UNDER CONSTRUCTION:

The Many Roads to Policy

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The Road Ahead

- Background: Framing the Conversation
  - Problem Definition
  - Policy Options
- Claims Making: Soft Law vs. Hard Law
- Iterative Regulation: An Alternate Construction

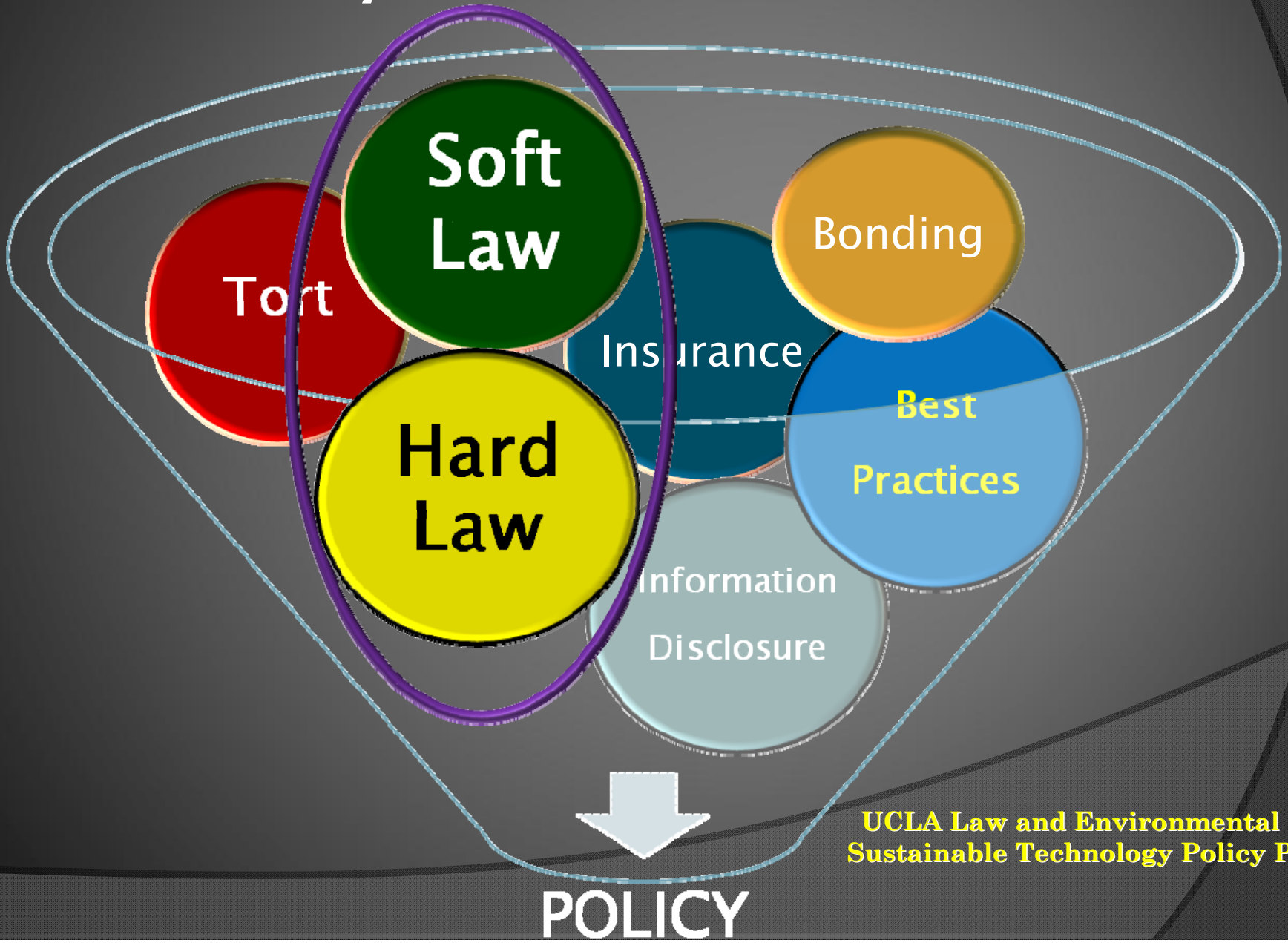
The Challenge

Development and deployment of an emerging technology

Negative public health and environmental impacts

All while operating under conditions of uncertainty

The State of the Discourse: The Policy Milieu



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The State of the Discourse: The Competing Claims

- Social Problems Theory
  - Claims-making
- Political Science Theory
  - Policy Streams and Policy Entrepreneurs

Problem Attributes:

- Impacts Many
- Lack of Timely
- Limited Gov't
- Speed of Development & Deployment

Constructing the Soft Law Narrative

- Business can effectively manage these concerns in the near to medium term
  - Hard law is impractical and unnecessary
- Driven by Two Sets of Claims
  - Incentives and Capacity of Business
  - Nature of Regulation

The Business Narrative: Incentives

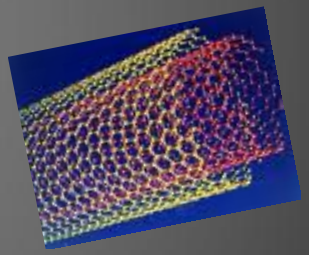
- Industry has strong incentives to adopt safe practices
  - Fear of Liability
  - Fear of Technology Stigma
  - The "Good Neighbor" Norm

Types of Incentive Slippage

- Calculated Slippage: Rational Actor in Action
  - Conflicting Norms/Incentives
- Routine Slippage: Coordination Mechanisms
  - Information Flow
  - Resource Allocation
  - Allocation of Authority
- Cognitive Slippage: Norm Activation Barriers
  - Defensive Denial
  - Norm Neutralization

The Business Narrative: Capacity

- Businesses are in the best position to respond to concerns
  - Businesses are agile, responding efficiently to changing conditions.
  - Businesses have explicit and tacit operation-specific knowledge
  - Businesses act effectively through trade associations and strategic alliances



The Regulatory Narrative

- Conventional Regulation Structure:
  - Rigid, top-down, one-size-fits-all approach

- Conventional Regulation Mechanisms:
  - Relies upon prescriptive "acceptable" exposure levels
  - Information and methodological gaps are barriers to its use.

The Regulatory Narrative: Structure

- Conventional regulation almost uniformly relies upon performance standards
- Conventional regulation tends to look to best technology/best practices
- Conventional regulation—in design and implementation—accounts for diversity

The Regulatory Narrative: Mechanisms

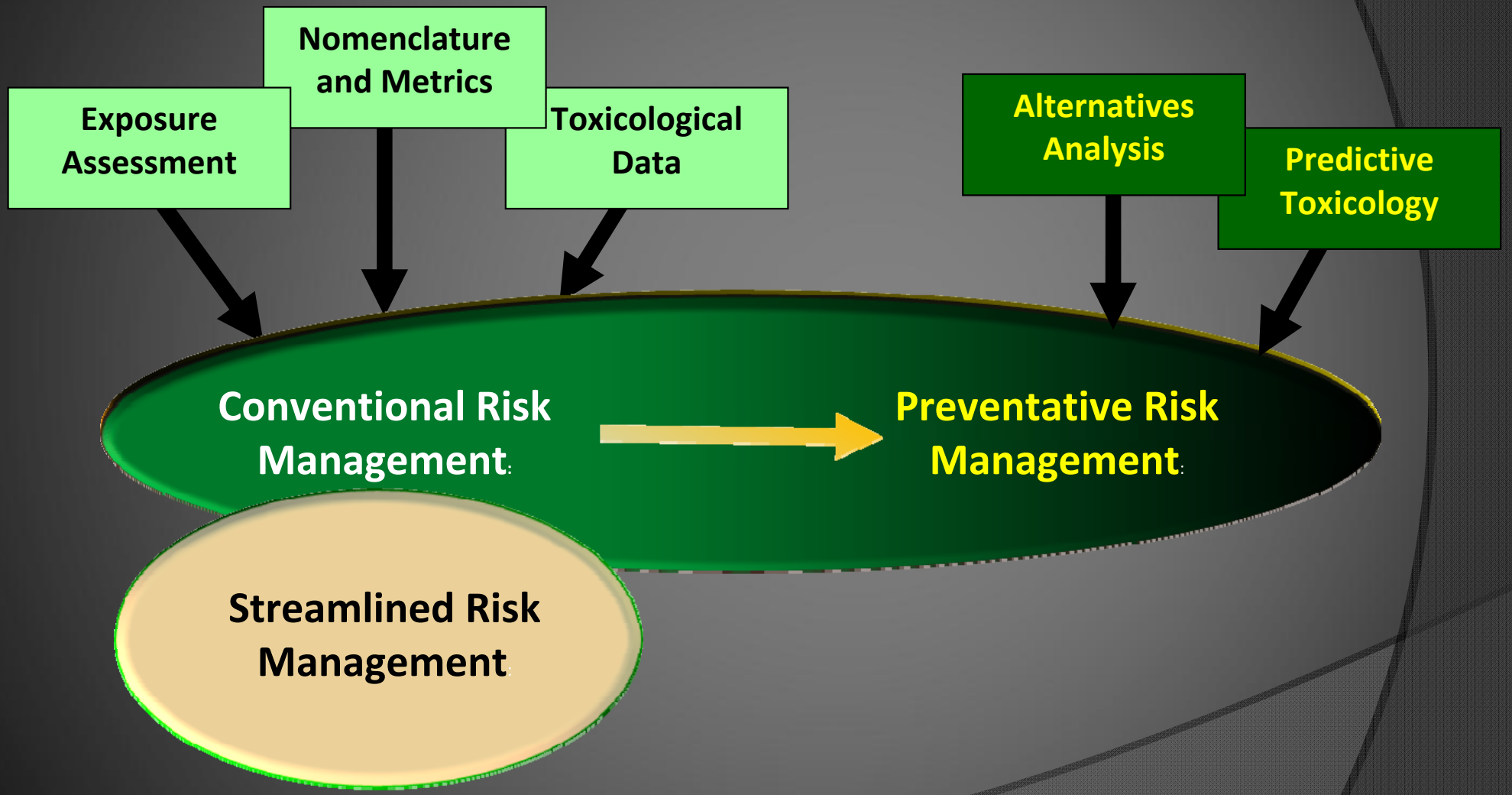
- Conventional Regulation does often set acceptable exposure levels

- Yet conventional regulation is a substantially broader umbrella
  - Information-based regulation
  - Management-based regulation
  - Qualitative risk management

Government Roles & Capacities

- Information Collection/Dissemination
- Coordination of Conflicting Approaches
- Quality Control and Enforcement
- Standard setting

Interative Regulation: Conceptual Model



Iterative Regulation: Streamlined Risk Management

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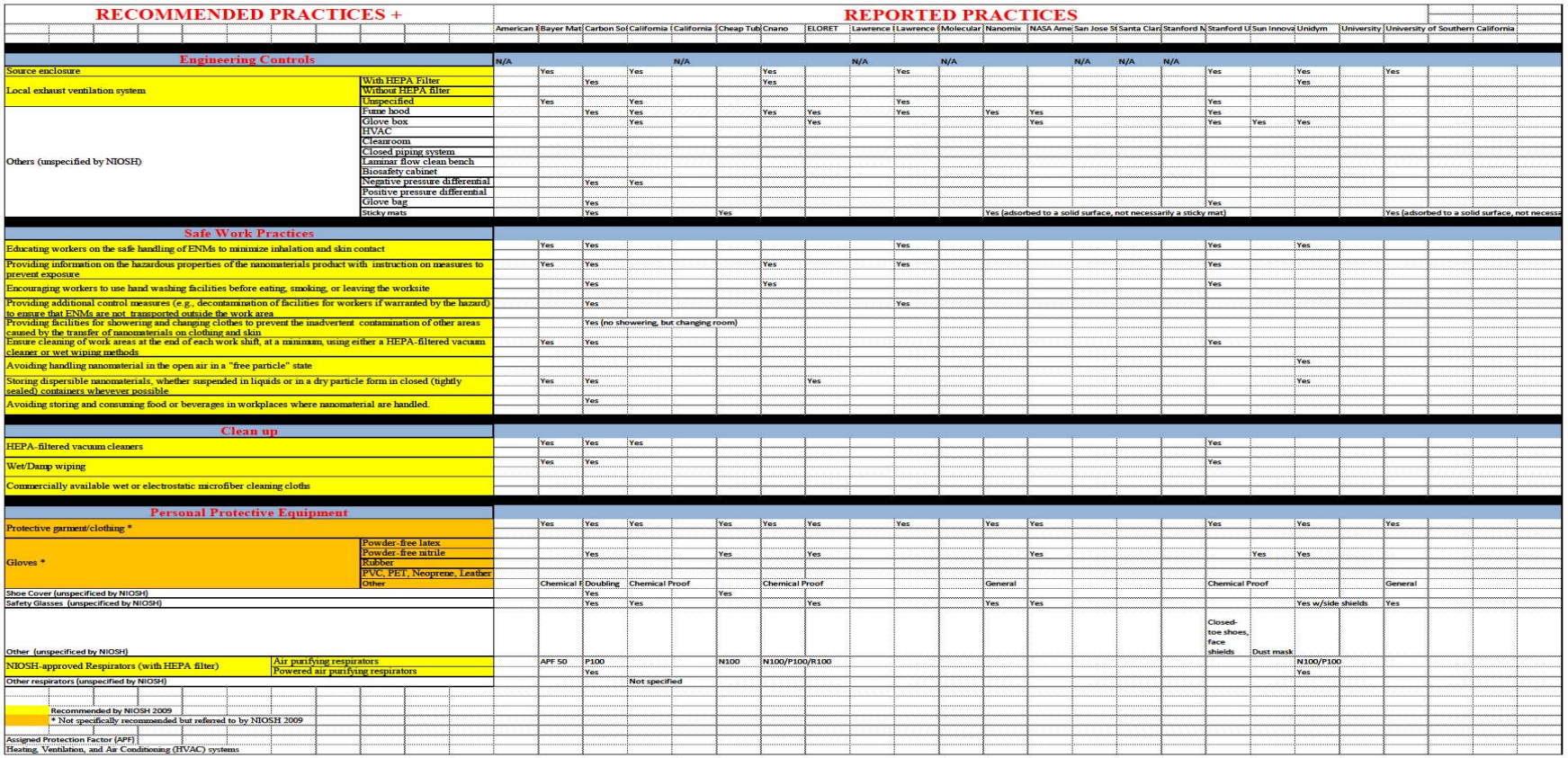
Best Practices?



RECOMMENDED PRACTICES +		REPORTED PRACTICES																				
		American E	Bayer Mat	Carbon So	California	California	Cheap Tub	Cnano	ELORET	Lawrence	Lawrence	Molecular	Nanomix	NASA Ame	San Jose St	Santa Clar	Stanford N	Stanford U	Sun Innova	Unidym	University	University of Southern California
Engineering Controls		N/A				N/A				N/A		N/A			N/A	N/A	N/A					
Source enclosure			Yes		Yes			Yes			Yes							Yes		Yes		Yes
Local exhaust ventilation system	With HEPA Filter			Yes				Yes												Yes		
	Without HEPA filter																					
	Unspecified		Yes		Yes						Yes							Yes				
Others (unspecified by NIOSH)	Fume hood			Yes	Yes			Yes	Yes		Yes		Yes	Yes				Yes				
	Glove box				Yes				Yes					Yes				Yes	Yes	Yes		
	HVAC																					
	Cleanroom																					
	Closed piping system																					
	Laminar flow clean bench																					
	Biosafety cabinet																					
	Negative pressure differential			Yes	Yes																	
	Positive pressure differential																					
	Glove bag			Yes														Yes				
	Sticky mats			Yes			Yes						Yes (adsorbed to a solid surface, not necessarily a sticky mat)									Yes (adsorbed to a solid surface, not necessa
Safe Work Practices																						
Educating workers on the safe handling of ENMs to minimize inhalation and skin contact			Yes	Yes							Yes							Yes		Yes		
Providing information on the hazardous properties of the nanomaterials product with instruction on measures to prevent exposure			Yes	Yes				Yes			Yes							Yes				
Encouraging workers to use hand washing facilities before eating, smoking, or leaving the worksite				Yes				Yes										Yes				
Providing additional control measures (e.g., decontamination of facilities for workers if warranted by the hazard) to ensure that ENMs are not transported outside the work area				Yes							Yes											
Providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas caused by the transfer of nanomaterials on clothing and skin				Yes (no showering, but changing room)																		
Ensure cleaning of work areas at the end of each work shift, at a minimum, using either a HEPA-filtered vacuum cleaner or wet wiping methods			Yes	Yes														Yes				
Avoiding handling nanomaterial in the open air in a "free particle" state																				Yes		
Storing dispersible nanomaterials, whether suspended in liquids or in a dry particle form in closed (tightly sealed) containers whevever possible			Yes	Yes					Yes											Yes		
Avoiding storing and consuming food or beverages in workplaces where nanomaterial are handled.				Yes																		
Clean up																						
HEPA-filtered vacuum cleaners			Yes	Yes	Yes													Yes				
Wet/Damp wiping			Yes	Yes														Yes				
Commercially available wet or electrostatic microfiber cleaning cloths																						
Personal Protective Equipment																						
Protective garment/clothing *			Yes	Yes	Yes		Yes	Yes	Yes		Yes		Yes	Yes				Yes		Yes		Yes
Gloves *	Powder-free latex																					
	Powder-free nitrile			Yes			Yes		Yes					Yes					Yes	Yes		
	Rubber																					
	PVC, PET, Neoprene, Leather																					
	Other		Chemical F	Doubling	Chemical Proof			Chemical Proof					General					Chemical Proof				General
Shoe Cover (unspecificed by NIOSH)				Yes			Yes															
Safety Glasses (unspecificed by NIOSH)				Yes	Yes				Yes				Yes	Yes						Yes w/side shields		Yes
Other (unspecificed by NIOSH)																		Closed-toe shoes, face shields	Dust mask			
NIOSH-approved Respirators (with HEPA filter)	Air purifying respirators		APF 50	P100			N100	N100/P100/R100												N100/P100		
	Powered air purifying respirators			Yes																Yes		
Other respirators (unspecified by NIOSH)					Not specified																	

Recommended by NIOSH 2009

* Not specifically recommended but referred to by NIOSH 2009

Assigned Protection Factor (APF)

Heating, Ventilation, and Air Conditioning (HVAC) systems