Nano Risk Management: Evolution of Guidance

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Environmental Defense Fund

DOE Nanoscale Science Research Centers Symposium:
Safe Handling of Engineered Nanoscale Materials
July 7, 2008
Argonne, IL

Key Elements for Nano Policy

- **Understand** potential uses
- **Identify** potential risks
- **Manage** potential risks
- **Communicate** to stakeholders

Nano Risk Management: Today's Objectives

- Explain the need
- Describe available guidance
- Discuss next steps

Environmental Defense Fund

Science Based

Bipartisan

Market Driven

Alliance Building

EDF Corporate Partnerships

McDonald's
citigroup
DUPONT
WAL★MART
SC Johnson
STARBUCKS COFFEE
GE
bp
Wegmans
Duke Energy
BON APPÉTIT
COMPASS GROUP
ABBOTT
Entergy
PINEHURST 1895
ROBERT MONDAVI
PHH
ALCOA
CATERPILLAR
INTERNATIONAL PAPER
ups
Bristol-Myers Squibb
FedEx Express
Norm Thompson
escape from the ordinary

Nano's Potential …

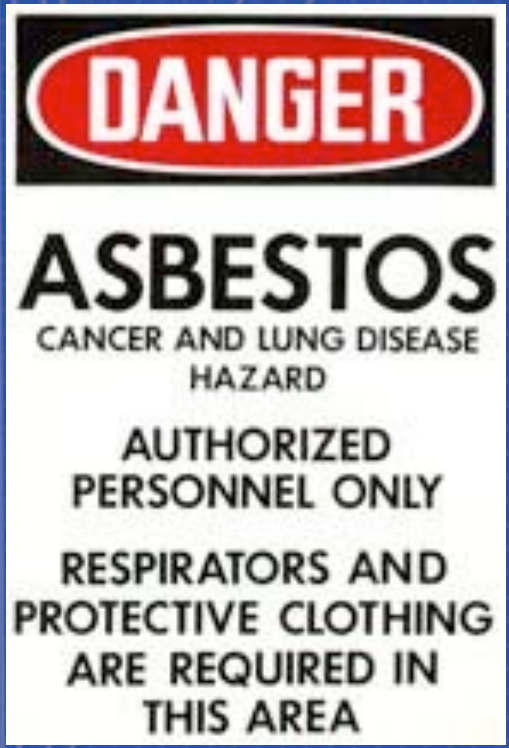
Benefits

- Clean Energy?
- Improved Materials?
- Waste Cleanup?
- Water Filtration?
- Advanced Medicines?

Risks

- Mobile?
- Reactive?
- Persistent?
- Unpredictable?

Situations to Avoid



External Pressures

NGOs

- Reports
- Campaigns
- Resolutions

Businesses

- Manufacturing
- Retail
- Insurance

Government Responses

Federal

- EPA
- FDA
- DOE
- NIOSH

State

- ?

International

- OECD
- UK, Australia, Germany …

Local

- Berkeley
- Cambridge

Drivers for Nano Policies

- Attractive applications
- EHS uncertainties
- Potential liabilities
- External pressures
- Evolving policy

What should developers do?

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October 2006

Review of Safety Practices in the Nanotechnology Industry

Phase One Report: Current Knowledge and Practices Regarding Environmental Health and Safety in the Nanotechnology Workplace

Prepared for the International Council on Nanotechnology
by the University of California, Santa Barbara

Researchers: Gina Garritsen, Li-Chin Huang, Keith Killpack, Maria Mircheva, Joseph Conti

Advisors: Dr. Patricia Holden, PI; Dr. Magali Delmas, Co-PI; Dr. Barbara Herr Harthorn, Co-PI; Dr. Rich Appelbaum, Co-PI

Released: October 18, 2006

RICE

Evolving Standards

- NIOSH
- DOE
- EDF / DuPont
- ASTM
- BSI
- ISO

Other Codes and Principles

NanoSafe (Luna)

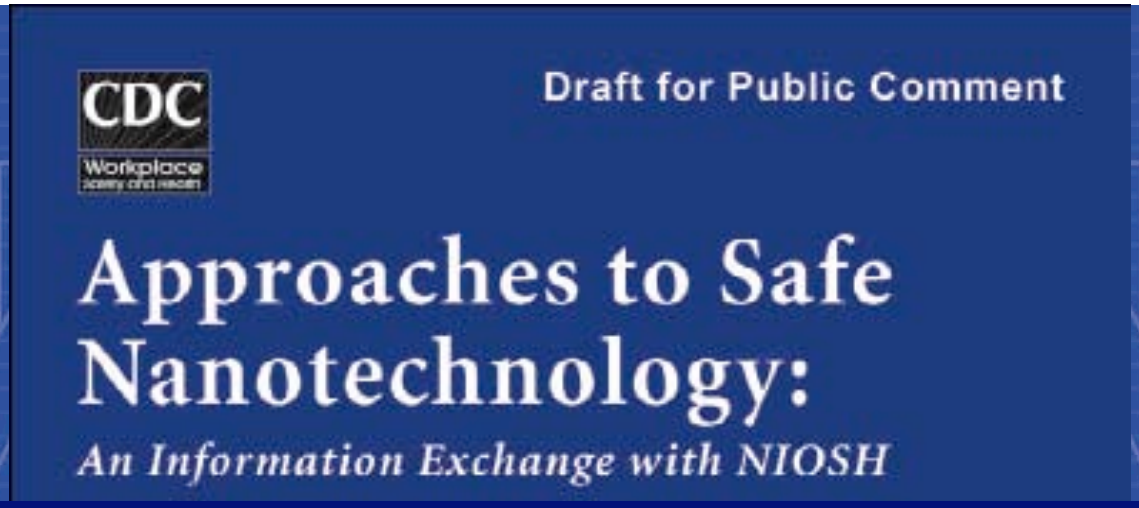
CENARIOS (Innovation Society)

Assured Nano (NanoCentral)

Principles for Responsible Nano (NGO coalition)

Responsible Nano Code (NIA)

November 2006



- **Controls needed given risks**
  - Hazards (health and safety)
  - Exposure
- **Risk management program recommended**
  - Hazards
  - Exposure
  - Training
  - Controls
  - Monitoring
- **Use best practices, but…**
  - No PPE guidelines available
  - No exposure limits established

June 2007

NSRC Revision 2. 6/15/07

Department of Energy

Nanoscale Science Research Centers

Approach to Nanomaterial ES&H

Revision 2 – June 2007

- **Risk management program needed**
  - Act responsibly in evaluating and controlling EHS risks
  - No specific guidance available…
  - … but some conventional practices may be effective
- **Cautious approach**
  - Treat "all new compounds, or those of unknown toxicity, as though they could be **acutely toxic** in the short run and **chronically toxic** in the long run."
- **Risk management program recommended**
  - Safety assessment
  - Match controls to properties
  - Communications
  - Monitoring
  - Response

June
2007

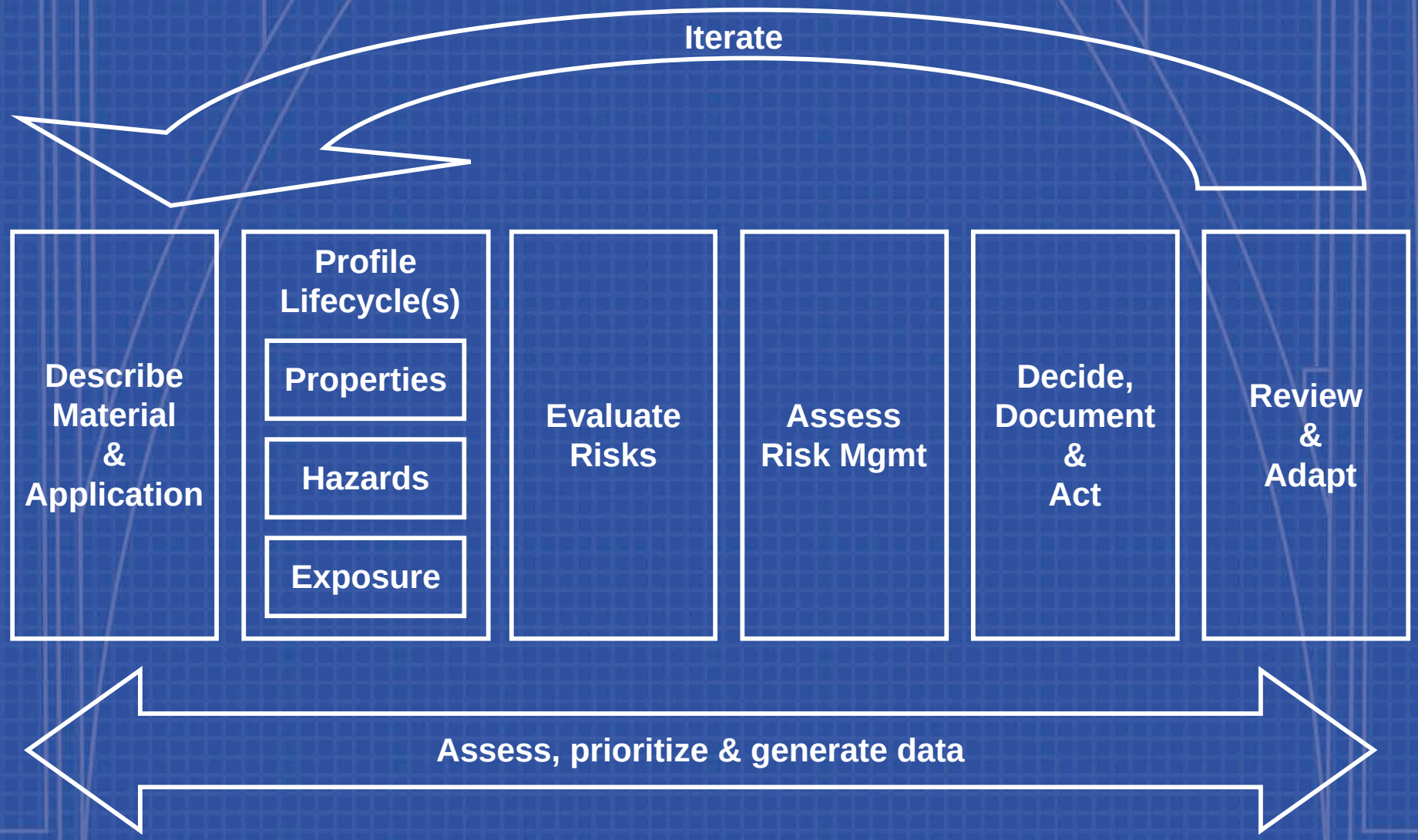
NANO
Risk Framework

- **Data-based risk assessment**
  - Lifecycle profiles of properties, hazards and exposure
  - Specific recommendations on type and amount of data needed
  - Options for addressing data gaps
- **Review and update**
  - Iterate throughout development process
  - Update based on new information or situations
- **Document information and actions**
  - Internal decision tool
  - External communications tool

DuPont
The miracles of science™

ENVIRONMENTAL DEFENSE
finding the ways that work

Nano Risk Framework



Output Worksheet

- Organize
- Record
- Share

OUTPUT WORKSHEET

An editable version of this Output Worksheet is available at www.NanoRiskFramework.com

Nanomaterial Risk Assessment Document — [nanomaterial]

Section 1: Describe Material and Its Applications
Develop basic descriptions — general overviews — of the nanoscale material and its intended uses.

General Overview: [a]

Material Description:
Material source or producer:
Manufacturing process:
Appearance:
Chemical composition:
Physical form/shape:
Concentration:
Size distribution:
Solubility:
State of aggregation or agglomeration:
Material CAS number (if applicable):

Material	CAS Number	Composition

Main applications (current or expected):

Stage of development:

General physical and mechanical properties of this material:

Past experience with this material or a similar material:

Potential benefits/positives of the material:

Potential risks/negatives of the material:
Health:
Environmental:

Sources of additional information:

[a] The general overview should contain descriptions sufficient to guide development of more detailed profiles of the material's properties related to hazard and exposure potential at various lifecycle stages (such as manufacture, use, and end-of-life). This overview should be developed from information in the possession of the user or available in the literature.

September
2007

- **Based on *The Control Principle***
  - "as a cautionary measure, occupational exposure to [unbound nanoparticles] should be minimized to levels that are **as low as reasonably practicable**."
- **Formal, written program with reviews and updates**
- **Assess and evaluate properties, hazards, exposure**
- **Specific guidance on controls and practices**
  - Controls: design, engineering, administrative, and PPE
  - Practices: maintenance, storage, transfer, cleanup, disposal
- **General guidance on medical surveillance, communication**

December 2007

PD 6699-2:2007

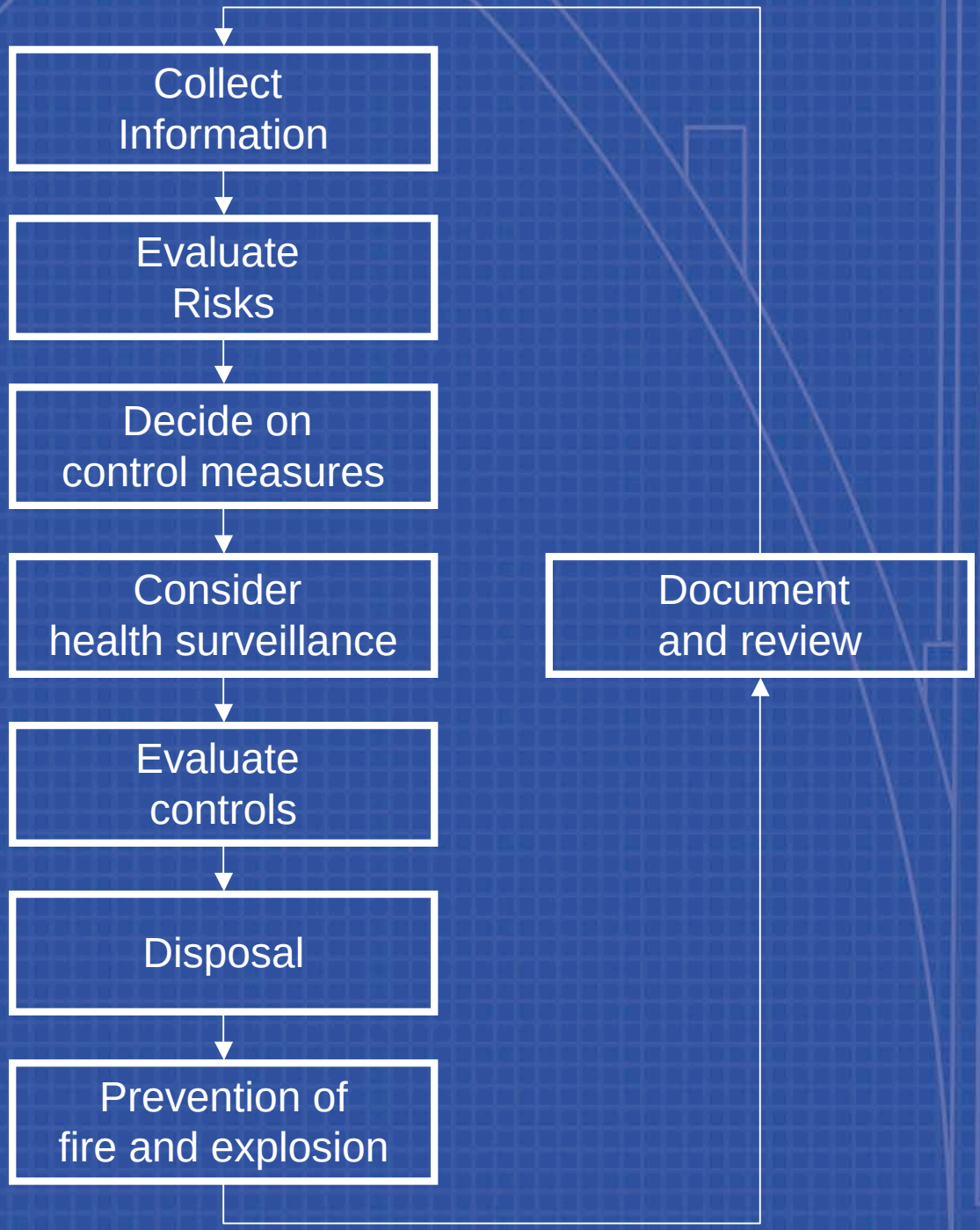
PUBLISHED DOCUMENT

Nanotechnologies –

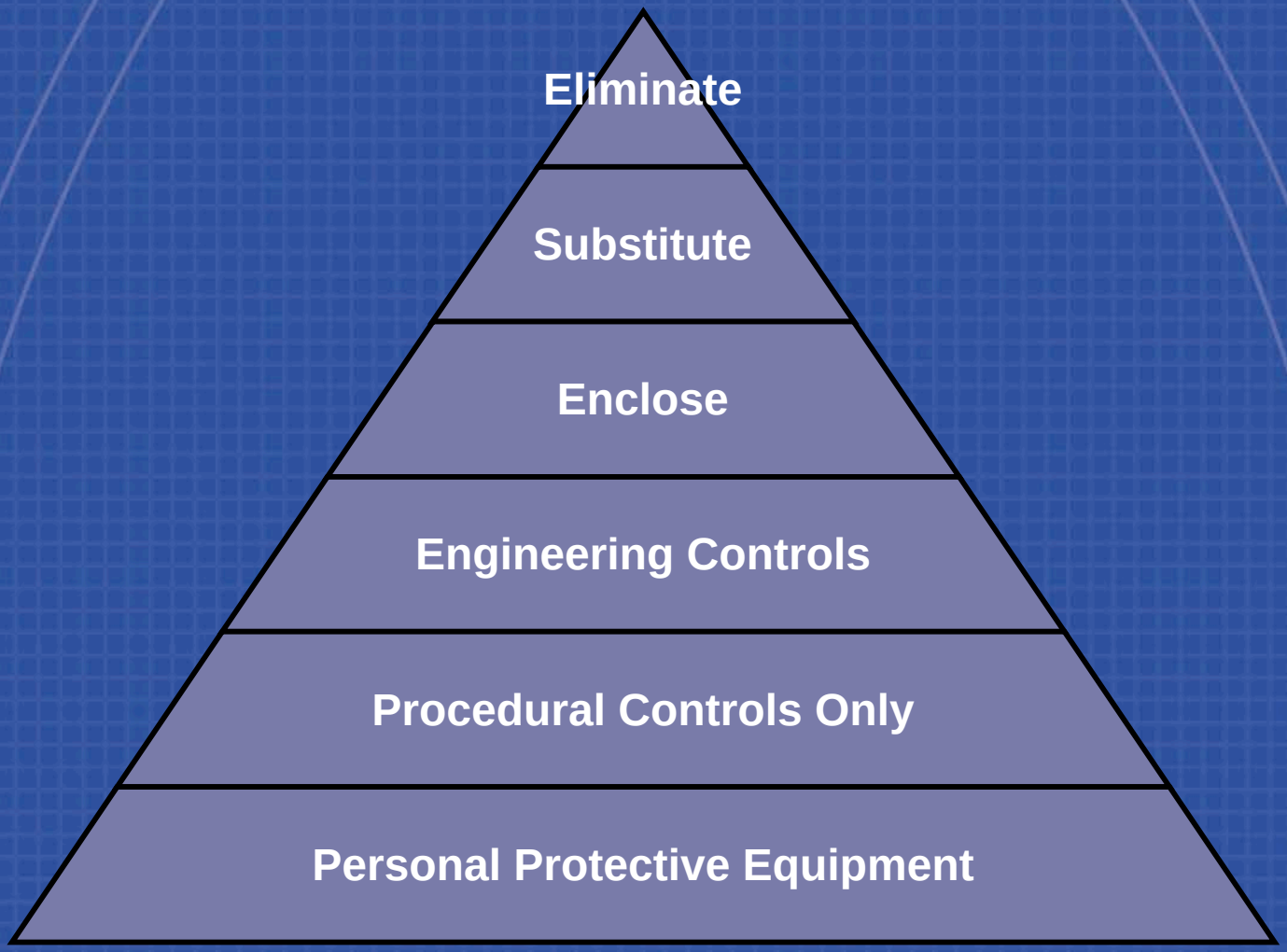
Part 2: Guide to safe handling and disposal of manufactured nanomaterials

- **Overall approach:**
  - Disciplined, information-driven process
  - Apply caution given uncertainty
  - Document and review
- **General suggestions:**
  - Questions on properties, hazards and exposure
  - Control strategies by material type (fibrous, CMAR, insoluble, soluble)
  - Exposure vs. health monitoring
- **Specific suggestions:**
  - Exposure limits by material type (fibrous, CMAR, insoluble, soluble)
  - Information for workers
  - Measurement devices and methods
  - Storage, cleanup and disposal procedures

Control of Substances Hazardous to Heath (COSHH)



Hierarchy of Control



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ISO

International Organization for Standardization

Nano Risk Framework in Practice

- Stewardship
- Supplier standards
- Risk evaluation
- Communication
- Decision making

Suggested Next Steps for DOE NSRC Guidance

- Enhance Assessment
  - Hazard
  - Use
- Enhance Communication
  - Upstream Inquiries
  - Downstream Instructions
  - Document Decisions
- Demonstrate in Practice

Key Elements for Nano Policy

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THANK YOU

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