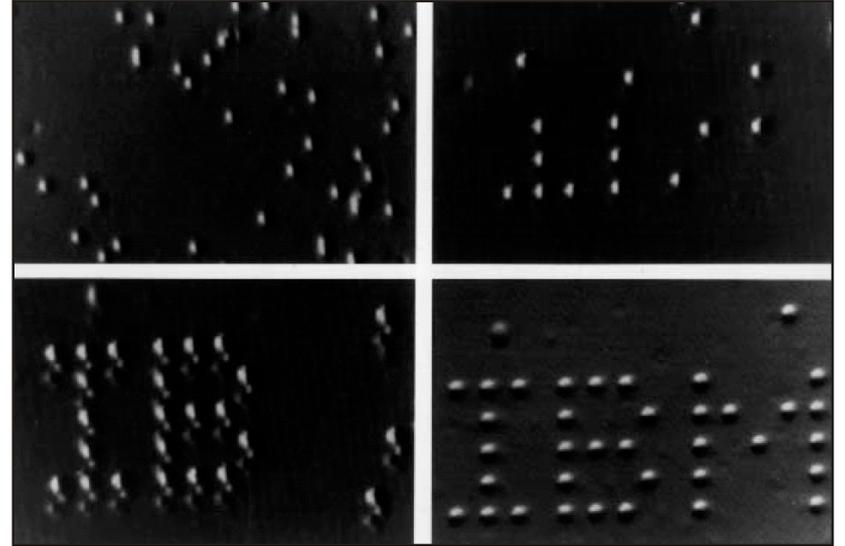


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# Potential Revolution in Manufacturing

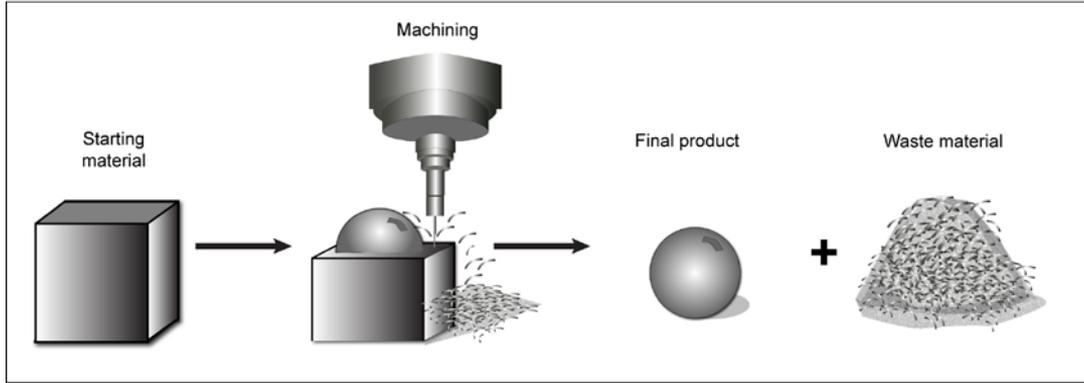
- See and manipulate one atom at a time – building molecular tools
  - Using 35 Xenon atoms to spell out a logo
- Copy nature – mimic self replication



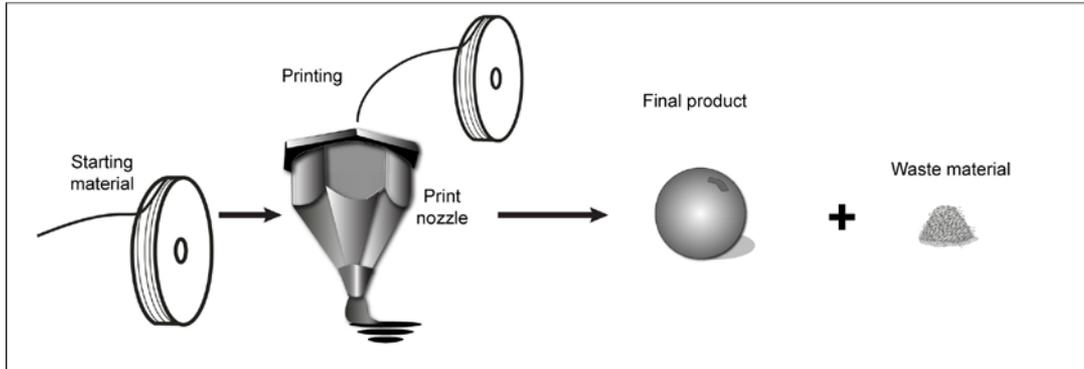
Source: IBM Research

# Rapid shift in manufacturing technology

## Subtractive manufacturing



## Additive manufacturing



# Materials and hazards in additive manufacturing

Polymers	Acrylonitrile-butadiene-styrene
	Poly(lactic acid)
	Propylene fumarate
	Poly(vinyl alcohol)
	Polystyrene
Solvents	Dimethyl fumarate
	Isopropanol
	Acetone
	Methyl Ethyl Ketone
	2-Butanone
Metals	Ti-6Al-4V
	IN 625 & IN 718 (Ni, Cr)
	17-4 PH stainless steel
	Cobalt chromium
Nanomaterials	nFe (steel sintering)
	nAg (sintering, conductivity)
	nCB, CNT (conductivity, stiffness, tensile strength)
	nSiO <sub>x</sub> (polymer strength)

Particle Emissions

Outgassing/VOC Emissions

Dermal Toxicity

Reactivity

Flammability

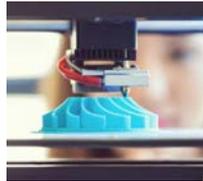
Combustibility

*Process-induced changes*

*Specific formulation*



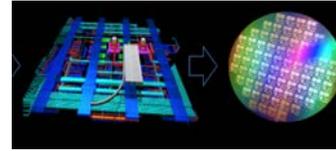
Additive  
Manufacturing



3D  
Printing



Functional Fabrics



Photonics



Flexible Sensors

# Advanced Manufacturing



Robotics



Light Weighting



Advanced Composites



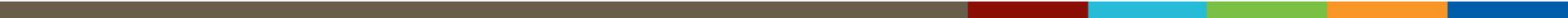
Clean  
Energy

**Some processes and some products.**



Engineered Biology

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# Immediately Dangerous To Life or Health (IDLH) Values/Skin Notations

**CURRENT INTELLIGENCE BULLETIN 66**

**Derivation of Immediately Dangerous to Life or Health (IDLH) Values**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



**IDLH**  
**IMMEDIATELY DANGEROUS to LIFE or HEALTH**  
**VALUE PROFILE**

Benzonitrile  
CAS<sup>®</sup> No. 100-47-0

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Center for Disease Control and Prevention  
National Institute of Occupational Safety and Health



Values to inform escape  
from hazardous environments

**NIOSH Skin Notation Profiles**  
**Aldrin**



IDLH
SRH
SYS
<b>SYS (FATAL)</b>
DIR
DIR (IRR)
DIR (COR)
SEN

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Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

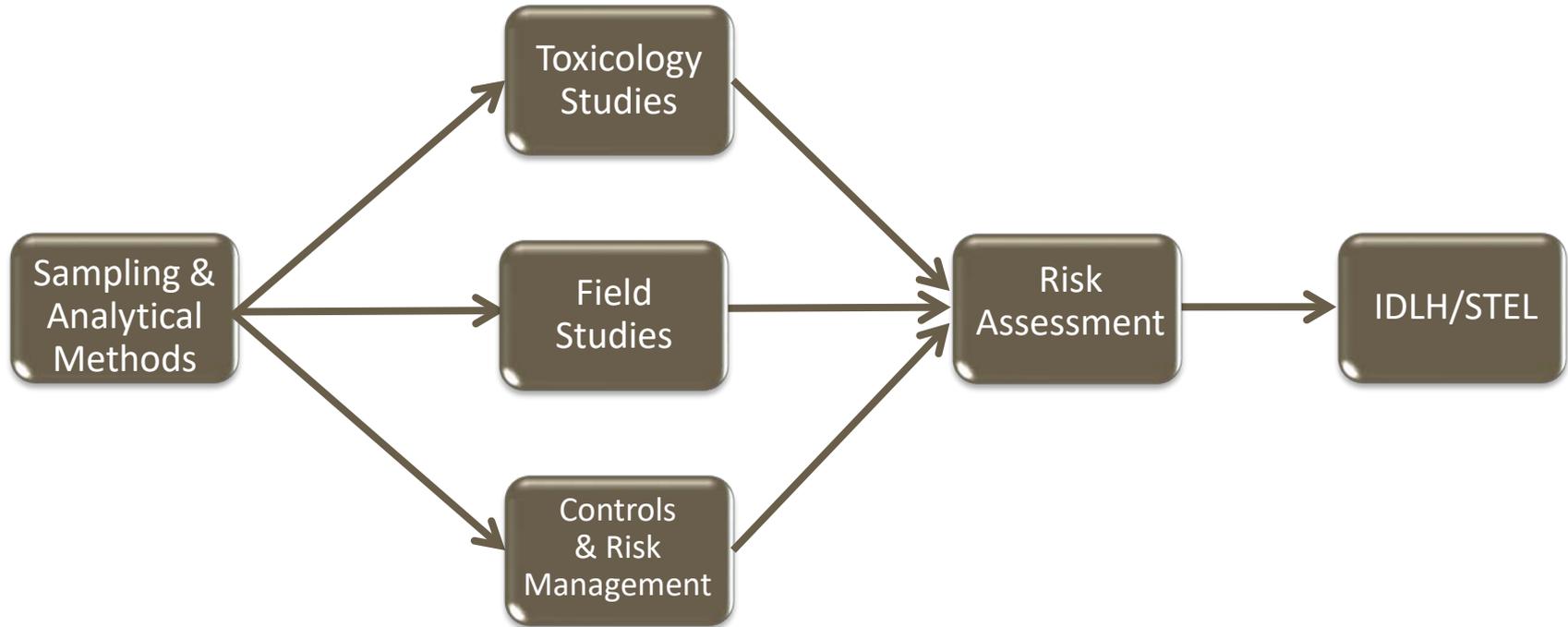


Skin notations to guide  
chemical handling

# Special project: Development of IDLH for peracetic acid

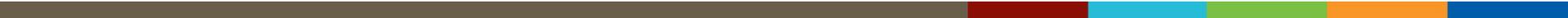
- Limited data to develop an IDLH
- Peracetic acid is crucial for infectious agent control in food supply (poultry processing) and hospitals

# NIOSH Project To Develop an IDLH\* For Peracetic Acid



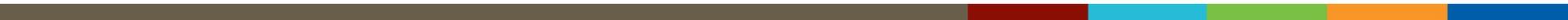
\*IDLH: Immediately Dangerous to Life and Health

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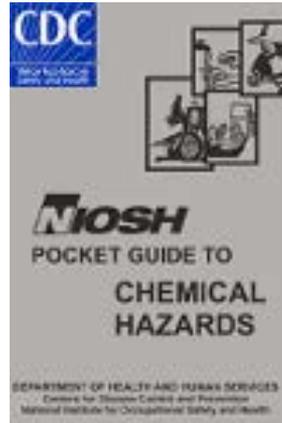
# NIOSH Pocket Guide and NIOSH Manual of Analytic Methods

- Two of NIOSH's most influential publications

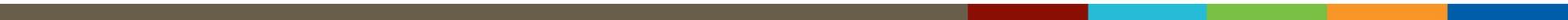


# NIOSH Pocket Guide

- Since 1974



# NIOSH Manual of Analytic Methods





## The National Institute for Occupational Safety and Health (NIOSH)

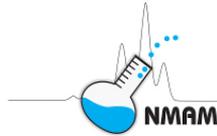
NIOSH



Promoting productive workplaces  
through safety and health research



# NIOSH Manual of Analytical Methods (NMAM) 5th Edition



NMAM is a collection of methods for sampling and analysis of contaminants in workplace air, surfaces, and in the blood and urine of workers who are occupationally exposed. These methods have been developed or adapted by NIOSH or its partners and have been evaluated according to established experimental protocols and performance criteria. NMAM also includes chapters on quality assurance, sampling, portable instrumentation, etc.

NIOSH recommends that the best method available be used for making each measurement. Methods published by others, such as [OSHA](#), [MSHA](#), [EPA](#), [ASTM](#), [ISO](#) or commercial suppliers of sampling and analytical equipment, may have advantages over NIOSH methods for a given sampling situation. (An Industrial Hygienist should determine the sampling protocol, considering analytical accuracy, cost, and optimum sample number.) Every method should undergo an initial evaluation to demonstrate performance. When a method is used in a laboratory that did not perform the initial evaluation, that laboratory should verify that comparable results can be obtained. NIOSH methods may need to be modified, and if modified, should be re-evaluated. Various [OSHA regulations](#) (e.g. benzene) mention performance criteria for evaluating whatever method is

**Newly Released:**  
**NIOSH Method 8320**

NIOSH 8320 is a sampling and analytical method for butyltin trichloride in urine.

[PDF - 375 KB]

Introduction to the NIOSH Manual of Analytical Methods Fifth edi... Share

STATE OF THE HEALTH EQUITY FORUM  
AUDITORIUM-A  
TOM HARKIN GLOBAL COMMUNICATIONS CENTER  
31 JANUARY 2019  
Part 1 of 4

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# NIOSH issues approvals for chemical and particulate hazards

- NIOSH evaluates some applications for Chemical Hazards
  - Ammonia (AM)
  - Chlorine (CL)
  - Chlorine Dioxide (CD)
  - Chloroacetophenone (CN)
  - Chlorobenzylidene Malononitril (CS)
  - Sulfur Dioxide (SD)
  - Formaldehyde (FM)
  - Hydrogen Chloride (HC)
  - Hydrogen Sulfide (HS)
  - Hydrogen Fluoride (HF)
  - Methylamine (MA)
  - Organic Vapors (OV)
  - Phosphine (PH)
  - CBRN
  - Others as requested



# NIOSH Hazard Assessment for CBRN Respiratory Protection

- NIOSH uses 11 test representative agents (TRAs) from 7 Chemical Families to evaluate Chemical, Biological, Radiological, and Nuclear air-purifying respirators (CBRN APRs)
- NIOSH periodically evaluates emerging CBRN threats—informed by intelligence agencies—to ensure current TRAs/Chemical Families remain representative of potential CBRN threats so that CBRN APRs remain protective for emergency responders
- CBRN Hazard Assessment completed in 2018—partnered with DoD and DHS
  - 204 chemicals and 46 radioisotopes evaluated against NIOSH’s current TRAs
  - Example evaluation criteria: chemical/physical properties and anticipated canister filtration behavior
  - 6 chemicals tested against 6 different NIOSH-approved CBRN canister models
  - **2018 Hazard Assessment conclusion: NIOSH’s current TRAs and Chemical Families remain representative of all identified CBRN threats; no change to NIOSH CBRN APR standard at this time.**

# Current NIOSH Risk Assessment and Management Activities for Respiratory Protection – NIOSH Pocket Guide

- Respirator recommendations for chemicals
- Based on
  - Assigned protection factors
  - Immediately dangerous to life or health
  - NIOSH Carcinogen Policy
  - NIOSH REL
  - NIOSH Selection Logic

## Silica, crystalline (as respirable dust)

### Respirator Recommendations

#### NIOSH

##### Up to 0.5 mg/m<sup>3</sup>:

(APF = 10) Any particulate respirator equipped with an N95, R95, or P95 filter (including N95, R95, and P95 filtering facepieces) except quarter-mask respirators. The following filters may also be used: N99, R99, P99, N100, R100, P100. [Click here](#) for information on selection of N, R, or P filters.

##### Up to 1.25 mg/m<sup>3</sup>:

(APF = 25) Any powered, air-purifying respirator with a high-efficiency particulate filter.  
(APF = 25) Any supplied-air respirator operated in a continuous-flow mode

##### Up to 2.5 mg/m<sup>3</sup>:

(APF = 50) Any air-purifying, full-facepiece respirator with an N100, R100, or P100 filter.  
[Click here](#) for information on selection of N, R, or P filters.

(APF = 50) Any powered, air-purifying respirator with a tight-fitting facepiece and a high-efficiency particulate filter

##### Up to 25 mg/m<sup>3</sup>:

(APF = 1000) Any supplied-air respirator operated in a pressure-demand or other positive-pressure mode

##### Emergency or planned entry into unknown concentrations or IDLH conditions:

(APF = 10,000) Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode

(APF = 10,000) Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained positive-pressure breathing apparatus

##### Escape:

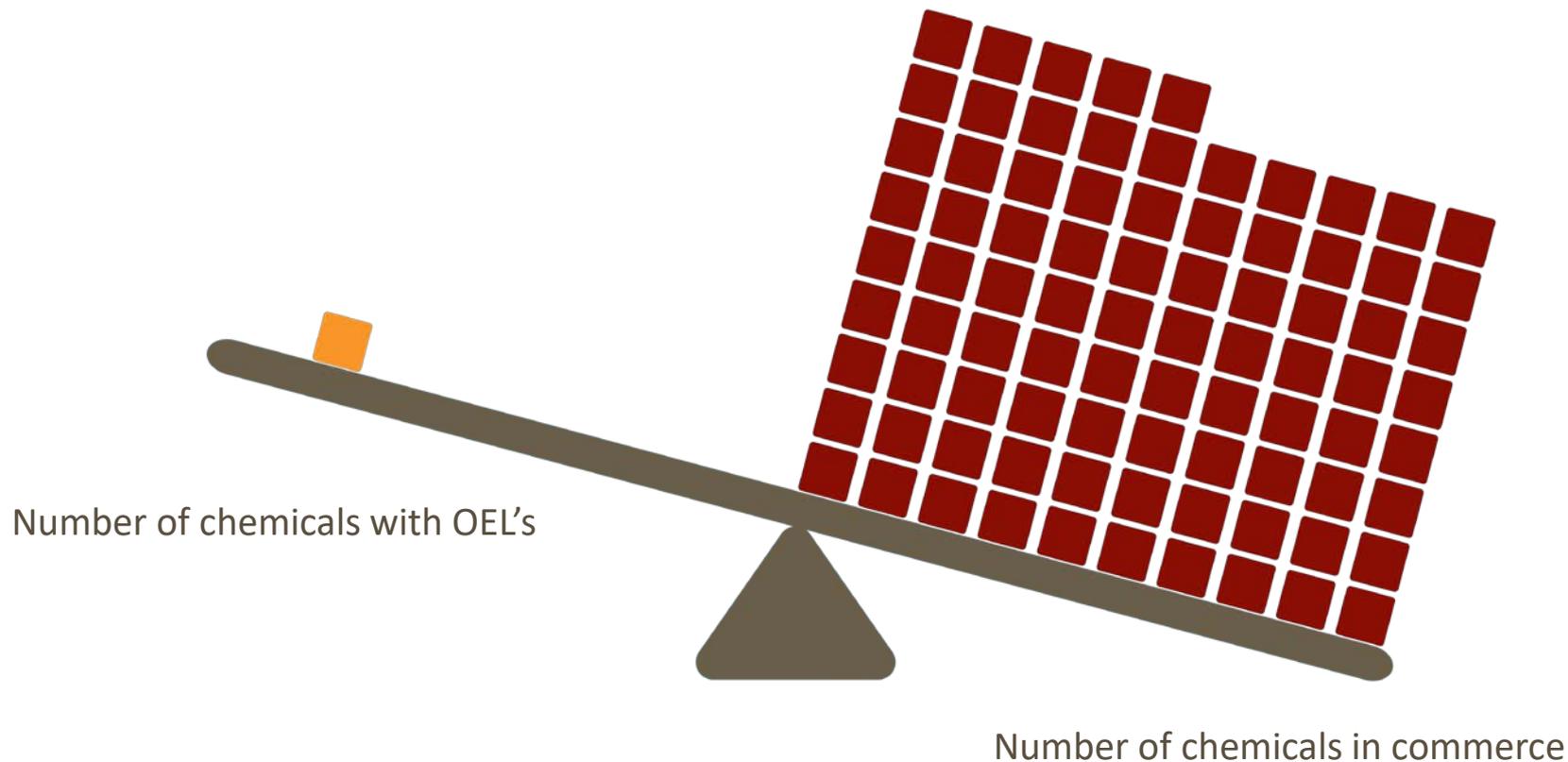
(APF = 50) Any air-purifying, full-facepiece respirator with an N100, R100, or P100 filter.  
[Click here](#) for information on selection of N, R, or P filters.

Any appropriate escape-type, self-contained breathing apparatus

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# Few chemicals have occupational exposure limits (OELs)



# Occupational Exposure Banding

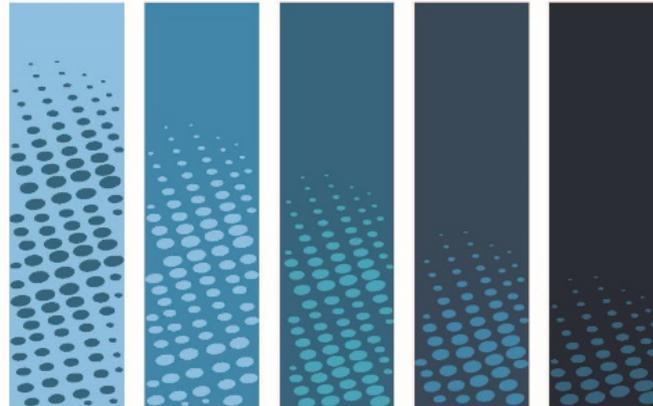
## Document Objective

To create a consistent and documented process to characterize chemical hazards so timely and well-informed risk management decisions can be made for chemicals lacking OELs.



## CURRENT INTELLIGENCE BULLETIN 69

# The NIOSH Occupational Exposure Banding Process for Chemical Risk Management



Centers for Disease Control  
and Prevention  
National Institute for Occupational  
Safety and Health

# What is Occupational Exposure Banding?

A mechanism to quickly and accurately assign chemicals into “categories” or “bands” based on their health outcomes and potency considerations



Higher Concentrations

Lower Concentrations

# Proposed NIOSH Occupational Exposure Bands

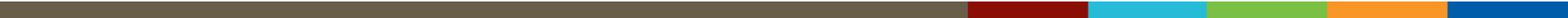
Occupational Exposure Band	Airborne Target Range for Particulate Concentration (mg/m <sup>3</sup> )	Airborne Target Range for Gas or Vapor Concentration (ppm)
A	>10mg/m <sup>3</sup>	>100 ppm
B	>1 to 10 mg/m <sup>3</sup>	>10 to 100 ppm
C	>0.1 to 1 mg/m <sup>3</sup>	>1 to 10 ppm
D	>0.01 to 0.1 mg/m <sup>3</sup>	>0.1 to 1 ppm
E	≤0.01 mg/m <sup>3</sup>	≤0.1 ppm

# IMPORTANT POINT

An OEB is not meant to replace an OEL, rather it serves as a starting point to inform risk management decisions.



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  - Exposome/Cumulative Risk Assessment
  - Collaboration on TSCA
  - Hazardous Drugs List
- 

# Prevention through Design

- Design out hazards
- Includes designing out chemical hazards



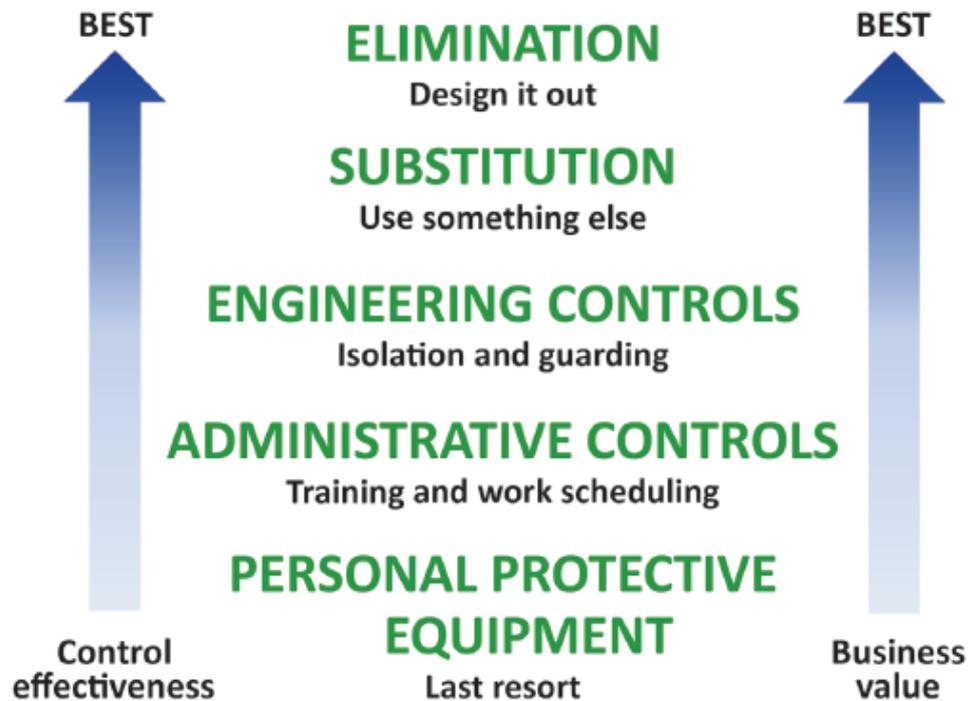
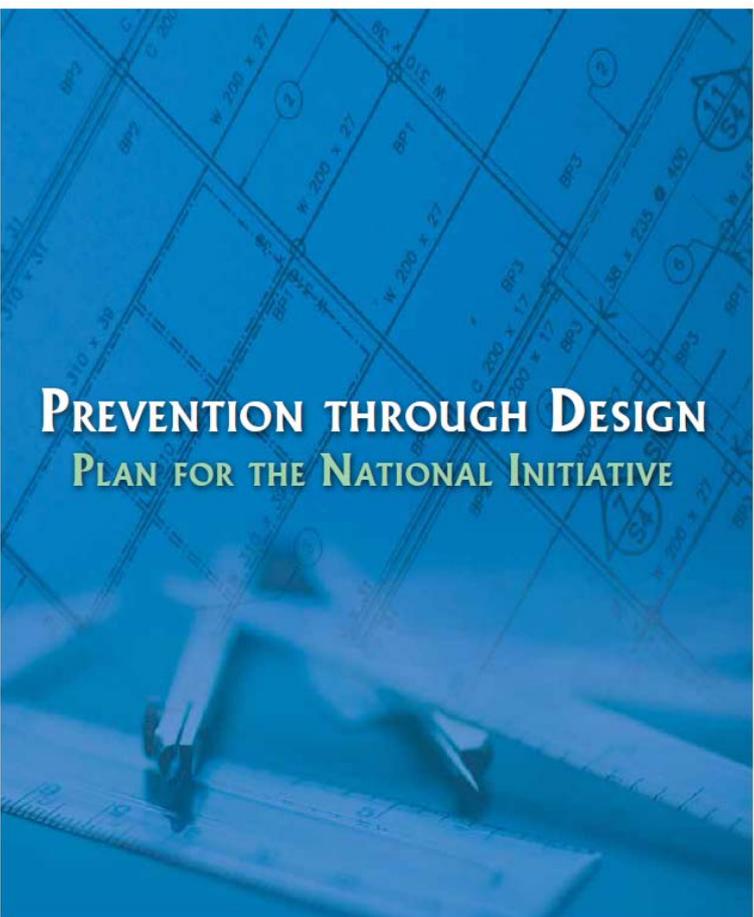


Figure 1. Prevention through Design using hierarchy of controls [Peterson 1973].



# PREVENTION THROUGH DESIGN

## PLAN FOR THE NATIONAL INITIATIVE

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



**NIOSH**



# The State of the National Initiative on Prevention through Design



PROGRESS REPORT 2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



# Examples of designing out chemical hazards

- Highway Asphalt paver fume control
- Asphalt warm-mix
- Interagency Chemical Alternative Assessment
- Molecule to market (nanoparticle examples)
- Altered chemistry of ceramic fibers



# ENGINEERING CONTROL GUIDELINES FOR HOT MIX ASPHALT PAVERS



## PART 1 New Highway-Class Pavers



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health



## Summary of the Making Green Jobs Safe Workshop

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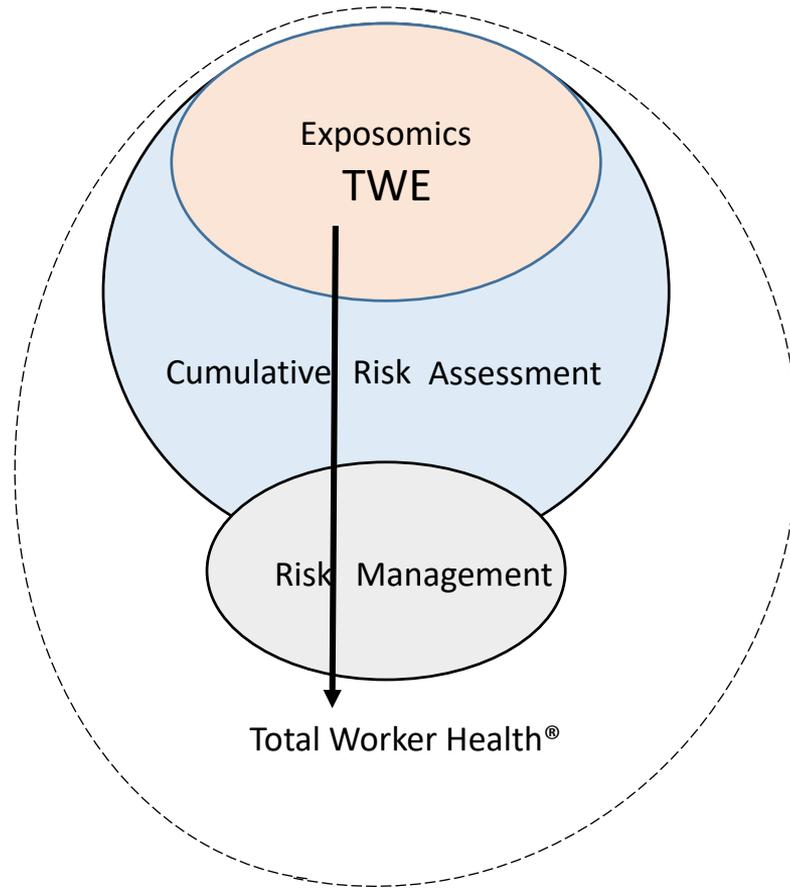
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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

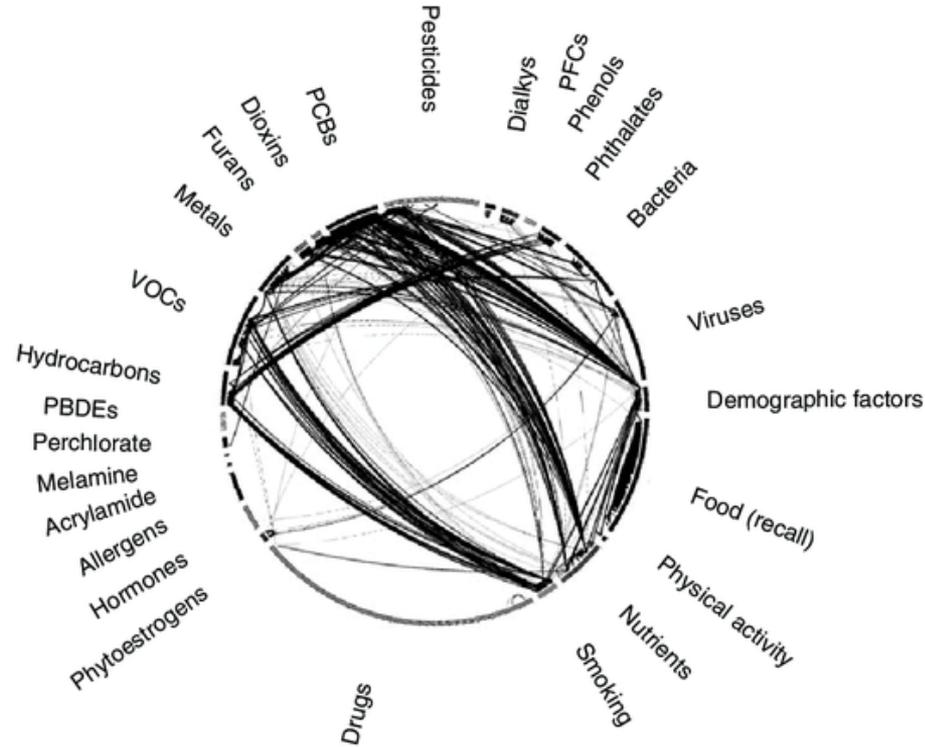
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- 

# Overview of holistic approaches to protect workers

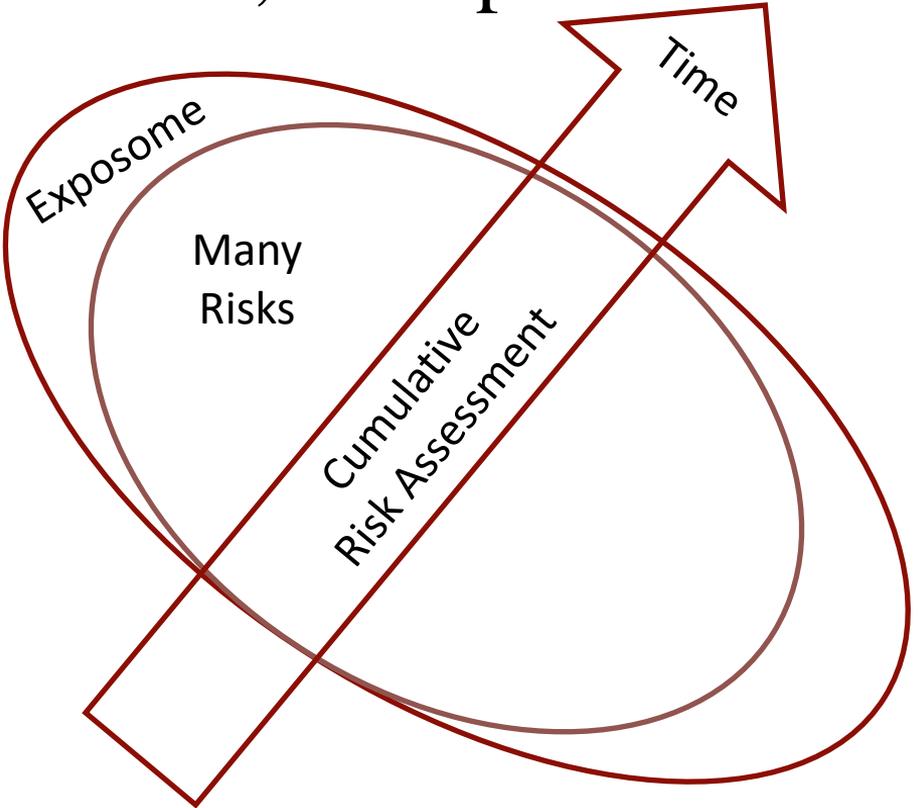


# Example of an overall exposome correlation globe



(Adapted from Patel and Manrai, 2015)

# Exposome/Cumulative Risk Assessment: multiple risks, multiple times



## Aggregate Exposure and Cumulative Risk Assessment—Integrating Occupational and Non-occupational Risk Factors

T. J. Lentz,<sup>1</sup> G. S. Dotson,<sup>1</sup> P. R. D. Williams,<sup>2</sup> A. Maler,<sup>3</sup> B. Gadagbul,<sup>4</sup>  
S. P. Pandai,<sup>1</sup> A. Lamba,<sup>5</sup> F. Hearl,<sup>6</sup> and M. Mumtaz<sup>7</sup>

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<sup>2</sup>E Risk Sciences, LLP, Boulder, Colorado

<sup>3</sup>Department of Environmental Health, University of Cincinnati College of Medicine, Cincinnati, Ohio

<sup>4</sup>Toxicology Excellence for Risk Assessment, Cincinnati, Ohio

<sup>5</sup>Office of Pollution Prevention and Toxics, Environmental Protection Agency, Washington, DC

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<sup>7</sup>Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Atlanta, Georgia

*Occupational exposure limits have traditionally focused on preventing morbidity and mortality arising from inhalation exposures to individual chemical stressors in the workplace. While central to occupational risk assessment, occupational exposure limits have limited application as a refined disease prevention tool because they do not account for all of the complexities of the work and non-occupational environments and are based on varying health endpoints. To be of greater utility, occupational exposure limits and other risk management tools could integrate broader consideration of risks from multiple exposure pathways and routes (aggregate risk) as well as the combined risk from exposure to both chemical and non-chemical stressors, within and beyond the workplace, including the possibility that such exposures may cause interactions or modify the toxic effects observed (cumulative risk). Although still at a rudimentary stage in many cases, a variety of methods and tools have been developed or are being used in allied risk assessment fields to incorporate such considerations in the risk assessment process. These approaches, which are collectively referred to as cumulative risk assessment, have potential to be adapted or modified for occupational scenarios and provide a tangible path forward for occupational risk assessment. Accounting for complex exposures in the workplace and the broader risks faced by the individual also requires a more complete consideration of the composite effects of occupational and non-occupational risk factors to fully assess and manage worker health problems. Barriers to integrating these different factors remain, but new and ongoing community-based and worker health-related initiatives may provide mechanisms for identifying and integrating risk from aggregate exposures and cumulative risks from all relevant sources, be they occupational or non-occupational.*

**Keywords** aggregate exposure, cumulative risk, occupational

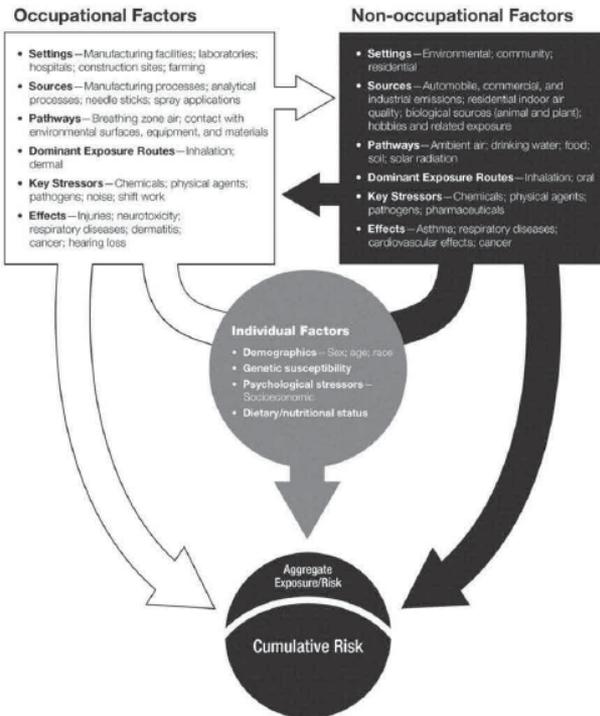
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### INTRODUCTION

Occupational exposure limits (OELs) have traditionally focused on preventing morbidity and mortality arising from inhalation exposures to individual chemical stressors in the workplace. While there are other strategies for pursuing or promoting risk prevention and avoidance of occupational hazards, many of which enhance effectiveness when used in conjunction with OELs, the theme of this manuscript and its accompanying manuscripts pertains specifically to the establishment of OELs and the potential for incorporating new science into this practice. The basis and impetus for OELs



**FIGURE 2.** Illustration of the relationship between key factors considered in cumulative risk assessment. This figure illustrates key risk factors that may contribute to aggregate and cumulative risk. The primary factors are organized into three categories: (1) occupational factors, (2) non-occupational factors, and (3) individual factors. For each category, examples of the primary settings, sources of risk, exposure routes, key stressors, and effects are included to aid in illustrating considerations that should be included in assessing aggregate and cumulative risk to various hazards.

uncertainties associated with the assessment are described, and estimates of cumulative risk are interpreted in the context of their significance, reliability, and overall confidence. Various approaches are available for addressing the variability and uncertainty in risk estimates including sensitivity analyses and one-dimensional and two-dimensional stochastic analyses such as with Monte Carlo simulation.

With respect to the second phase of cumulative risk assessment, several techniques have been developed to examine environmental and occupational exposures. Three of the more common techniques are (1) exposure monitoring, (2) exposure modeling, and (3) biomonitoring. These methods are intended to provide estimates of the external exposure concentration to which the target population has been exposed or to provide

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- **Collaboration on TSCA**
- Hazardous Drugs List

# Frank Lautenberg Chemical Safety Act (LCSA) for the 21<sup>st</sup> Century

- Signed into law June 22, 2016
- Makes significant changes to the Toxic Substance Control Act (TSCA)
- EPA requested NIOSH assistance
- Workers are identified as a “susceptible population.”

H. R. 2576

One Hundred Fourteenth Congress  
of the  
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,  
the fourth day of January, two thousand and sixteen*

An Act

To modernize the Toxic Substances Control Act, and for other purposes.

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “Frank R. Lautenberg Chemical Safety for the 21st Century Act”.

(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

**TITLE I—CHEMICAL SAFETY**

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Manufacturing and processing notices.

Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Exports of elemental mercury.

Sec. 11. Confidential information.

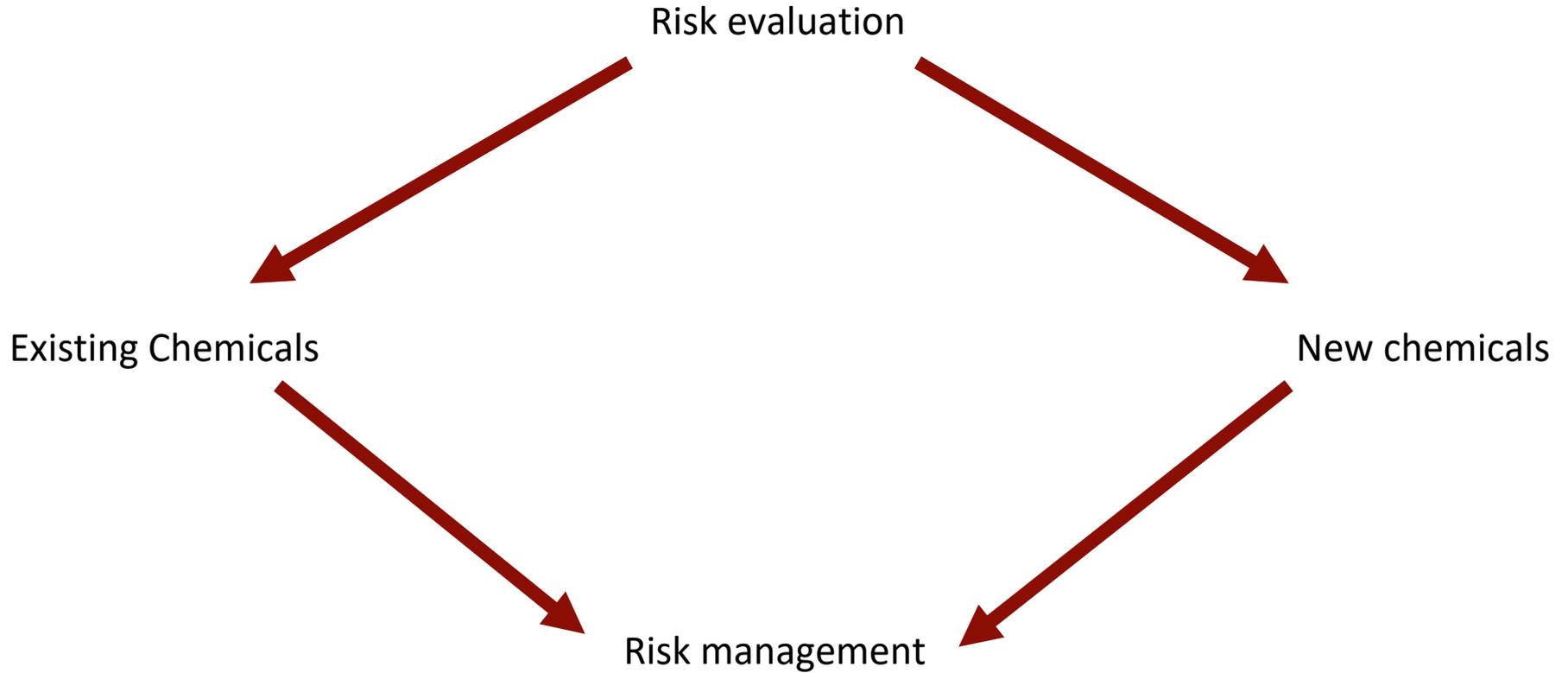
Sec. 12. Penalties.

Sec. 13. State-Federal relationship.

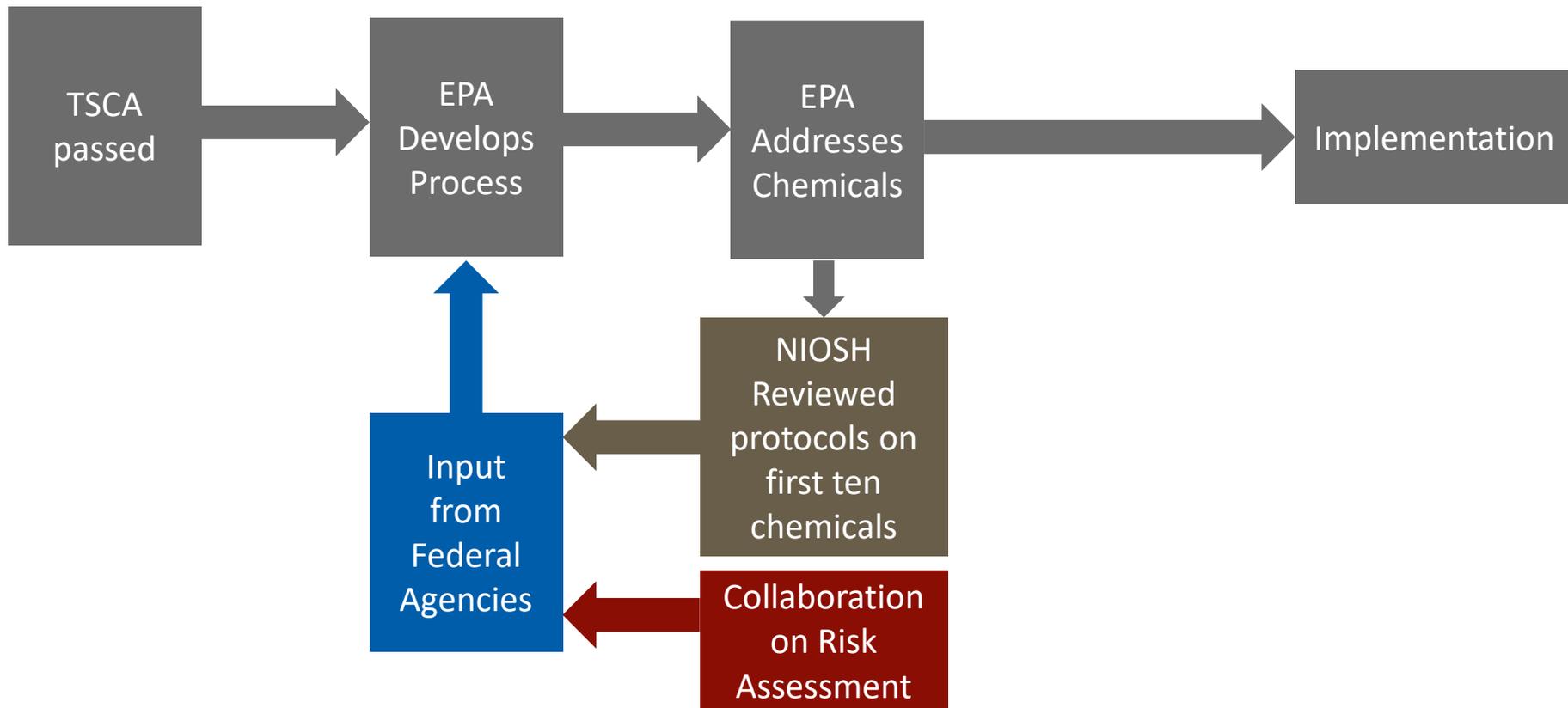
Sec. 14. Judicial review.

Sec. 15. Citizens' civil actions.

# New TSCA Approach



# NIOSH Support of EPA in Implementing the Toxic Substances Control Act



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# Exposure of workers exposed to hazardous drugs

- Approximately 8 million workers are potentially exposed to hazardous medications in the course of their work
- Exposure may be via inhalation or through direct contact with contaminated sources.

National Institute for Occupational Safety and Health. Medical surveillance for healthcare workers exposed to hazardous drugs, (DHHS (NIOSH) Publication No. 2013-103). Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. Retrieved from <http://www.cdc.gov/niosh/docs/wpsolutions/2013-103/pdfs/2013-103.pdf>

# Hazardous Drugs in Healthcare



Healthcare  
Workers

+



Handling  
Hazardous Drugs



Cancer  
Reproductive Health Effects  
Others

# Managing the risk of handling hazardous drugs

- Policies and Procedures for Developing the NIOSH List of Antineoplastic and other Hazardous Drugs in Healthcare Settings
- NIOSH list of Antineoplastic and other Hazardous Drugs in Health Care Settings, 2018 (Since 2004)
- Table 5, risk management guidance
- Broad partnership with various agencies and organizations

# Questions for Board of Scientific Counselors

- What chemical guidance priorities should NIOSH focus on?
- Should NIOSH enhance its chemical guidance efforts?
- What areas of chemical hazards is NIOSH not focusing on but should consider?

# Acknowledgments

- Kathleen MacMahon
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