Revealing Data Gaps & Needs: Dynamic Risk Management for an Evolving Science

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**Revealing Data Gaps & Needs: Dynamic Risk Management for an Evolving Science**

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OUTLINE

- Summary of Drivers
- Usage & Regulatory Information
- Assessment Methodology
- Results & Recommendations
- Path Forward
Nanomaterials

Substances with at least one dimension between approximately 1 and 100 nanometers (nm)

- Natural Processes
- Engineered: Designed at nanoscale
- Incidental: Industrial Processes
Nano-Composite Coatings

Accomplishment:
Composite coatings combining nanocrystalline particles with an amorphous metal matrix have been developed that give an order of magnitude decrease in component wear, good corrosion prevention in salt environments, and enable system operation under demanding lubricant starvation requirements.

Impact:
This advancement satisfies operational requirements for endurance and reliability of F-35 aircraft. Conventional coatings are unable to satisfy the full range of operation conditions. This advanced coating is being certified for F-35 aircraft gears and is also being validated in component-level testing for gears in the RL-10 liquid rocket engine turbopump.
Accomplishment:

Electrically conductive structural composites, polymers, paints, adhesives and ceramics have been produced by adding nickel nanostrands that are 100-150 nanometers in diameter and up to a millimeter in length.

Impact:

Significant protection from lightning strike damage, required for all-weather aircraft operation, has been demonstrated with nickel nanostrands. Conductive polymers using nickel nanostrands are being validated for shielding of electronic components from electromagnetic pulses, saving 150 lbs per aircraft over the current metal shielding. Electrically conductive coatings using nickel nanostrands are now fielded in other critical DoD applications.
## Summary of Drivers

<table>
<thead>
<tr>
<th>U.S. Federal Regulations</th>
<th>U.S. State Regulations</th>
<th>International Regulations</th>
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<tbody>
<tr>
<td>• U.S. Environmental Protection Agency has proposed regulation of nanomaterials through the Toxic Substances Control Act (TSCA)</td>
<td>• California has taken the lead in addressing nanomaterials as an EC, largely through voluntary reporting efforts</td>
<td>• The European Union (EU) is regulating nanomaterials under the Regulation, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation</td>
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<td>• With respect to statutes such as the Clean Air Act (CAA) or Clean Water Act (CWA), the USEPA maintains the authority to regulate nanomaterials as pollutants</td>
<td>• California and several other states have listed nanomaterials as a priority contaminant of concern</td>
<td>• Individual countries are also reviewing their regulatory regimes with respect to nanomaterials</td>
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**Phase I Impact Assessment Methodology**

Scanning drives the process by indicating scientific and regulatory activity surrounding a chemical or material.

Screening focuses the process by determining whether the chemical or material is of interest to the Department of Defense (DoD).

Phase I integrates scientific/regulatory information with DoD use information in order to assess where risk may lie.
Phase I Impact Assessment
Input and Output

Subject Matter Experts (SMEs) from throughout DoD are asked questions spanning 5 functional areas:

- Environment, Safety and Health (ESH)
- Acquisition/Research, Development, Test and Evaluation (A/RDT&E)
- Production, Operation, Maintenance and Disposal of Assets (POMD)
- Training and Readiness (T&R)
- Cleanup

Each question is scored twice. Comments are also collected.
Dynamic:
Characterized by continuous change, activity, or progress.

A dynamic scientific and regulatory climate calls for a dynamic approach to risk assessment.
## Scanning

<table>
<thead>
<tr>
<th>Standard Process</th>
<th>Modified Process</th>
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<tbody>
<tr>
<td>Literature, periodicals, and regulatory communication discuss one chemical,</td>
<td>Literature often discusses ‘nanomaterials’ as a broad category. Which ones are</td>
</tr>
<tr>
<td>material, or small family of chemicals/materials at a time.</td>
<td>most prominent?</td>
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![Metal-Based Nanomaterials](image)

- Gold
- Aluminum
- Silver

**Metal-Based Nanomaterials**
### Screening

<table>
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<tr>
<td>Search public and DoD <strong>databases</strong> for information about the <strong>locations</strong> and <strong>quantities</strong> of the chemical or material of interest.</td>
<td>Nanomaterial use is not currently being recorded in the standard databases.</td>
</tr>
<tr>
<td>This determines the <strong>magnitude</strong> of the issue. (How widespread is use? How much is being used?)</td>
<td>Information was collected from public and DoD <strong>reports</strong>. Locations and quantities were generally not available—however, <strong>types of nanomaterials</strong> were.</td>
</tr>
<tr>
<td></td>
<td><strong>Metals, Metal Oxides</strong></td>
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### Phase I Impact Assessment

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<tr>
<td>Questions within the assessment are generally focused around a <strong>primary driver</strong> (a new or changing regulation, a specific use of a chemical, a specific geographic area, etc.).</td>
<td>For nanomaterials, there is no single, primary driver.</td>
</tr>
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<td>The risk is assessed across <strong>5 functional areas</strong> to develop a clear picture of exactly where the risk lies.</td>
<td>1 functional area (Cleanup) was dropped due to lack of available information.</td>
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<td></td>
<td>The questions within the remaining 4 functional areas were <strong>edited to address some unique uncertainties</strong> associated with nanomaterials.</td>
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Results

Overall Risk
- Environment, Safety and Health
- Training / Readiness
- Acquisition / Research, Development, Testing, and Evaluation
- Production, Operations, Maintenance, and Disposal of Assets

Environment, Safety and Health
- E1 Human Health
- E2 Occupational Health (civilian and uniformed)
- E3 Ecological Health
- E4 Community, Public and Worker Relations

Training / Readiness
- RT1 Training Activities (Activity Specific)
- RT2 Training Activities (System Specific)

Acquisition / Research, Development, Testing, and Evaluation
- R1 Material Laboratory and Field Scale Activities
- R2 Material Labeling
- R3 Cost and Schedule
- R4 Material Availability

Production, Operations, Maintenance, and Disposal of Assets
- O1 Infrastructure Improvements
- O2 Analytical Techniques
- O3 Production and Maintenance Operations
- O4 Product Labeling
- O5 Waste Handling, Storage, Transport, and Disposal (HST&D)
- O6 Industrial Hygiene Controls

Overall Risk

ECAS (left) and ICAT (right) results.
Obstacles Encountered

- **Unknown benefits of nanotechnology**
  (Weighing risk against an unknown reward)

- **Communication between multidisciplinary experts**
  (Speaking different technical languages)

- **Gaining access to use/location information**

- **Insufficient Analytical Capabilities**
  (Complete, Integrated Characterization of Materials)
Nanomaterial Characterization

- Agglomeration
- Surface Specification
- Surface Charge
- Surface Functionality
- Porosity
- Surface Area
- Concentration
- Shape
- Size
- Composition
- Structure
- Size Distribution
Nanomaterial Characterization

Transmission Electron Microscopy:
Particle Size and Distribution, Surface Area, Shape, Agglomeration, Structure, and Composition (Lacking Concentration and Surface Charge)

Inductively Couple Plasma – Mass Spectrometry:
Concentration and Composition (Lacking Particle Size and Distribution, Surface Charge and Area, Shape, Agglomeration, and Structure)
Nanotoxicology

DISEASES ASSOCIATED TO NANOPARTICLE EXPOSURE

C. Buza, I. Pacheco, & K. Robbie, Nanomaterials and nanoparticles: Sources and toxicity, Biointerphases 2 (2007) MR17-MR71

NANOPARTICLES INTERNALIZED IN CELLS

Brain

Nanoparticle inhalation

Lungs

Brain

Nanoparticle inhalation

Lungs

Circulatory system

Heart

Other organs

Lymphatic system

Skin

Gastro-intestinal system

Crohn's disease
Colon cancer

Orthopedic implant wear debris
Auto-immune diseases
Dermatitis
Urticaria
Vasculitis

Mitocondrion

Nucleus

Cytoplasm

Membrane

Lipid vesicle

Nanoparticles ingestion

Gastro-intestinal system

Crohn's disease
Colon cancer

Orthopedic implant wear debris
Auto-immune diseases
Dermatitis
Urticaria
Vasculitis

Heart

Arrhythmia
Heart disease
Death

Diseases of unknown etiology in kidneys, liver

Podoconiosis
Kaposi's sarcoma
Auto-immune diseases dermatitis

Neurological diseases:
Parkinson's disease
Alzheimer's disease

Asthma
Bronchitis
Emphysema
Cancer

Arteriosclerosis
Vasoconstriction
Thrombus
High blood pressure

Mitocondrion

Nucleus

Cytoplasm

Membrane

Lipid vesicle

Nanoparticles ingestion

Gastro-intestinal system

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Orthopedic implant wear debris
Auto-immune diseases
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Kaposi's sarcoma
Auto-immune diseases dermatitis
Dose Response Evaluation

- Classical Models of Toxicity
  - Whole System
  - Reproductive Endpoints
  - Neurological Effects
  - Immune System Effects
  - Carcinogenic Effects

- Obstacles
  - Keeping nanoparticles separate from one another for studies (Agglomeration & Aggregation Issues)
  - Variation between in vitro, in vivo, and real world exposure scenarios
Nanomaterial Life Cycle in the Environment
The Path Forward

- Continue to develop analytical methods for nanoscale detection and monitoring
- Begin cataloging where DoD is using nanomaterials, in what quantities, and for which applications.
- Begin modifying/creating databases to store data and information about DoD nanomaterials.
- Engage with the public and regulatory communities.