

HUMAN &
ENVIRONMENTAL
EXPOSURE
ASSESSMENT OF
NANOMATERIALS

National
Nanotechnology
Initiative

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www.nano.gov/html/meetings/exposure



NNI EHS Strategy Development

- q Nanotechnology Environmental and Health Implications (NEHI) Working Group formed as informal body in 2003, formalized in 2005
- q Extraordinary collaboration between research and regulatory agencies
- q Began with review of respective agencies' jurisdictions, responsibilities
- q Industry and non-governmental organizations provided input throughout
- q Environmental, health, and safety research needs published in September 2006: http://www.nano.gov/NNI_EHS_research_needs.pdf
- q Public meeting held in January 2007 to gather additional input from research community and public
- q Interim document for public comment, "Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials" published in August 2007: http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf
- q First comprehensive NNI strategy document published in February 2008: http://www.nano.gov/NNI_EHS_Research_Strategy.pdf

The National Nanotechnology Initiative: EHS Strategy

Strategy for Nanotechnology-Related Environmental, Health, and Safety Research (February 2008):
www.nano.gov/NNI_EHS_Research_Strategy.pdf

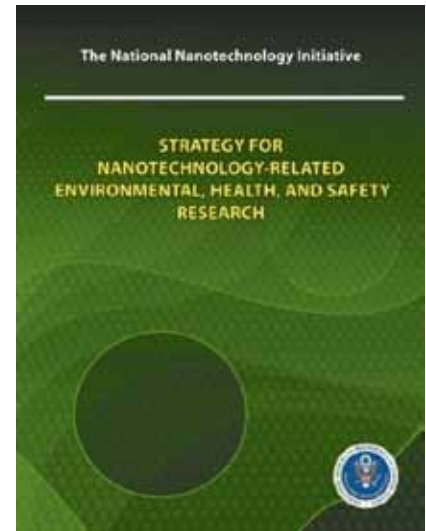
q Process:

1. Identify priority needs
2. Assess existing research
3. Analyze strengths and weaknesses
4. Periodic updates and revisions

q Five research categories:

1. Instrumentation, metrology and analytical methods (NIST lead)
2. Nanomaterials and human health (NIH lead)
3. Nanomaterials and the environment (EPA lead)
4. Human and environmental exposure assessment (NIOSH lead)
5. Risk management methods (FDA and EPA lead)

q Includes list of FY '06 funded EHS projects



Consensus Agency Roles and Responsibilities

| Research Need | Instrument., Metrology, and Analytical Methods | Nanomtl. and Human Health | Nanomtl. and the Environment | Human & Environmental Exposure Assessment | Risk Management Methods |
|---------------|--|---------------------------|------------------------------|---|-------------------------|
| Agency | | | | | |
| NIH | ☉☐ | ☉ | ☐ | ☐ | |
| NIST | ☉ | ☉ | ☉ | ☉ | ☉ |
| EPA | ☉☐ | ☉☐ | ☉ | ☉☐ | ☉ |
| FDA | ☐ | ☐ | ☐ | ☐ | ☉ |
| NIOSH | ☉☐ | ☉☐ | ☉ | ☉ | ☉☐ |
| NSF | ☉ | ☉ | ☉ | ☉ | ☉ |
| DOD | ☐ | ☐ | ☉☐ | ☐ | ☉☐ |
| DOE | ☉☐ | ☐ | ☉☐ | ☐ | ☐ |
| USDA/CREES | ☐ | ☉☐ | ☉☐ | ☐ | ☐ |
| DOT | | ☐ | ☐ | ☐ | ☐ |
| OSHA | ☐ | ☐ | | ☐ | ☐ |
| CPSC | ☉☐ | ☐ | ☐ | ☉☐ | ☉☐ |
| USGS | ☉☐ | | ☉☐ | ☉☐ | |

☉ - **Coordinating Agency**

Leadership role in coordinating and communicating with other NNI agencies

☉ - **Contributor**

Have funded or are planning to fund or conduct research in category

☐ - **User**

Have expressed a need for, or expectation to make use of, research outputs or information to support missions & responsibilities



Exposure Assessment: Scope

This area addresses research on the systematic collection, analysis, and interpretation of data obtained over time on human exposure to nanomaterials in the workplace and other indoor and outdoor environments; research to determine the presence of these materials or their byproducts in the environment; research on the determinants of exposures to support interpretation of limited or surrogate workplace and environmental data; monitoring of the health experience of individuals exposed to nanomaterials; and monitoring outcomes in habitats impacted by nanomaterials.

* from Environmental, Health, and Safety Research Needs for ENM (September 2006):
http://www.nano.gov/NNI_EHS_research_needs.pdf



Exposure Assessment: Research Needs

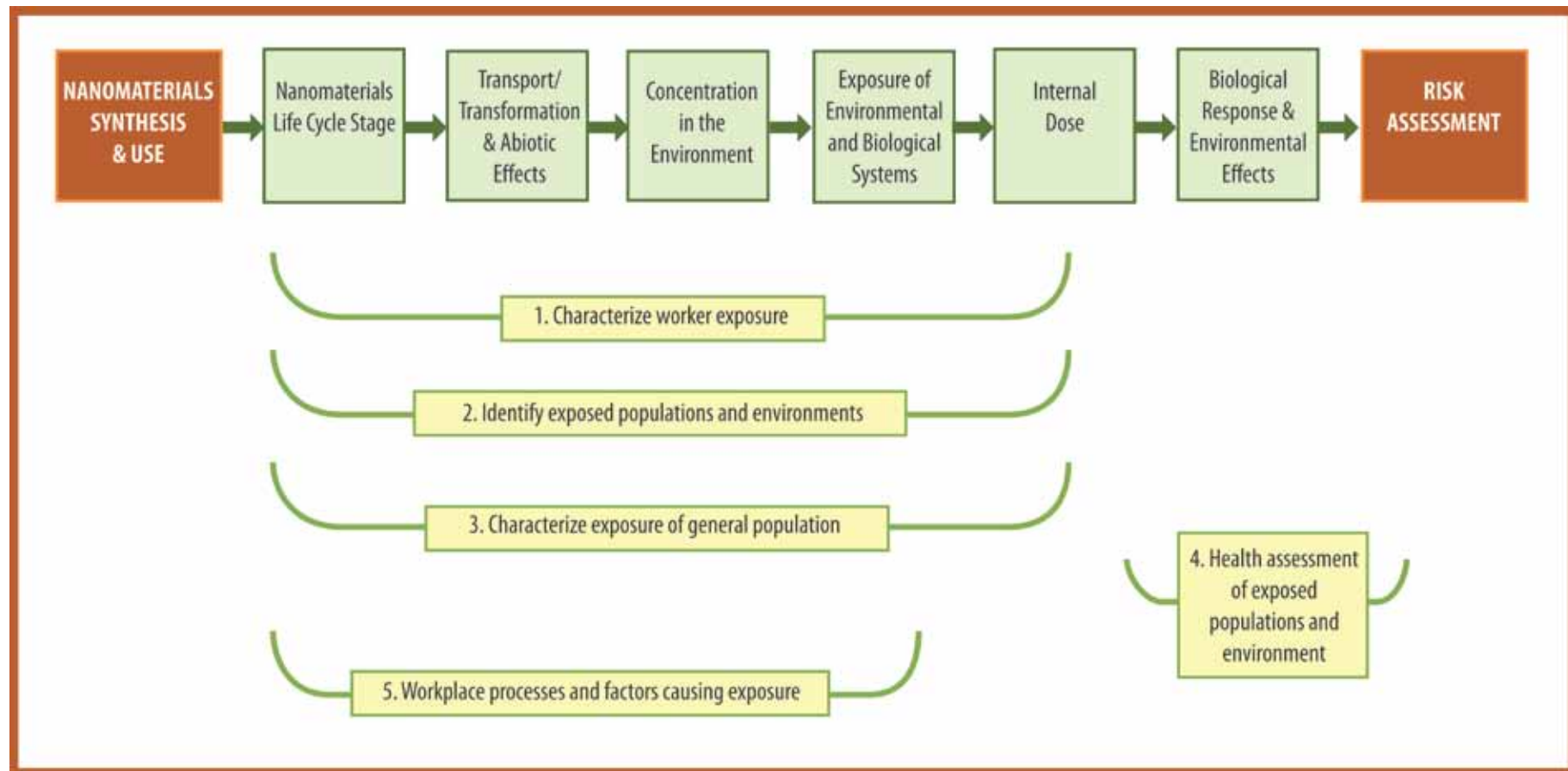
- Characterize exposure among workers
- Identify population groups and environments exposed to ENM
- Characterize exposure to the general population
- Characterize health of exposed populations and environments
- Understand workplace processes and factors that determine exposure to ENM

| | Near-Term Research 0-5 yrs | Mid-Term Research 5-10 yrs | Long-Term Research >10 yrs |
|--|-------------------------------|-------------------------------|-------------------------------|
| Research Need #1: Characterize Exposure Among Workers <ul style="list-style-type: none"> • Develop qualitative and quantitative exposure survey protocols • Explore utility and feasibility of exposure registries | | | |
| Research Need #2: Identify population groups and environments exposed to engineered nanoscale materials <ul style="list-style-type: none"> • Conduct geo-spatial analysis of nanomaterial manufacturing and use | | | |

| | | |
|--|--|--|
| | <ul style="list-style-type: none"> • Conduct population analysis of nanomaterial-containing product | |
| | Research Need #3: Characterize exposure to the general population from industrial processes and industrial and consumer products containing nanomaterials <ul style="list-style-type: none"> • Develop qualitative and quantitative exposure survey protocols • Explore utility and feasibility of exposure registries • Develop predictive models of population exposure | |
| | Research Need #4: Characterize health of exposed populations and environments <ul style="list-style-type: none"> • Analyze health surveillance data • Conduct epidemiological studies • Conduct surveillance of biota | |
| | Research Need #5: Understand workplace processes and factors that determine exposure to nanomaterials | |



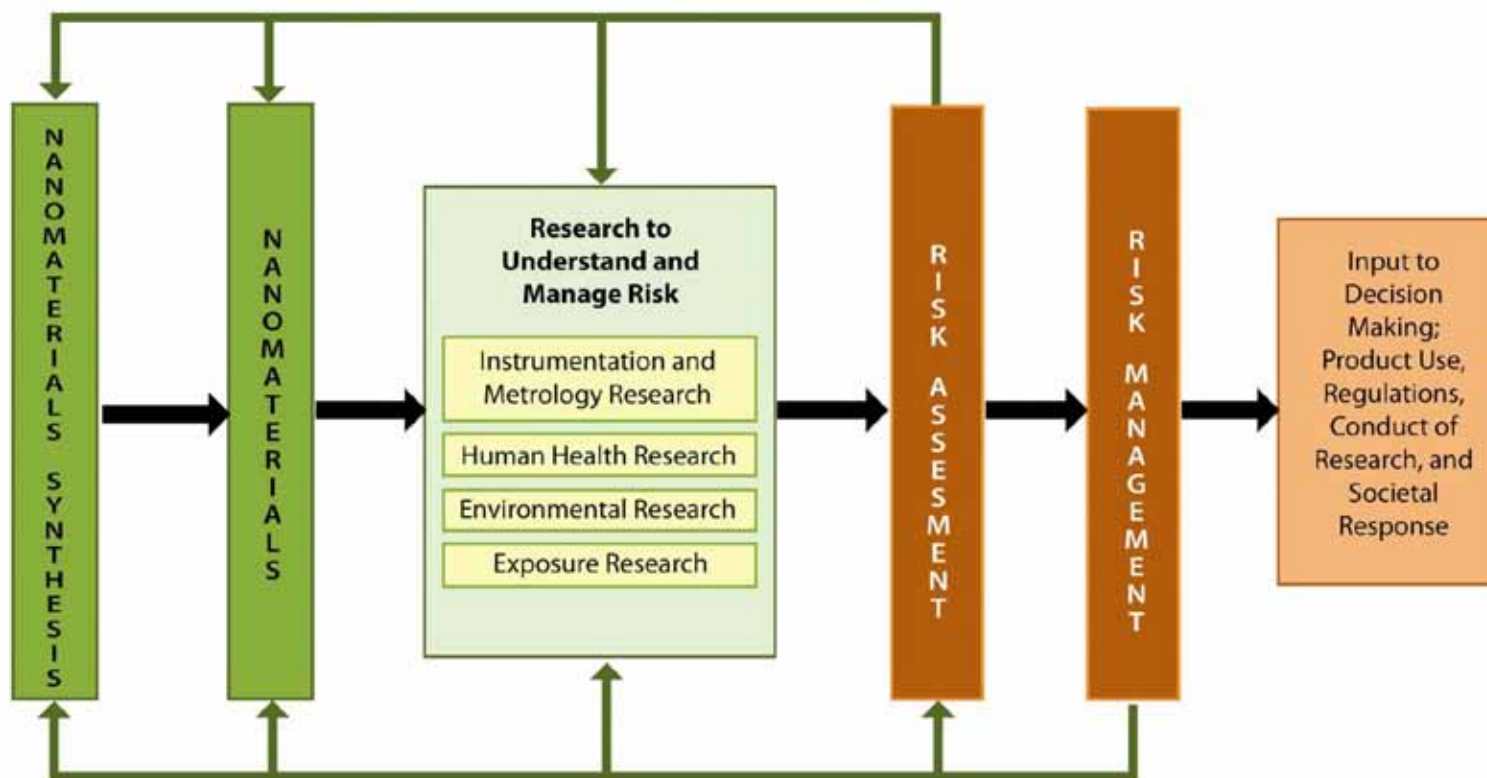
Risk Assessment





The National Nanotechnology Initiative: EHS Strategy

Role of nanotechnology-related EHS research in risk management of nanomaterials*



* from Strategy for Nanotechnology-Related Environmental, Health, and Safety Research (February 2008):
http://www.nano.gov/NNI_EHS_Research_Strategy.pdf



- The NEHI Working Group will conduct periodic progress review and will update the research needs and priorities, taking into consideration advances from private sector and international entities
- Convene workshops addressing each research category over the timeframe 2008-2010 to assess the state of science, current research, and to reassess areas of weakness and gaps. Participants will include, for example, representatives from both contributor and user NNI agencies, academia, non-governmental organizations, and industry



- to provide an open forum to facilitate effective communication among stakeholders about progress achieved in Human and Environmental Exposure Assessment research category and about path forward for addressing research needs in this category by
 - ✓ Bringing stakeholders together to build dialogue and to facilitate collaborations;
 - ✓ Discussing State of the Science to compare the progress of ongoing research to research needs and to identify gaps and emerging trends;
 - ✓ Relating progress and next steps to adaptive management of the research needs strategy.



Day 1

| | |
|-------|---|
| 8:00 | Welcome and background |
| 8:30 | State-of-the-science presentations |
| 11:10 | Group discussion |
| 12:00 | Lunch |
| 13:30 | Break-out discussions on research needs |
| 16:00 | Break |
| 16:30 | Open discussion on state-of-the-science |



Day 1

- Where are we in addressing research needs?
- Where do we need to be in addressing research needs in 5 years?
- Are the current research needs framed correctly in consideration of evolving understanding of the state of the science? What are the emerging trends?



Day 2

| | |
|-------|---|
| 8:00 | Recap of Day 1 |
| 8:15 | Break-out discussions on general issues |
| 10:45 | Break |
| 11:15 | Open discussion on path forward |
| 12:30 | Closing |



Day 2

- What is the role of informatics and how exchange of information could be made more efficient?
- How can cross-cutting research issues be addressed?
- What are the barriers for addressing cross-cutting research issues?
- What is the role of government/academia/industry/NGOs?
- What mechanisms exist or should be established to address research needs?



- Background information on state-of-the-science and critical research gaps to update research needs and priorities of the US Federal Government strategy
- NNI report on “Progress in Human and Environmental Exposure Assessment”
- New collaborations