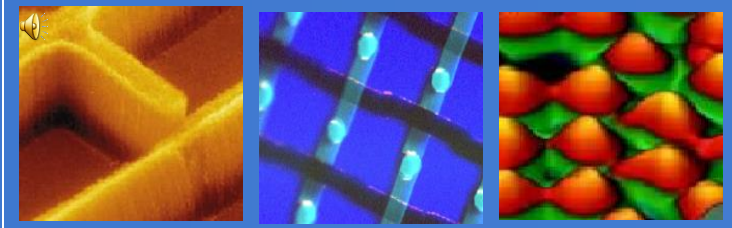


Assessing the Risks of Emerging Nanomaterials

Nanotechnology and OEHS Harmonization

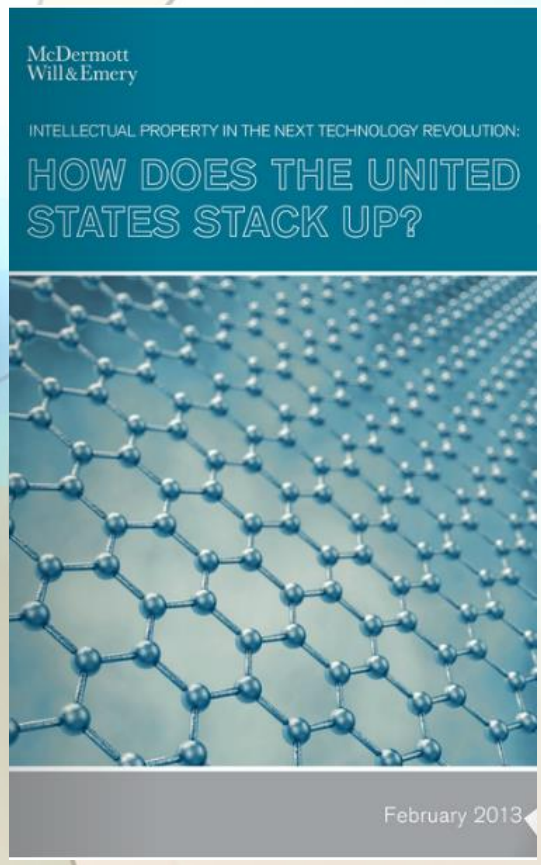
"A Global Approach"

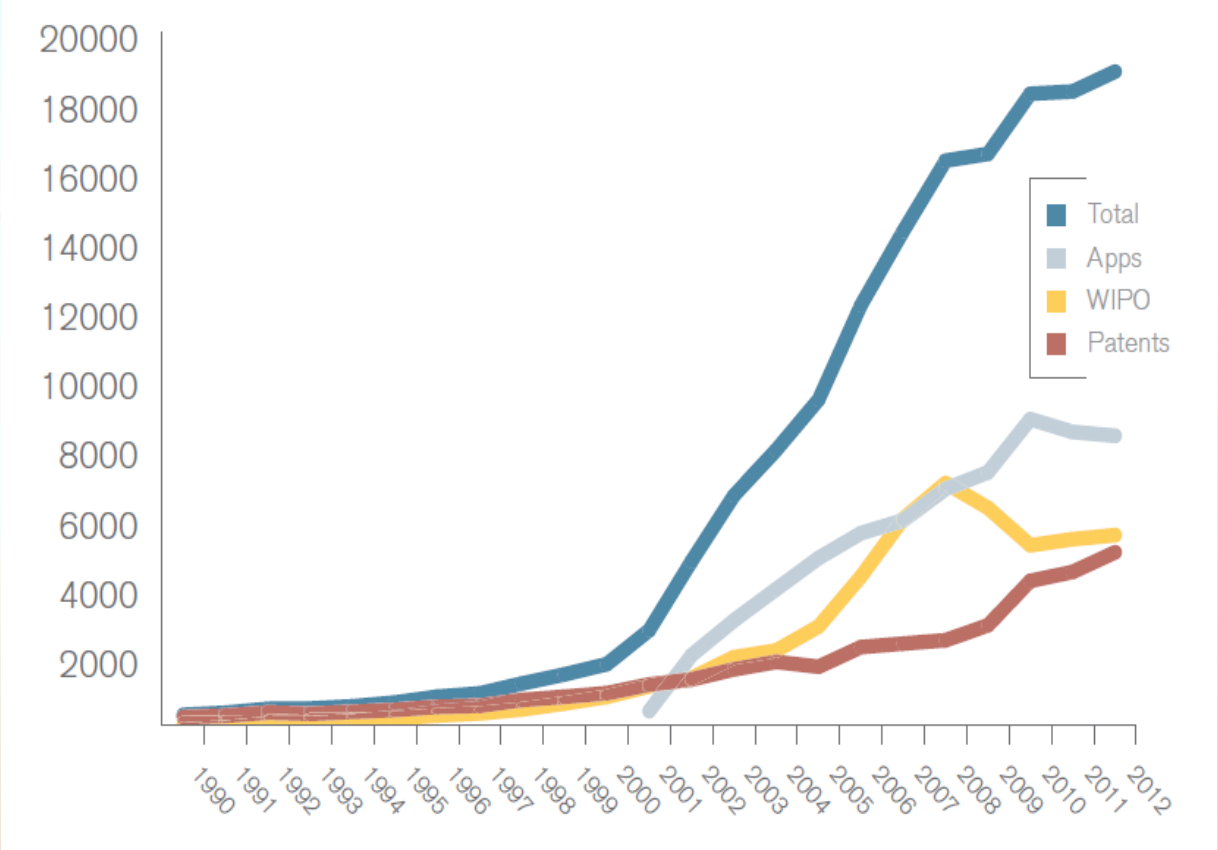
Nanomanufacturing Summit 2013
12th Annual NanoBusiness Conference
University of Pennsylvania
(*November 17, 2013*)

nanoTox Field Services Capabilities

- Global Provider of Nanotechnology OEHS Program Services
- Originator of the nanoTox Categorization System
- Regulatory Compliance Specialists (US and EU)
- Fast-Track OEHS Program Evaluations and Assessments
  - Fundamental OEHS Program Elements
  - Hazard Identification & Development
  - Exposure Containment & Control
  - Communication, Education & Training
- Health And Safety Plan – HASP Development Specialists
- Medical Management, Surveillance and Registry Experts

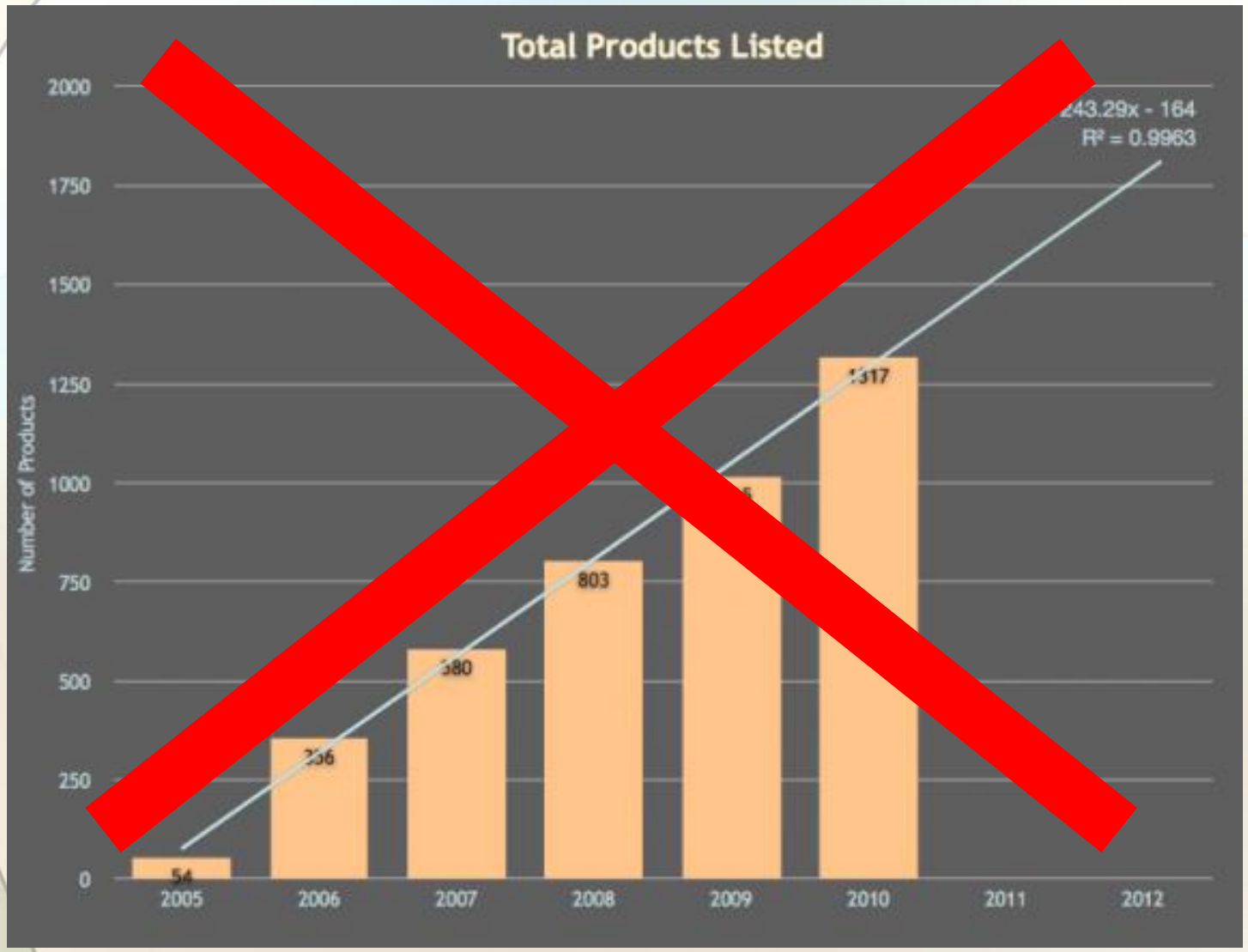
McDermott Will & Emery





"Nanotechnology patent literature" is defined as U.S. Published Patent Applications, U.S. Granted Patents and Published International Patent Applications having the term "nano*" in the claims, title or abstract. While the U.S. Patent Office (USPTO) has a nanotechnology class, specifically Class 977, the results of searching only Class 977 were found to be too narrow and did not apply to International Patent Applications. (WIPO - World Intellectual Property Organisation)

McDermott Will & Emery's 2012 "Nanotechnology: Who will be the leaders in the fifth technology revolution?"


Total Products Listed
Number of Products
2000
1750
1500
1250
1000
750
500
250
0
243.29x - 164
R² = 0.9963
54
803
2005
2006
2007
2008
2009
2010
2011
2012






vitamins &
supplements


Regulatory Considerations

"Setting the Standard in Exposure Assessment"

Toxicology, Industrial Hygiene & Medical Management

Major Regulatory Criteria *(US-EPA)*

TSCA – Materials Management

- Pre-Manufacturing Notice & Significant New Use Rules

  When the chemicals being innovated are novel in their physicochemical characteristics, they may not currently be on the Toxic Substances Control Act approved list. Thus the company may need to prepare and submit either a Pre-Manufacturing or Significant New Use Notice to EPA with these regulatory filings required before significant distribution can occur.

EPA United States Environmental Protection Agency

TSCA Section 5 Violation History *(2012 – July 18, 2013)*

U.S. ENVIRONM

Enforcement & Compliance History Online (ECHO)

Recent Additions | Contact Us

You are here: EPA Home » Compliance and Enforcement » ECHO » Search Data » Search Results

ECHO Enforcement and Compliance History Online

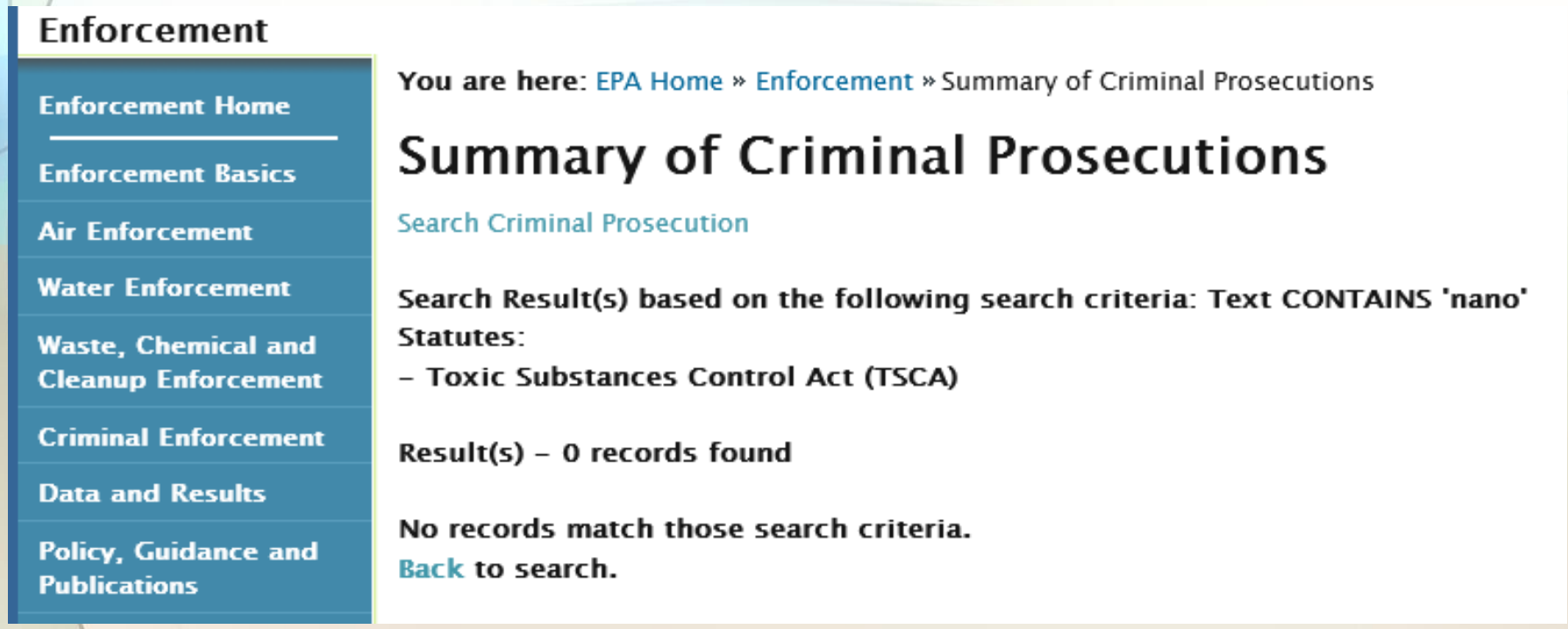
Search Results (EPA Enforcement Cases)

11 Cases Returned

Case Number	Case Name	Case Type	Primary Law/Section	Filed/Issued	Settlement Date	Federal Penalty Assessed or Agreed To
HQ-2012-5018	Dover Chemical Case Report Facility Report	Judicial	TSCA/5A/5B	2012-02-07	2012-08-31	$1,400,000
HQ-2012-5024	INEOS ChlorAmericas Inc Case Report Facility Report	Judicial	TSCA/5A/5B	2012-09-07	2012-11-07	$175,000
HQ-2011-5004	Eastman Kodak Company Case Report Facility Report	Administrative - Formal	TSCA/5A/5B		2011-10-19	$41,748
02-2012-9226	Sanyo Corporation of America Case Report Facility Report	Administrative - Formal	TSCA/5A/5B	2011-12-05	2011-12-05	$12,705
05-2012-0050	Rahn USA Corp. Case Report Facility Report	Administrative - Formal	TSCA/5H	2012-04-12	2012-04-12	$3,100
HQ-2013-5004	Cytec Industries Inc. Case Report Facility Report	Administrative - Formal	TSCA/5A/5B		2012-12-06	

EPA United States Environmental Protection Agency

TSCA Criminal Prosecution History, Keyword Nano *(2006 – July 18, 2013)*



Enforcement

- Enforcement Home
- Enforcement Basics
- Air Enforcement
- Water Enforcement
- Waste, Chemical and Cleanup Enforcement
- Criminal Enforcement
- Data and Results
- Policy, Guidance and Publications

You are here: EPA Home » Enforcement » Summary of Criminal Prosecutions

Summary of Criminal Prosecutions

Search Criminal Prosecution

Search Result(s) based on the following search criteria: Text CONTAINS 'nano'
Statutes:
– Toxic Substances Control Act (TSCA)

Result(s) – 0 records found

No records match those search criteria.
Back to search.

Major Regulatory Criteria *(US-EPA)*

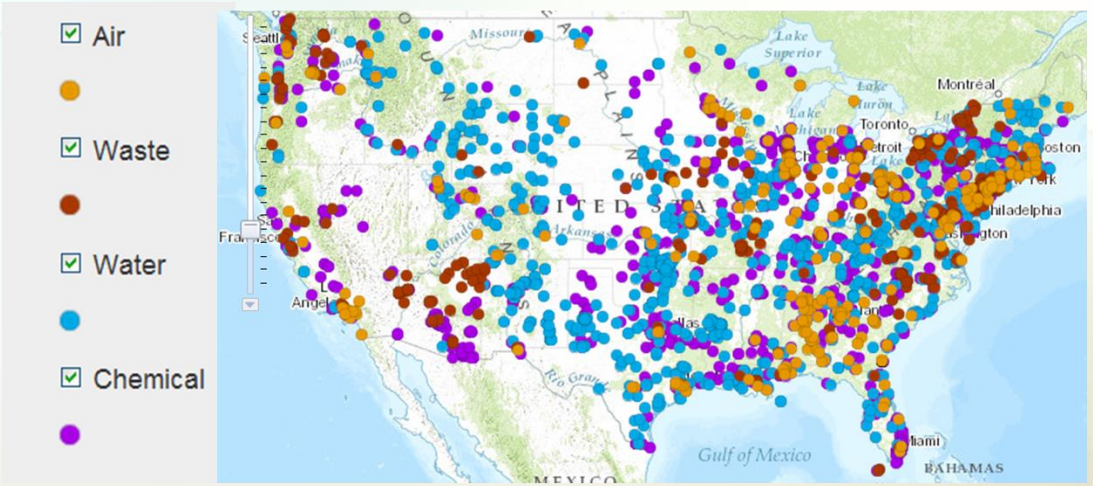
NEPA – Manufacturing Management

- Clean Water Act
- Clean Air Act
- Hazardous Waste Management
- Community Right-to-Know
- Storm Water Pollution Prevention Program

Enforcement Annual Results for Fiscal Year 2012

- **$252 million in criminal fines and civil penalties** assessed to deter pollution

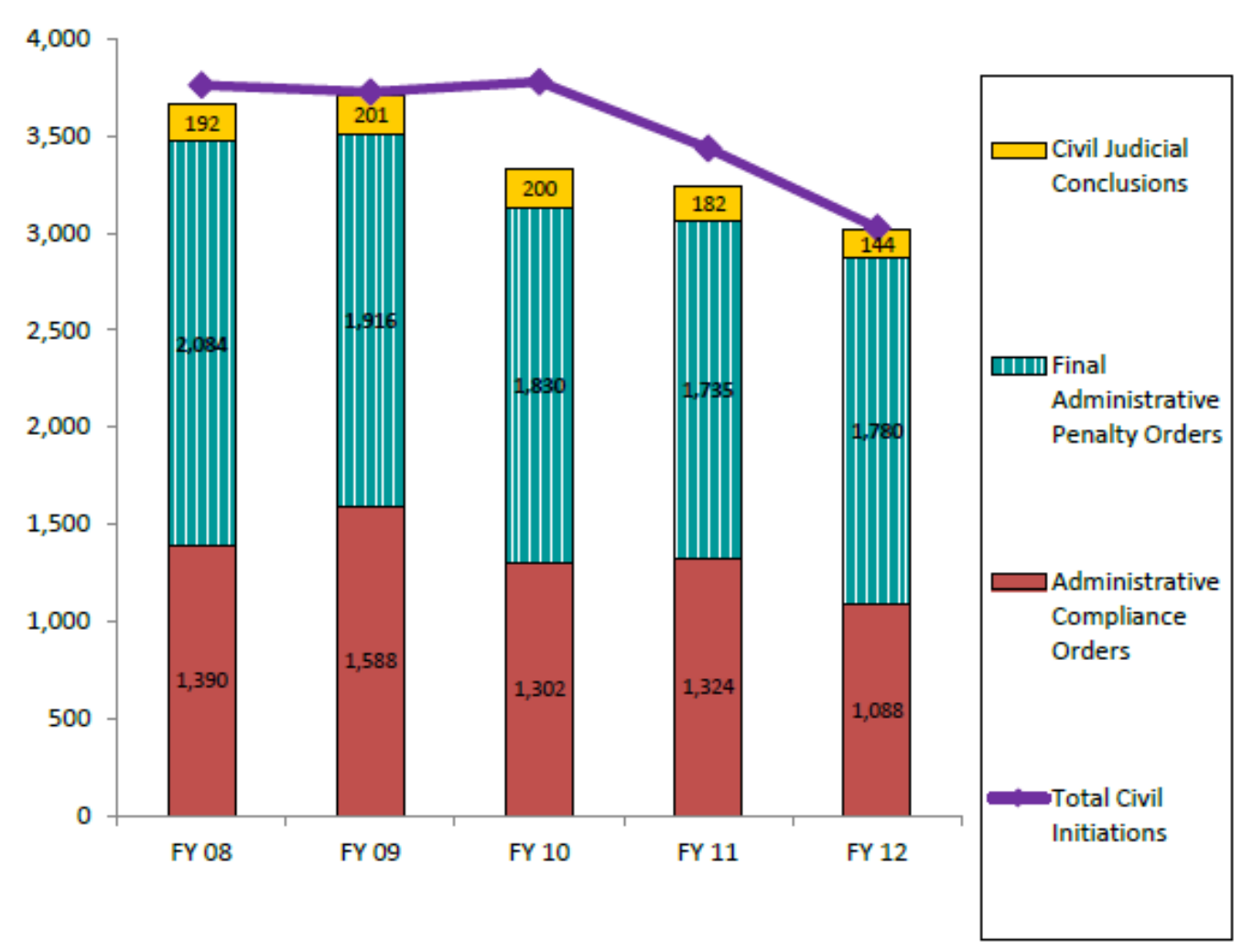
- **6.6 billion pounds of pollution and hazardous waste** reduced, eliminated, properly disposed of or treated



- **$44 million in additional investments** for supplemental environmental projects that benefit communities

- **Improving compliance with drinking water regulations by 60%:** Sustained and focused enforcement attention on serious violators of clean drinking water standards has resulted in dramatic improvements in compliance.

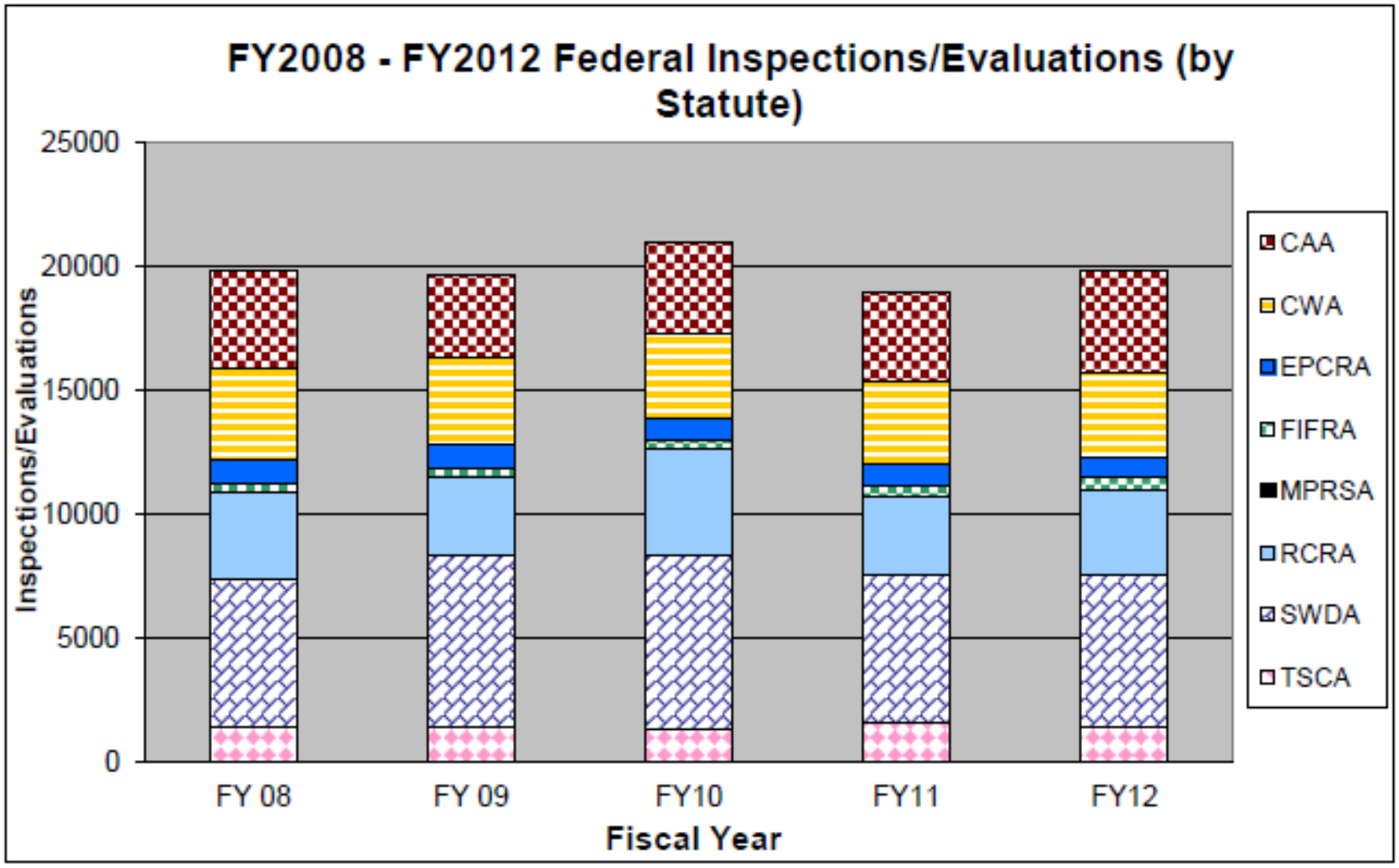
EPA Civil Enforcement Case Initiations and Conclusions



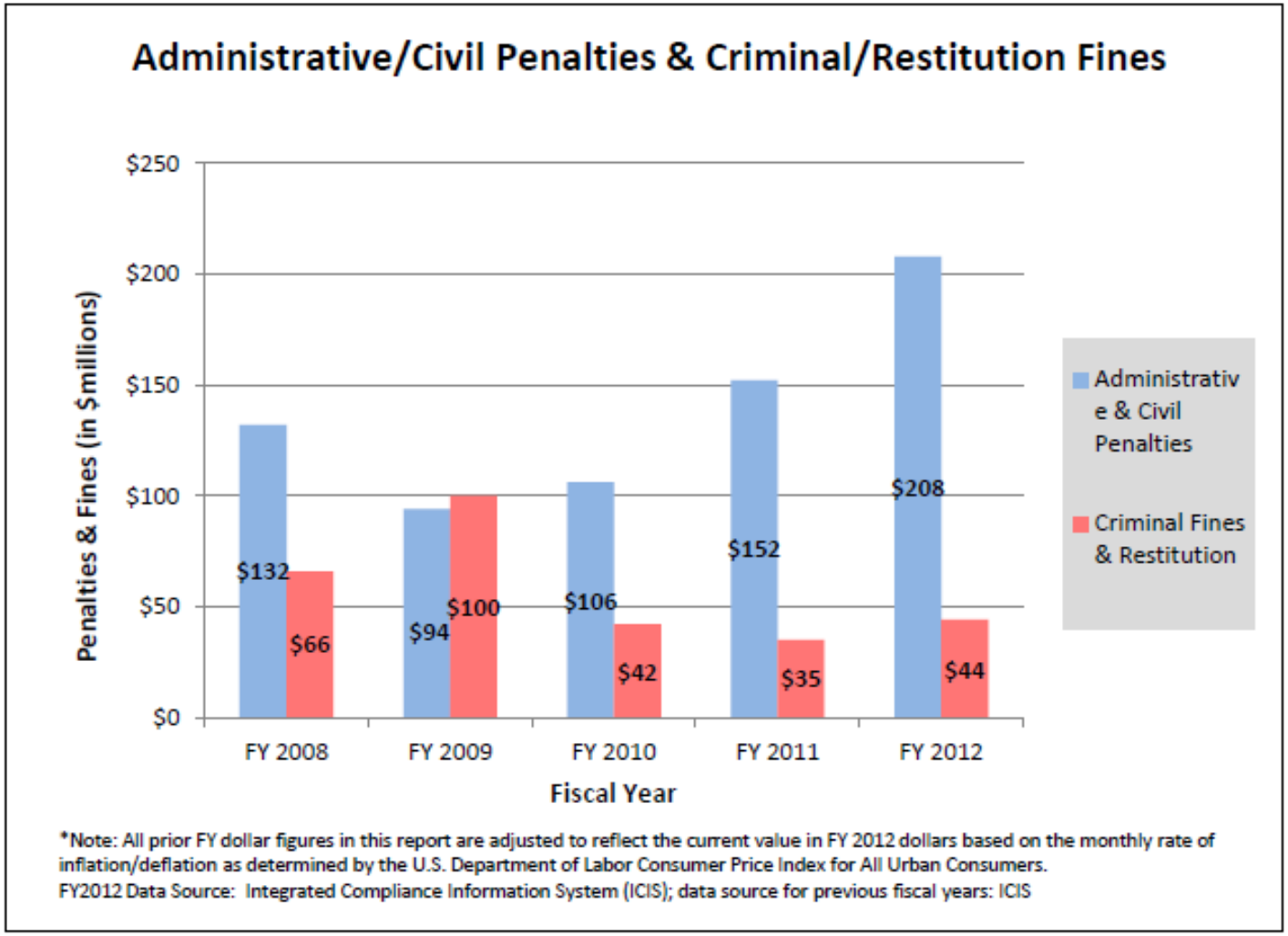
- In FY 2012, EPA concluded **3,012 civil judicial and administrative cases.**

- EPA Initiated a total of **3,027 civil enforcement cases (judicial and administrative) in FY 2012.**

Number of Inspections - Evaluations Conducted by EPA



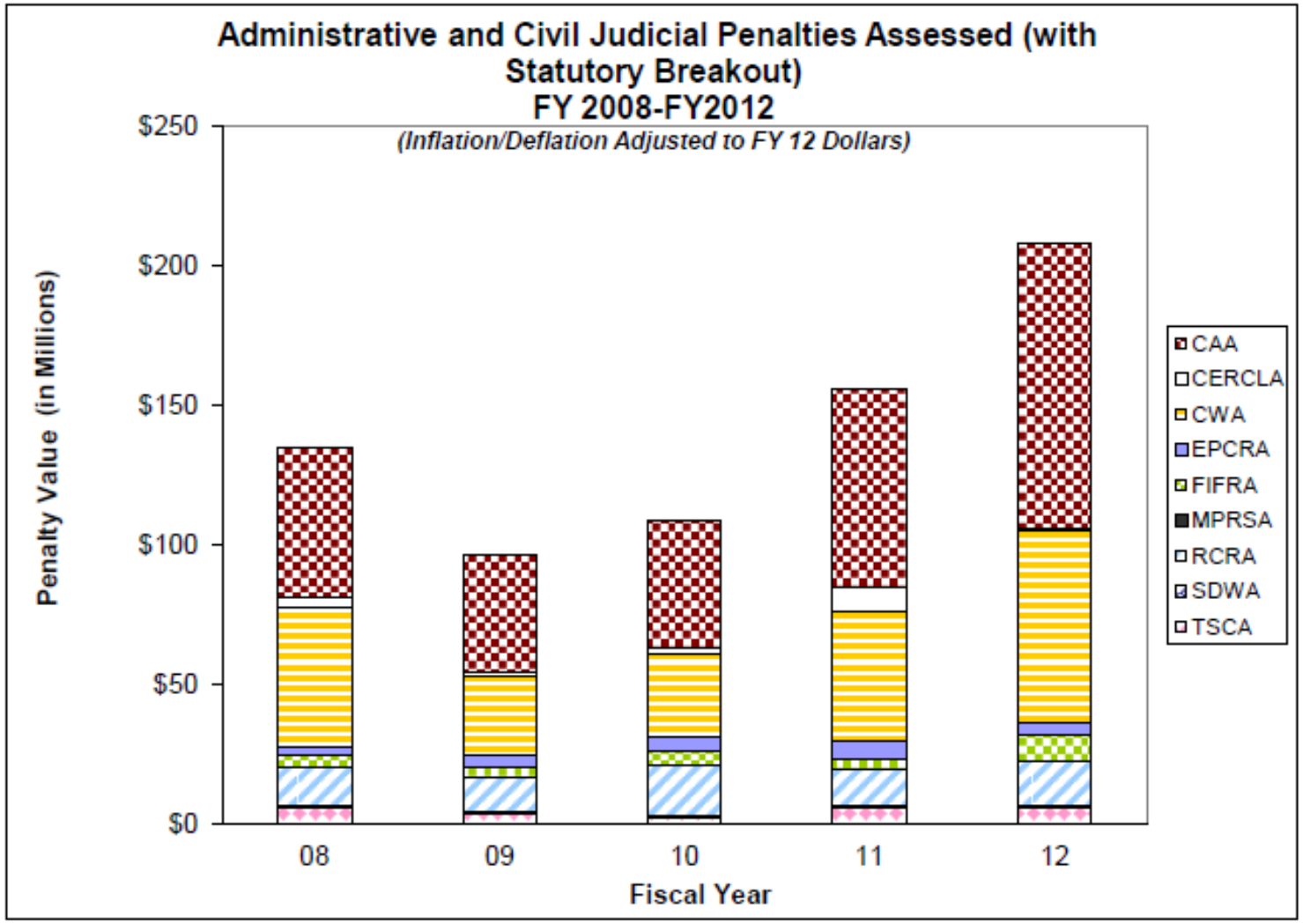
Civil Penalties & Criminal Fines Assessed



- In FY 2012, EPA enforcement actions required companies to pay over **$200 million in civil penalties (administrative and judicial) – an all-time record amount.**

- In FY 2012, EPA criminal prosecutions resulted in **$44 million in criminal fines and restitution.**

FY2012 Enforcement & Compliance Annual Results



Major Regulatory Criteria *(US-OSHA)*

Employer's General Duty Clause

- The employer has an obligation to protect workers from serious and recognized workplace hazards even where there is no standard**.**
- Employers must take whatever abatement actions are feasible to eliminate hazards.
- Examples (Ergonomics, Indoor Air Quality, Workplace Violence, Occupational Exposures, etc.)

Major Regulatory Criteria *(US-OSHA)*

Right-To-Know; Material Safety Data Sheets

The second broad duty requires each employer to "comply with occupational safety and health standards promulgated under this chapter" of which the Hazard Communication Standard - a worker's "right-to-know" - is arguably the most important:

The purpose of [HCS] is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

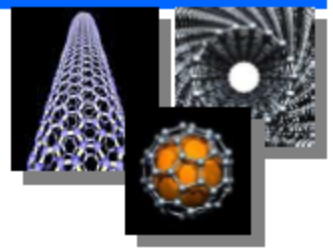
UNITED STATES
DEPARTMENT OF LABOR

OSHA and Nanotechnology: Current Activities and Regulatory Considerations

TAPPI 2006 International Conference on Nanotechnology
April 26, 2006

Loretta D. Schuman, Ph.D., D.A.B.T.
Office of Chemical Hazards - Nonmetals
Directorate of Standards and Guidance
Occupational Safety and Health Administration
Washington, D.C. 20210

OSHA Occupational Safety and Health Administration



OSHA and Nanotechnology: Current Activities and Regulatory Considerations
TAPPI Conference – 2006 *(L. D. Schuman, Ph.D, DABT, Senior Toxicologist)*

MATERIAL SAFETY DATA SHEET

Manufacturer: Phone: Fax: E-mail:

Product: Single Wall Carbon Nanotubes

Section 1 Product Identification

Chemical Name:	Carbon Fullerene
Formula:	Carbon
Chemical Family:	Synthetic Graphite
Synonyms:	Single Wall Carbon Nanotubes, SWNT
CAS Number:	7782-42-5 (Graphite)

Section 2 Composition and Information on Ingredients

Component	%	OSHA/PEL	ACGIH/TLV
Synthetic graphite	Up to 100%	15 mg/m^3 (total dust) 5 mg/m^3 (respirable fraction)	2 mg/m^3 TWA
Metallic impurity	Balance		

Section 3 Hazards Identification

Potential Health Effects

Eye Contact:	May cause eye irritation
Skin Contact:	No known hazards, but may be mildly irritating
Inhalation:	May cause irritation to respiratory tract
Ingestion:	No known hazards, but may irritate gastrointestinal tract
Acute and Chronic Health Effects:	High concentration of dusts may be irritating to eyes, skin, mucus membranes and respiratory tract.

Section 11 Toxicological Information

Effects: No known toxicological effects

MATERIAL SAFETY DATA SHEET

SECTION 1. - - - - - - - - - CHEMICAL IDENTIFICATION- - - - - - - - - -

NAME: CARBON NANOTUBES, MULTI-WALL

SECTION 2. - - - - - COMPOSITION/INFORMATION ON INGREDIENTS - - - - - -
CAS #:NONE
EC NO: 231-153-3

SECTION 3. - - - - - - - - - - HAZARDS IDENTIFICATION - - - - - - - - -
LABEL PRECAUTIONARY STATEMENTS IRRITANT IRRITATING TO EYES AND RESPIRATORY SYSTEM. IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL ADVICE. WEAR SUITABLE PROTECTIVE CLOTHING.

SECTION 11. - - - - - - - - - TOXICOLOGICAL INFORMATION - - - - - - - -
ACUTE EFFECTS MAY BE HARMFUL IF ABSORBED THROUGH THE SKIN. MAY BE HARMFUL IF SWALLOWED. TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL, PHYSICAL, AND TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED. MAY CAUSE SKIN IRRITATION. CAUSES EYE IRRITATION. MATERIAL IS IRRITATING TO MUCOUS MEMBRANES AND UPPER RESPIRATORY TRACT. MAY BE HARMFUL BY INHALATION, INGESTION, OR SKIN ABSORPTION.

SECTION 15. - - - - - - - - - REGULATORY INFORMATION - - - - - - - - - -
EUROPEAN INFORMATION IRRITANT R 36/37 IRRITATING TO EYES AND RESPIRATORY SYSTEM. S 26 IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL ADVICE. S 36 WEAR SUITABLE PROTECTIVE CLOTHING.

Note lack of CAS and PEL/TLV

2010 Commonwealth of Australia Study

safe work australia

RESEARCH REPORT

An Evaluation of MSDS and Labels associated with the Use of Engineered Nanomaterials

JCHAS 550 1–8

ARTICLE IN PRESS

RESEARCH ARTICLE

A critical evaluation of material safety data sheets (MSDSs) for engineered nanomaterials

Material safety data sheets (MSDSs) provide employers, employees, emergency responders, and the general public with basic information about the hazards associated with chemicals that are used in the workplace and are a part of every-day commerce. They are a primary information resource used by health, safety, and environmental professionals in communicating the hazards of chemicals and in making risk management decisions. Engineered nanomaterials represent a growing class of materials being manufactured and introduced into multiple business sectors. MSDSs were obtained from a total of 44 manufacturers using Internet search engines, and a simple ranking scheme was developed to evaluate the content of the data sheets. The MSDSs were reviewed using the ranking scheme, and categorized on the quality and completeness of information as it pertains to hazard identification, exposure controls, personal protective equipment (PPE), and toxicological information being communicated about the engineered nanomaterial. The ranking scheme used to evaluate the MSDSs for engineered nanomaterials was based on the determination that the data sheet should include information on specific physical properties, including particle size or particle size distribution, and physical form; specific toxicological and health effects; and protective measures that can be taken to control potential exposures. The first MSDSs for nanomaterials began to appear around 2006, so these were collected in the time period of 2007–2008. Comparison of MSDSs and changes over time were evaluated as MSDSs were obtained again in 2010–2011. The majority (67%) of the MSDSs obtained in 2010–2011 still provided insufficient data for communicating the potential hazards of engineered nanomaterials.

2013 Follow-Up on OSHA Identified MSDS Problem in Nanotechnology

NANOLAB, INC.
179 Bear Hill Road
Waltham, MA 02451
Phone (781) 609 2722
Fax (781) 609 2899
http://www.nano-lab.com

Revised on 2012/10/15
Revision no. 6

MATERIAL SAFETY DATA SHEE T

SECTION 1. - - - - - - - - - CHEMICAL IDENTIFICATION- - - - - - - - - -

NAME: CARBON NANOTUBES, MULTI-WALL – APPLICABLE TO NANOLAB PRODUCT CODES: PD15L1-5, PD15L5-20, PD30L1-5, PD30L5-20, IG-CNT

SECTION 2. - - - - - COMPOSITION/INFORMATION ON INGREDIENTS - - - - - -
CARBON NANOTUBES, >95%, CAS NUMBER: 308-068-56-6
INORGANIC IMPURITIES <5%
ALUMINUM OXIDE, CAS NUMBER: 1344-28-1
IRON OXIDE, CAS NUMBER: 1345-25-1

2013 Follow-Up on OSHA Identified MSDS Problem in Nanotechnology

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http://www.nano-lab.com

Revised on 2012/10/15
Revision no. 6

MATERIAL SAFETY DATA SHEE T

SECTION 8. - - - - - - EXPOSURE CONTROLS/PERSONAL PROTECTION- - - - - -
SAFETY SHOWER AND EYE BATH. MECHANICAL EXHAUST REQUIRED. WASH THOROUGHLY AFTER HANDLING. DO NOT BREATHE DUST. AVOID CONTACT WITH EYES, SKIN AND CLOTHING. AVOID PROLONGED OR REPEATED EXPOSURE. FOR NUISANCE EXPOSURE, USE NIOSH OR CEN APPROVED TYPE P95 (US) OR TYPE P1 (EU EN 143) PARTICLE RESPIRATOR. FOR HIGHER LEVEL PROTECTION, USE TYPE OV/AG/P99 (US) OR TYPE ABEK-P2 (EU EN 143) RESPIRATOR CARTRIDGES. COMPATIBLE CHEMICAL-RESISTANT GLOVES. CHEMICAL SAFETY GOGGLES. KEEP TIGHTLY CLOSED.
OSHA PERMISSIBLE EXPOSURE LIMIT (PEL) FOR GENERAL INDUSTRY: 15MG/M^3 TWA

FDA's Approach to Regulation of Nanotechnology Products

- FDA is maintaining its product-focused, science-based regulatory policy.
- FDA's approach respects variations in legal standards for different product-classes.
- Where premarket review authority exists, attention to nanomaterials is being incorporated into standing procedures.
- Where statutory authority does not provide for premarket review, consultation is encouraged to reduce the risk of unintended harm to human or animal health.
- FDA will continue post-market monitoring.
- Industry remains responsible for ensuring that its products meet all applicable legal requirements, including safety standards.
- FDA will collaborate, as appropriate, with domestic and international counterparts on regulatory policy issues.
- Both for products that are not subject to premarket review and those that are, FDA will offer technical advice and guidance, as needed, to help industry meet its regulatory and statutory obligations.

http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm301114.htm

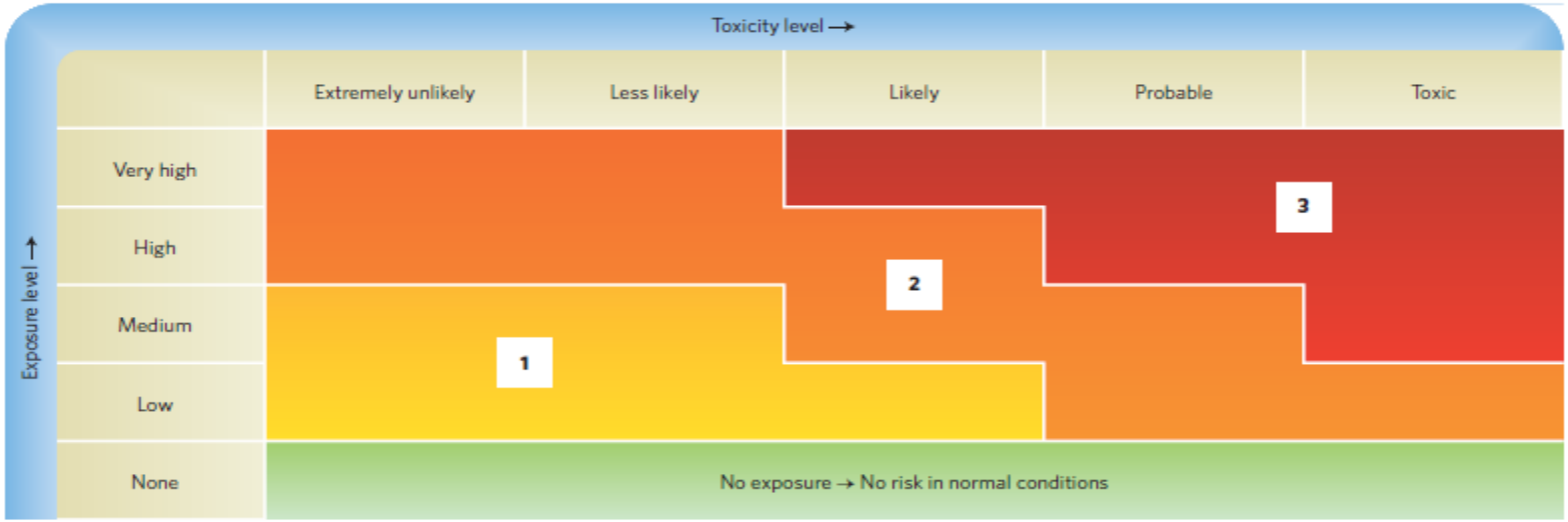
Evaluation of Consumer Products

The potential safety and health risks of nanomaterials, as with other compounds that are incorporated into consumer products, can be assessed under existing CPSC statutes, regulations and guidelines. **Neither the Consumer Product Safety Act (CPSA) nor the Federal Hazardous Substances Act (FHSA) requires the pre-market registration or approval of products. Thus, it is usually not until a product has been distributed in commerce that the CPSC would evaluate a product's potential risk to the public.**

FY 2014 Performance Budget Request

The CPSC has been identified as a key agency in addressing environmental, health, and safety (EHS) issues associated with nanomaterial use and is collaborating with other federal agencies within the initiative to support the development of exposure and risk assessments of nanomaterials, to collect information on products reported to contain nanomaterials, and to flag reports of incidents that involve nanotechnology and consumer products. The CPSC's proposed investment will enable the CPSC to continue to participate in this interagency initiative and will support the development of methods and quantitative data on exposure and potential health risks of nanomaterials in consumer products.

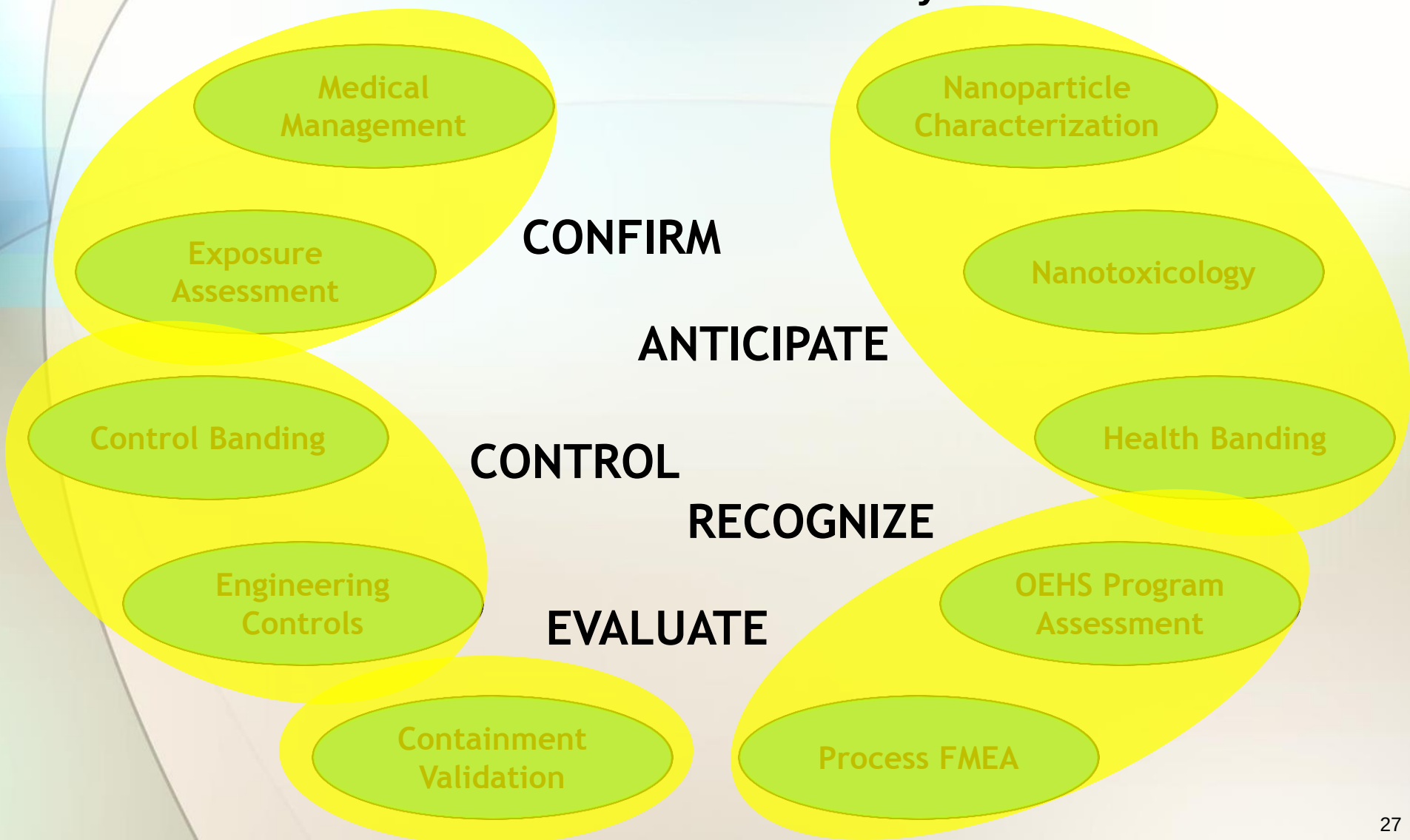
The Insurability of Nanomaterial Production Risk *(M. Mullins, F. Murphy, L. Baublyte, E. M. McAlea and S. A. M. Tofail; Nature Nanotechnology, Vol 8, April, 2013)*



Risk level	Situation	Underwriting decision
1 (low)	Acceptable	Insurable
2 (moderate)	To be improved	Insurable subject to extra precautionary measures taken to manage worker's exposure to nanomaterials. This may include adherence to standard operating procedures to reduce exposure or chemical coating to reduce the toxicity (if applicable). Another alternative would be to adjust the contract wording to limit exposure to a claims made basis only (the occurence has to take place during the insured period thus eliminating long-tailed risk).
3 (high)	Unacceptable	Uninsurable

Control banding for underwriters. Exposure and hazard risk are estimated from qualitative and/or quantitative data and the resultant risk location used to calculate insurance premium.

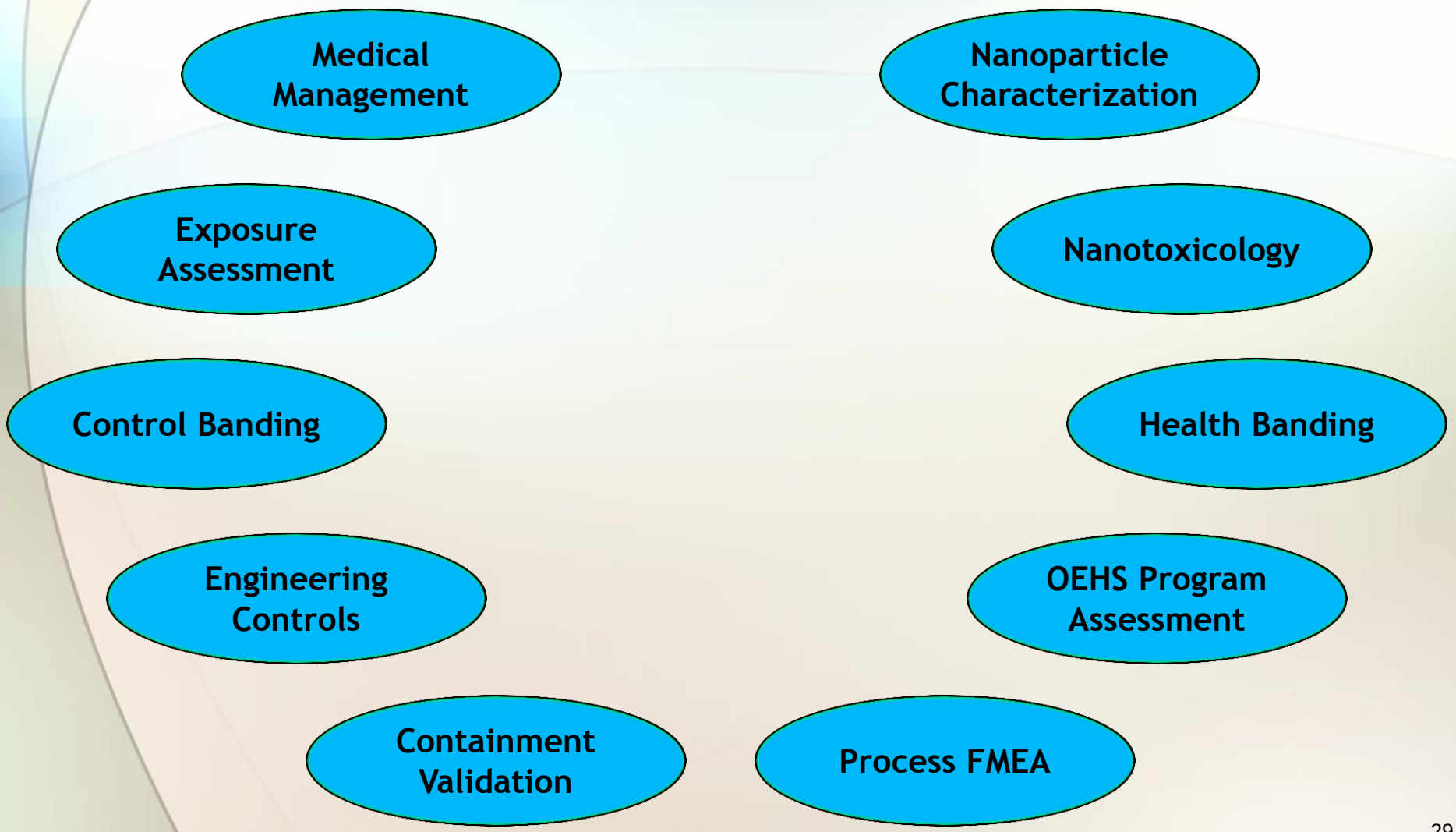
Nanomaterial OEHS Lifecycle



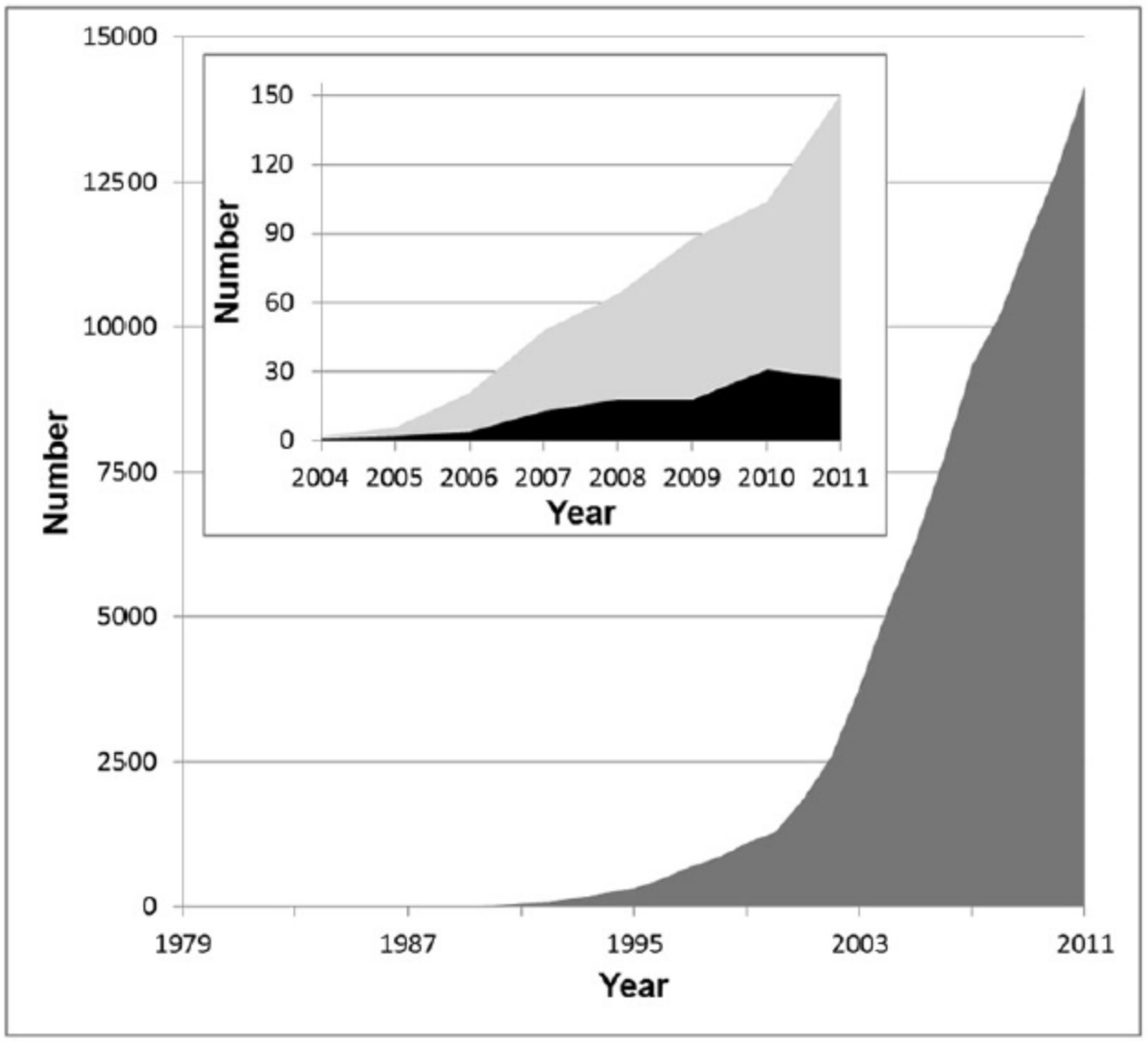
Compound Characteristics that Affect Exposure

Low	Risk	High
Wet	Physical Form	Dry
Large	Particle Size	Small
Dense	Density	Light
Spherical	Particle Shape	Feathery
No	Electrostatic	Yes
Limited	Routes of Ingestion	Unlimited
Low	Bio Availability	High
Fast/ Reversible	Acute / Chronic	Slow / Irreversible
None	'gens	All

Nanomaterial OEHS Lifecycle

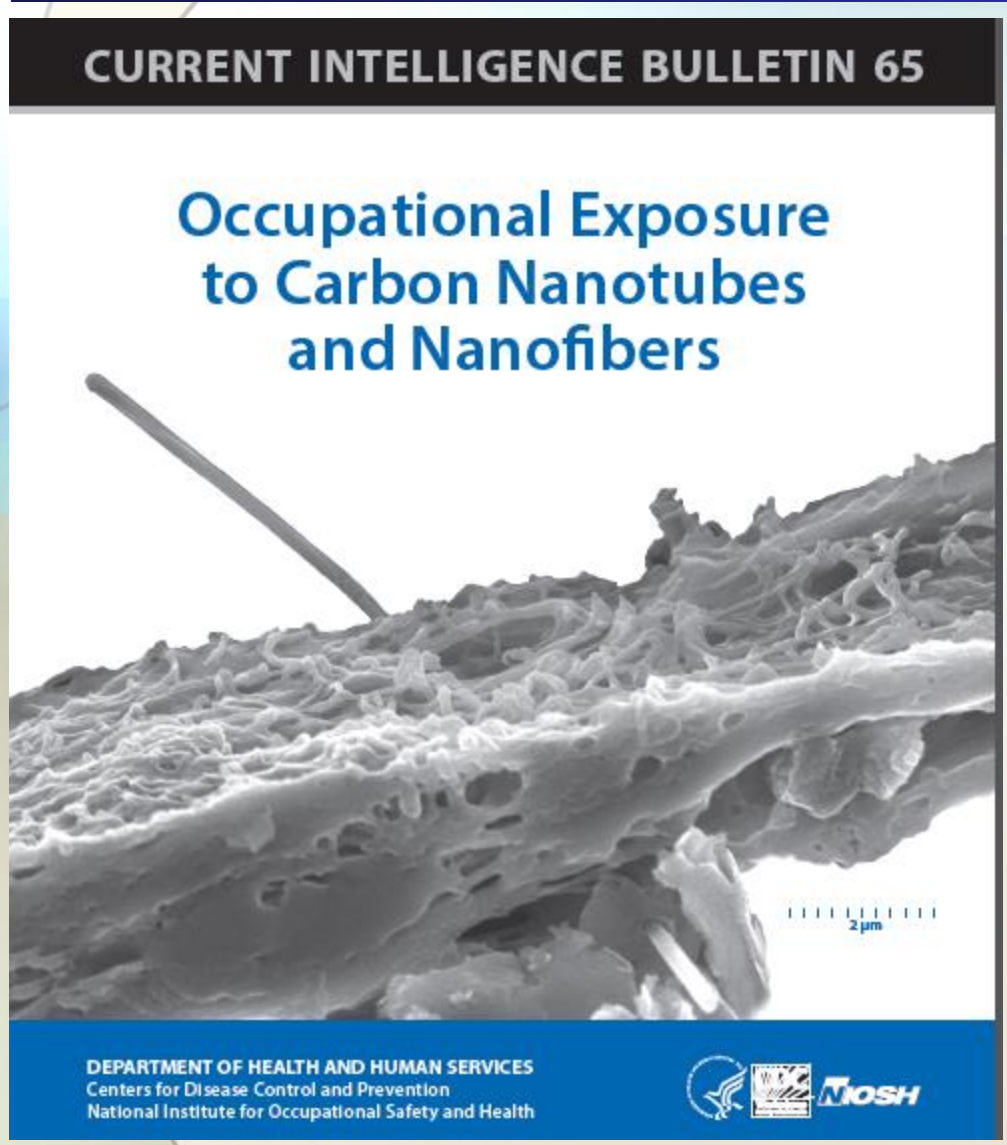


Established in 1871
SMW
Swiss Medical Weekly
Formerly: Schweizerische Medizinische Wochenschrift
The European Journal of Medical Sciences



The number of publications in the field of nanotechnology is increasing exponentially. **The dark grey area in the main graph depicts the publications per year** listed in the ISI Web of Knowledge database (all databases) for the search term “nano”. In the inset, **the light grey area shows the search result for the keyword “nanotoxicology” and the black area the hits for “nanotoxicology AND lung”.**

Swiss Med Wkly. 2013;143:w13758



REL = 1 µg/m^3

REL is based on a mass dose metric

NIOSH Method 5040

Total Elemental Carbon

LOQ = 1 µg/m^3

New Findings on Lung Tumor Formation in Laboratory Mice Exposed to Multi-Walled Carbon Nanotubes; V. Castranova, C. L Geraci, P. Schulte; Society of Toxicology, 2013 Annual Meeting

Mice receiving both the initiator chemical plus exposure to MWCNT were significantly more likely to develop tumors (90% incidence) and have more tumors (an average of 3.3 tumors/mouse lung) than mice receiving the initiator chemical alone (50% of mice developing tumors with an average of 1.4 tumors/lung). Additionally, mice exposed to MWCNT and to MWCNT plus the initiator chemical had larger tumors than the respective control groups. The number of tumors per animal exposed to MWCNT alone was not significantly elevated compared with the number per animal in the controls. **These results indicate that MWCNT can increase the risk of cancer in mice exposed to a known carcinogen. The study does not suggest that MWCNTs alone cause cancer in mice.**

Several earlier studies in the scientific literature indicated that MWCNT could have the potential to initiate or promote cancer. The new NIOSH study is the first to show that MWCNT is a cancer promoter in a laboratory experiment, and reports the growth of lung tumors in laboratory mice following inhalation exposure to MWCNT rather than injection, instillation, or aspiration. Inhalation exposure most closely resembles the exposure route of greatest concern in the workplace. In the study, laboratory mice were exposed to one type of MWCNT through inhalation at a concentration of 5 milligrams per cubic meter of air for five hours per day for a period of 15 days.

Titanium Dioxide Nanoparticles *(Excerpted)*

Hongbo Shi, Ruth Magaye, Vincent Castranova and Jinshun Zhao (Particle and Fibre Toxicology 2013, 10:15)

Gastrointestinal Absorption

TiO2 NPs have also been shown to be absorbed from the GIT (25, 80, and 155 nm). TiO2 NPs may be absorbed through the GIT through the lymphoid tissues surrounding it.

Dermal Absorption

Several studies have investigated dermal penetration by TiO2 NPs with results demonstrating that TiO2 particles did not penetrate viable skin, even though the particle size was less than 100 nm and the SC was damaged. Further observation with **scanning electron microscopy (SEM) showed that although some TiO2 particles had lodged into vacant hair follicles, it did not penetrate the dermis or viable epidermis**.

Pulmonary Absorption

Muhlfeld et al. suggested that a small fraction of TiO2 NPs (20 nm) are transported from the airway lumen of adult male WKY/NCrl BR rats to the interstitial tissue and subsequently released into the systemic circulation. TiO2 NPs also migrated to the alveolar interstitium to a significantly greater extent than TiO2 FPs after either inhalation exposure or intratracheal instillation. Studies by Wang et al. on murine brain reported that intra-nasally instilled TiO2 NPs (80 nm rutile, 155 nm anatase) can be taken up by sensory nerves and translocate to the brain. Even though the inhalation, intratracheal instillation and intranasal studies in regards to pulmonary absorption are few they suggest that **TiO2 NPs can translocate from the lung into the circulatory system to systemic tissue and from the nasal cavity into sensory nerves to the nervous system.** Available data suggest that the rate of NP migration to the circulatory system is low.

Titanium Dioxide Nanoparticles *(Excerpted)*

Hongbo Shi, Ruth Magaye, Vincent Castranova and Jinshun Zhao (Particle and Fibre Toxicology 2013, 10:15)

Acute Toxicity

Studies exposing the pulmonary system to produced both local and systemic symptoms. Research evidence demonstrates that can be absorbed through the lung or GIT into the systemic circulation and then distributed in different organs such as the liver, kidneys, spleen, or even the brain. **Distribution and accumulation of TiO2 NPs in the organs could induce organ injuries and inflammatory responses.**

Chronic Toxicity

TiO2 NPs exhibit moderate toxicity, inducing pulmonary inflammatory response and enhanced proliferation of pulmonary cells at relatively high doses. In all the different study conditions, pulmonary toxicity seems to be a common finding with endpoints of oxidative stress and inflammation.

Titanium Dioxide Nanoparticles *(Excerpted)*

Hongbo Shi, Ruth Magaye, Vincent Castranova and Jinshun Zhao (Particle and Fibre Toxicology 2013, 10:15)

Genotoxicity

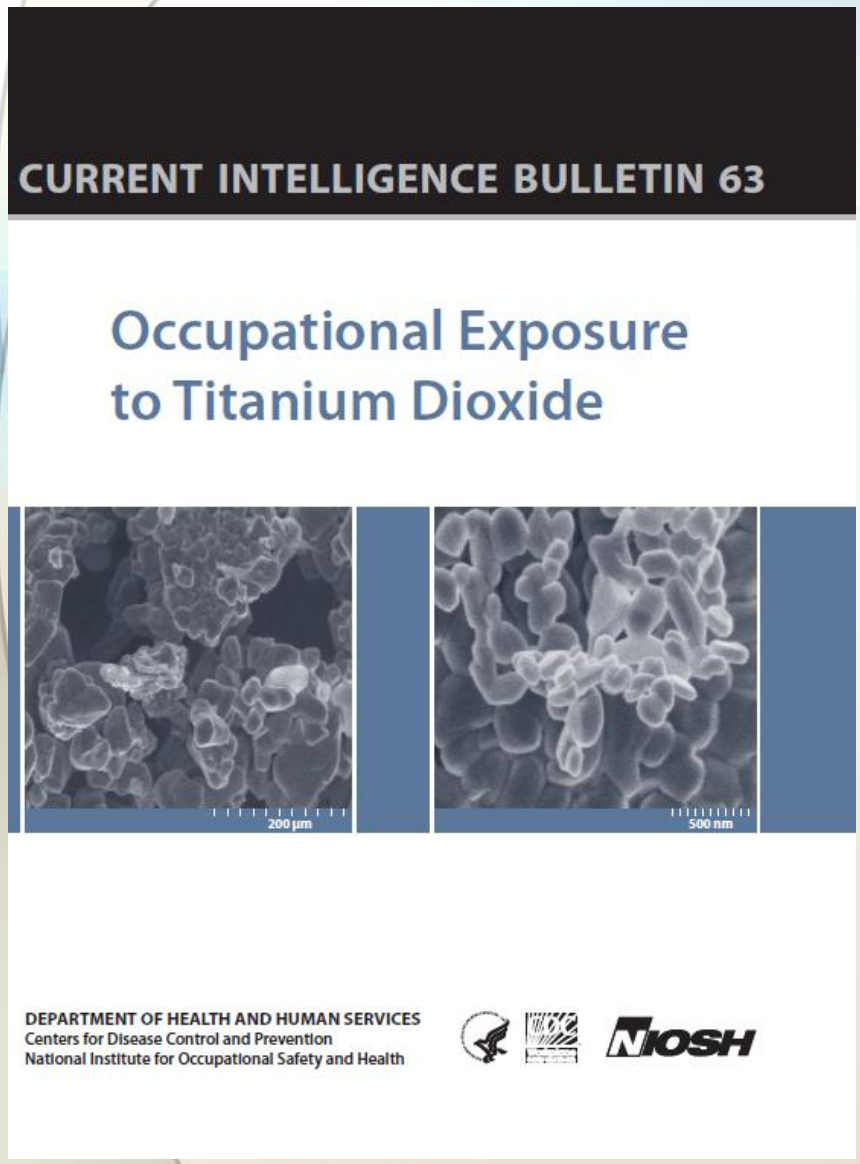
In summary, many in vivo and in vitro studies were conducted to investigate the genotoxicity of TiO2 FPs and NPs, but **results are conflicting**. Some studies indicate that TiO2 NPs are genotoxic, whereas the others give negative results.

Reproductive and developmental toxicity

Although experimental evidence shows that absorbed TiO2 particles may be able to move across the placenta into fetal tissue, **it has not yet been established whether human exposure to TiO2 particles causes reproductive and developmental toxicities.**

Carcinogenicity

Pulmonary studies support the carcinogenicity of TiO2 NPs in pulomary studies. However, exposure modes such as intragastric or dermal exposure do not indicate that TiO2 NPs are carcinogenic.



REL = 2.4 mg/m^3 for Fine Aerosols (0.1 µm – 3 µm)

REL = 0.3 mg/m^3 for Ultrafine Aerosols (<0.1 µm)

REL is based on a 10-hr TWA

NIOSH Method 0600

Respirable Aerosol Sampling

National Institute for Occupational Safety and Health NIOSH

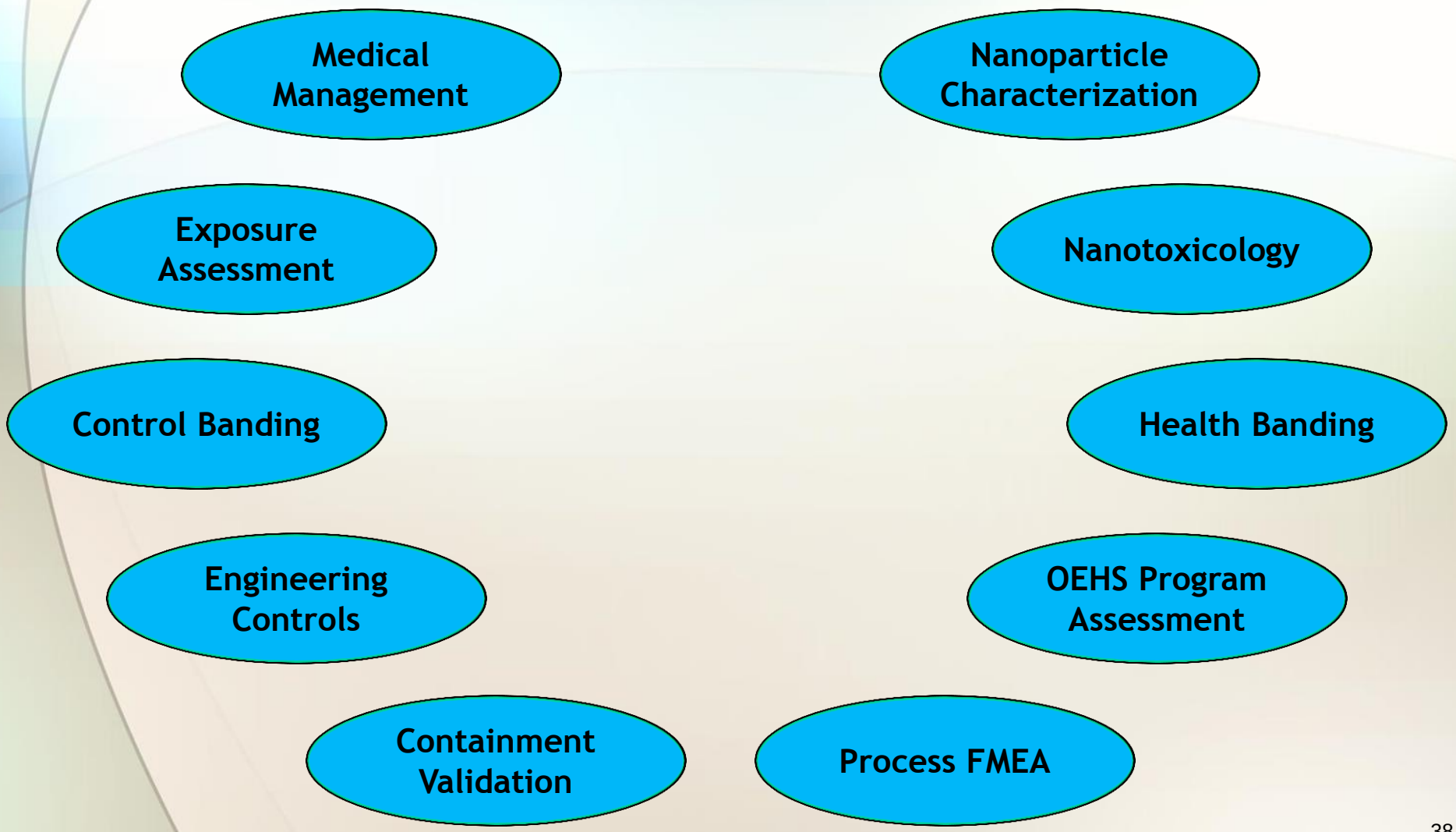
Key Toxicological Findings

Pulmonary Exposure To:

- SWCNT's Causes Rapid and Persistent Fibrosis in Mice
- MWCNT's Can Reach the Intrapleural Space in Mice (Site of Mesothelioma for Asbestos)
- SWCNT's Can Interfere With Cell Division (In Petri Dish)
- Certain Nanoparticles (SWCNT's or TiO_2) Can Cause Cardiovascular Dysfunction
- MWCNT's or TiO_2 Nanowires can Induce Inflammatory Mediators in Certain Regions of the Brain

Courtesy of Laura Hodson, MSPH, CIH; NIOSH; May, 2013 AIHce, PDC 418
"Occupational Exposure Assessment in the Nanotechnology Industry"

Nanomaterial OEHS Lifecycle



Health Banding:

nanoTox Categorization is a logical system of classifying nanoparticles whereby each species of interest is placed into a health band based upon its ability to cause biophysical harm, Recommended Exposure Level, or other toxicological properties. The data utilized for deriving this assessment are acquired from a professional review of the current toxicological literature and summarizes available knowledge as of the date of reporting.

The study typically offers the following toxicological information:

Common Applications and Environments
Physicochemical Properties
Environmental and Toxicological Mode(s)/Mechanism(s) of Action
Toxicokinetics
Human Health Effects Summary
Animal Toxicology Summary
Recommended Exposure Limit (REL)
Industrial Hygiene Sampling and Analytical Method
Medical Surveillance
Environmental Fate and Effects
Categorization
References

nanoTox Categorization – GHS Compliant

Criteria	Nanomaterial Categorization				
	E (5)	D (4)	C (3)	B (2)	A (1)
REL	< 1 μg/m³	1 to < 10 μg/m³	10 to <100 μg/m³	0.10 to <1 mg/m³	>1 mg/m³
Acute Toxicity - Oral	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Acute Toxicity - Dermal	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Acute Toxicity - Inhalation	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Aspiration Hazard	Moderate to Severe			None to Moderate	
Corrosion/Irritation - Skin	Extreme	Severe to Extreme	Moderate to Severe	None to Moderate	None
Corrosion/Irritation - Eye	Severe to Extreme		Moderate	None to Moderate	
Respiratory Sensitization	Severe to Extreme		Moderate	None to Moderate	
Skin Sensitization	Severe to Extreme		Moderate	None to Moderate	
Germ Cell Mutagenicity	Severe		Yes	None	
Carcinogenicity	Defined Medical Case Studies		Suspected-Confirmed Animal	Negative	
Reproductive Toxicity - Fertility	Moderate to Known (Lactation)		Slight to Moderate	None to Slight	
Reproductive Toxicity - Development	Moderate to Known		Slight to Moderate	None to Slight	
Specific Target Organ Toxicity - Single Dose:	Severe to Extreme		Mild to Severe	None to Mild	
Specific Target Organ Toxicity - Repeated Dose:	Moderate to Severe			None to Moderate	

8. Ma-Hock L, Treumann S, Strauss V, ... Ravenzwaay B, Landsiedel R [2009] ... exposed for 3 months. Toxicolo...

9. Kagan VE, Konduru N... Yanamala N, Kapralo... Klein-Seetharaman... neutrophil inv... DOI:10.10...

10

1. ... lish. Respi...

13(c). Eye. Moss CE, W... the subpleural ...

14. British Standar... manufactured nanom...

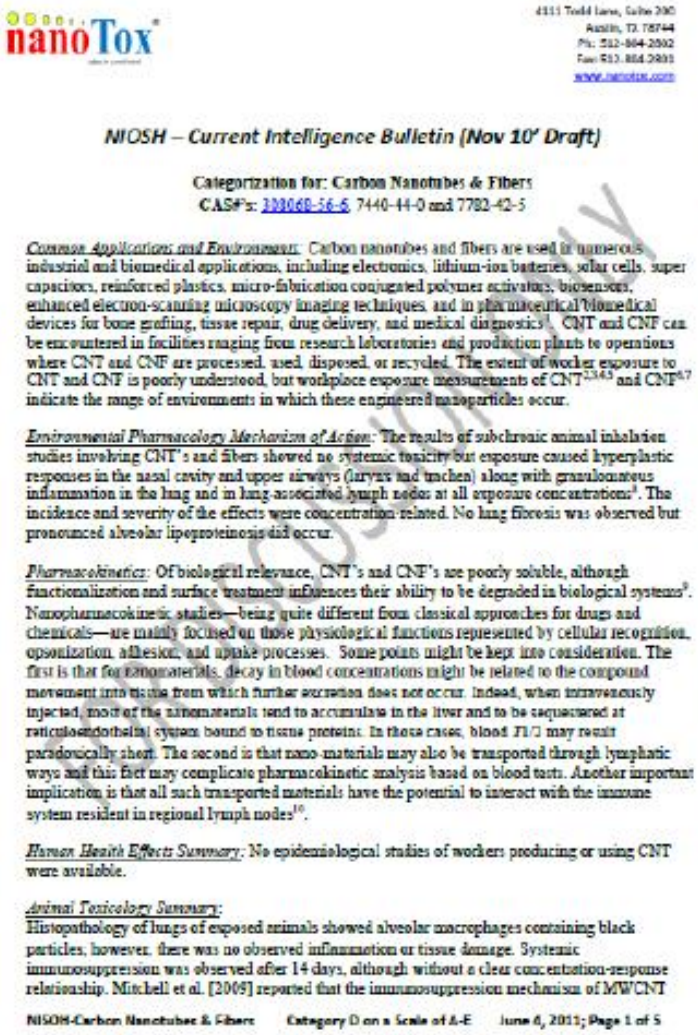
15. Bayer MaterialScience. Bayer MaterialScience. http...

16. Nanocyl (2009) Responsible ... European Responsible Care Confer... cefic.be/Files/Downloads/04_Nanocy...

17. IEA (2009) Criteria for assessment of ... http://www.cpsv.de/ita/en/tic/nanoparticle/...

18. NIOSH [1977]. Occupational exposure samp... Department of Health, Education, and Welfare. Pu... National Institute for Occupational Safety and Health.

19. Leidel NA, Busch KA [1994]. Statistical design and a... Harris RL, Cralley LJ, Cralley LV, eds. Patty's Industrial H... Part A. New York, NY: John Wiley and Sons, Inc. pp. 453-58...



nanoTox

4111 Todd Lane, Suite 200
Austin, TX 78744
Ph: 512-864-2002
Fax: 512-864-2001
www.nanotox.com

NIOSH – Current Intelligence Bulletin (Nov 10' Draft)

Categorization for: Carbon Nanotubes & Fibers
CAS#'s: 308068-56-6, 7440-44-0 and 7782-42-5

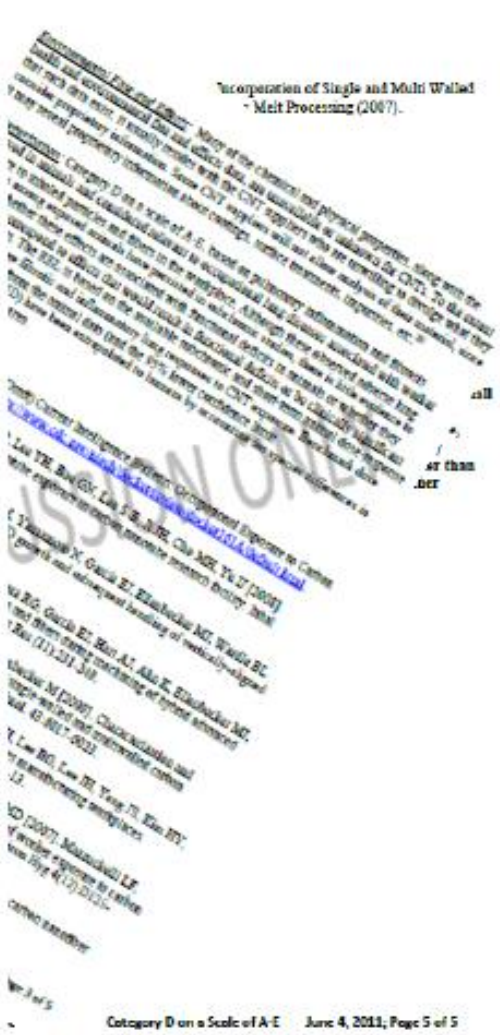
Common Applications and Environment: Carbon nanotubes and fibers are used in numerous industrial and biomedical applications, including electronics, lithium-ion batteries, solar cells, super capacitors, reinforced plastics, micro-fabrication conjugated polymer actuators, biosensors, enhanced electron-scanning microscopy imaging techniques, and in pharmaceutical/biomedical devices for bone grafting, tissue repair, drug delivery, and medical diagnostics[1]. CNT and CNF can be encountered in facilities ranging from research laboratories and production plants to operations where CNT and CNF are processed, used, disposed, or recycled. The extent of worker exposure to CNT and CNF is poorly understood, but workplace exposure measurements of CNT[2,3,4,5] and CNF[6,7] indicate the range of environments in which these engineered nanoparticles occur.

Environmental Pharmacology Mechanism of Action: The results of subchronic animal inhalation studies involving CNT's and fibers showed no systemic toxicity but exposure caused hyperplastic responses in the nasal cavity and upper airways (larynx and trachea) along with granulomatous inflammation in the lung and in lung-associated lymph nodes at all exposure concentrations[8]. The incidence and severity of the effects were concentration-related. No lung fibrosis was observed but pronounced alveolar lipoproteinosis did occur.

Pharmacokinetics: Of biological relevance, CNT's and CNF's are poorly soluble, although functionalization and surface treatment influences their ability to be degraded in biological systems[9]. Nanopharmacokinetic studies—being quite different from classical approaches for drugs and chemicals—are mainly focused on those physiological functions represented by cellular recognition, opsonization, adhesion, and uptake processes. Some points might be kept into consideration. The first is that for nanomaterials, decay in blood concentrations might be related to the compound movement into tissue from which further excretion does not occur. Indeed, when intravenously injected, most of the nanomaterials tend to accumulate in the liver and to be sequestered at reticuloendothelial system bound to tissue proteins. In these cases, blood $T1/2$ may result paradoxically short. The second is that nano-materials may also be transported through lymphatic ways and this fact may complicate pharmacokinetic analysis based on blood tests. Another important implication is that all such transported materials have the potential to interact with the immune system resident in regional lymph nodes[10].

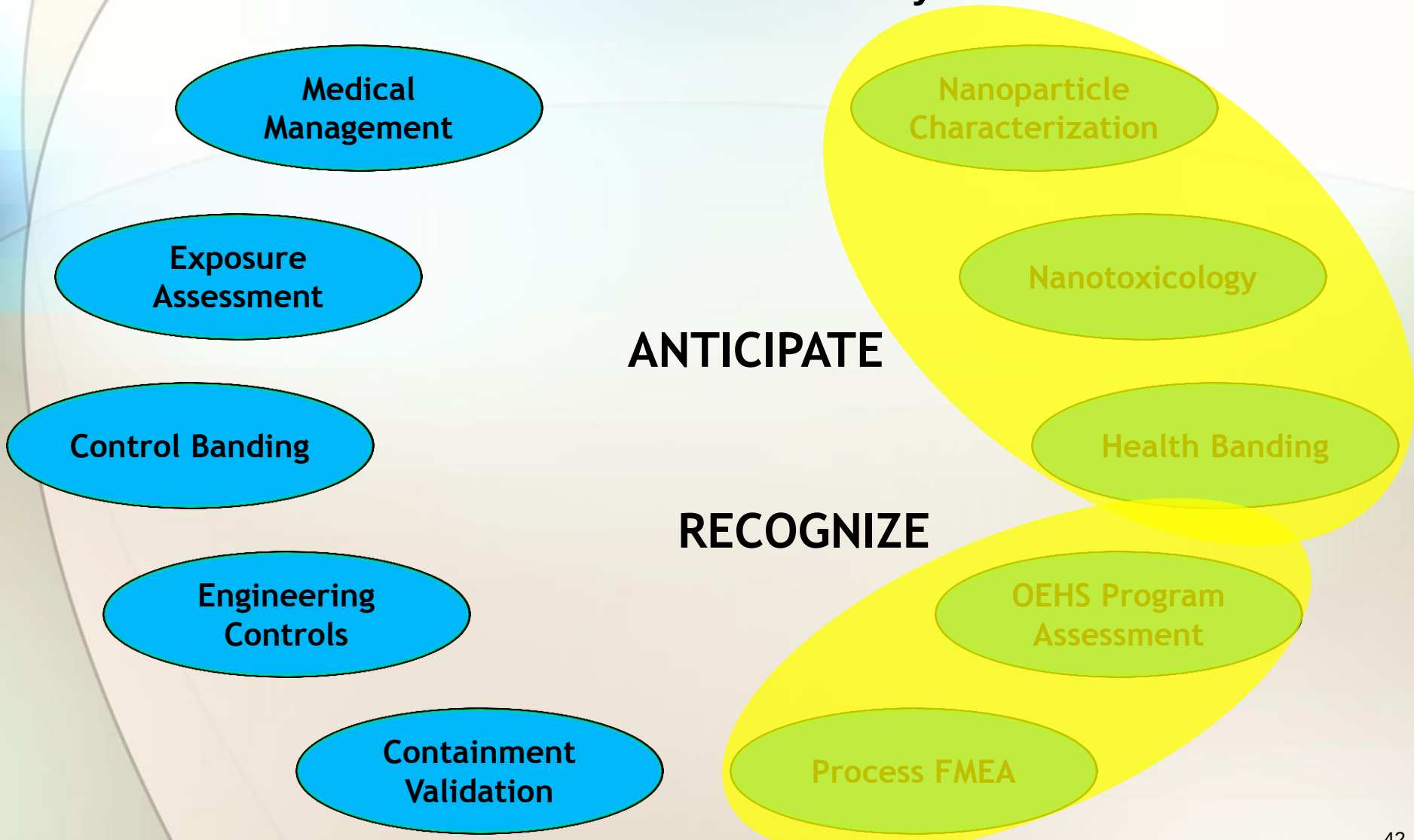
Human Health Effects Summary: No epidemiological studies of workers producing or using CNT were available.

Animal Toxicology Summary:
Histopathology of lungs of exposed animals showed alveolar macrophages containing black particles, however, there was no observed inflammation or tissue damage. Systemic immunosuppression was observed after 14 days, although without a clear concentration-response relationship. Mitchell et al. [2009] reported that the immunosuppression mechanism of MWCNT



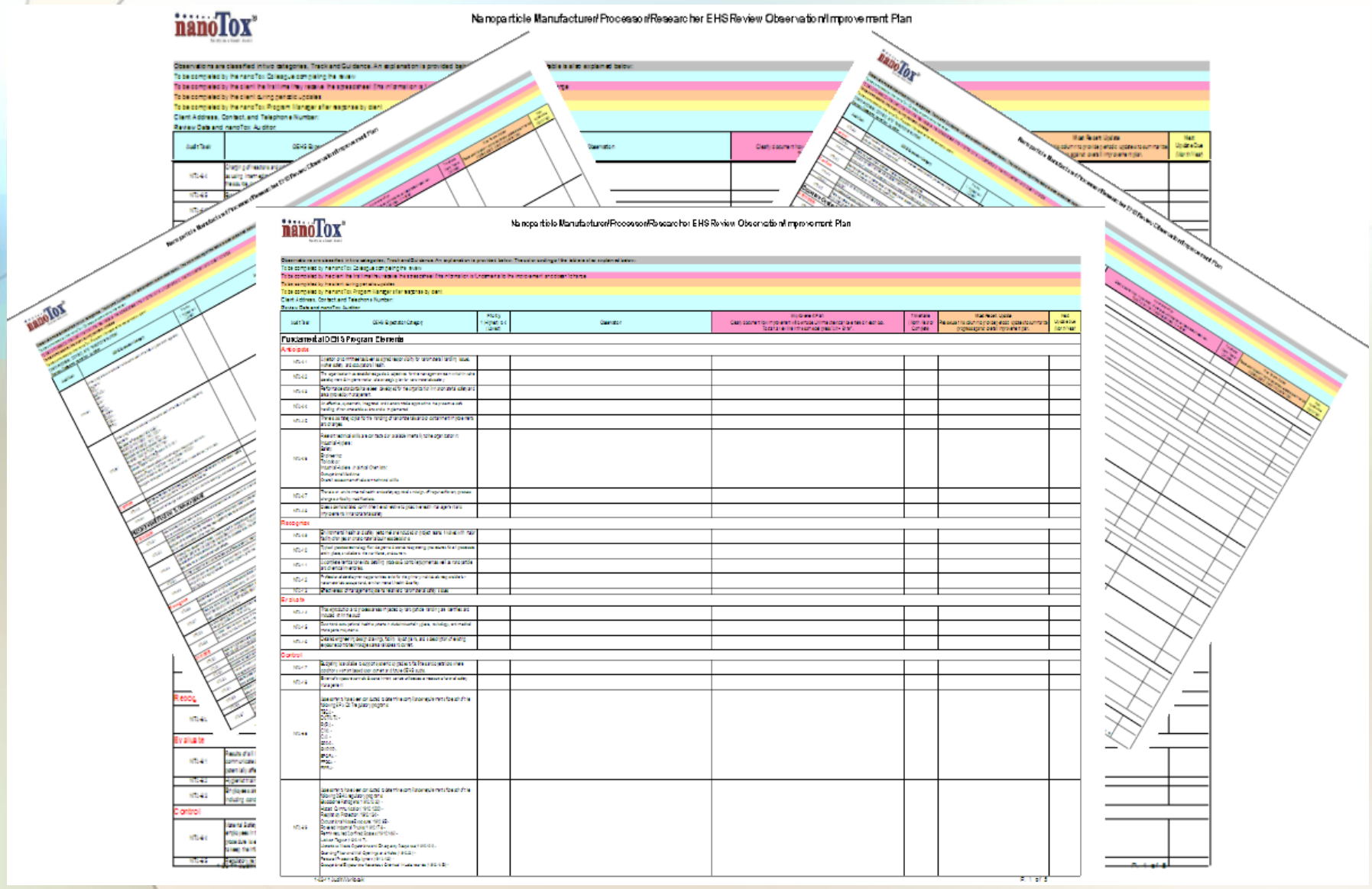
...ncorporation of Single and Multi Walled ... Melt Processing (2007).

Nanomaterial OEHS Lifecycle



OEHS Program Assessment:

- Designed to Minimize Burden and Expedite Evaluation
  - *Based on Interviews and OEHS Program Experience*
  - *Minimizes Cost by Fast-Tracking the Assessment Process*
  - *Provides Cliental With OEHS Resources Needed for Compliance*
- Utilizes a Comprehensive OEHS Assessment Process
  - Fundamental OEHS Program Elements *(XX Facets)*
  - Hazard Identification & Evaluation *(XX Facets)*
  - Exposure Containment & Control *(XX Facets)*
  - Communication, Education & Training *(XX Facets)*
- Yields a Living OEHS Program (HASP Compliant)
  - Client Updateable as Program Changes are Implemented

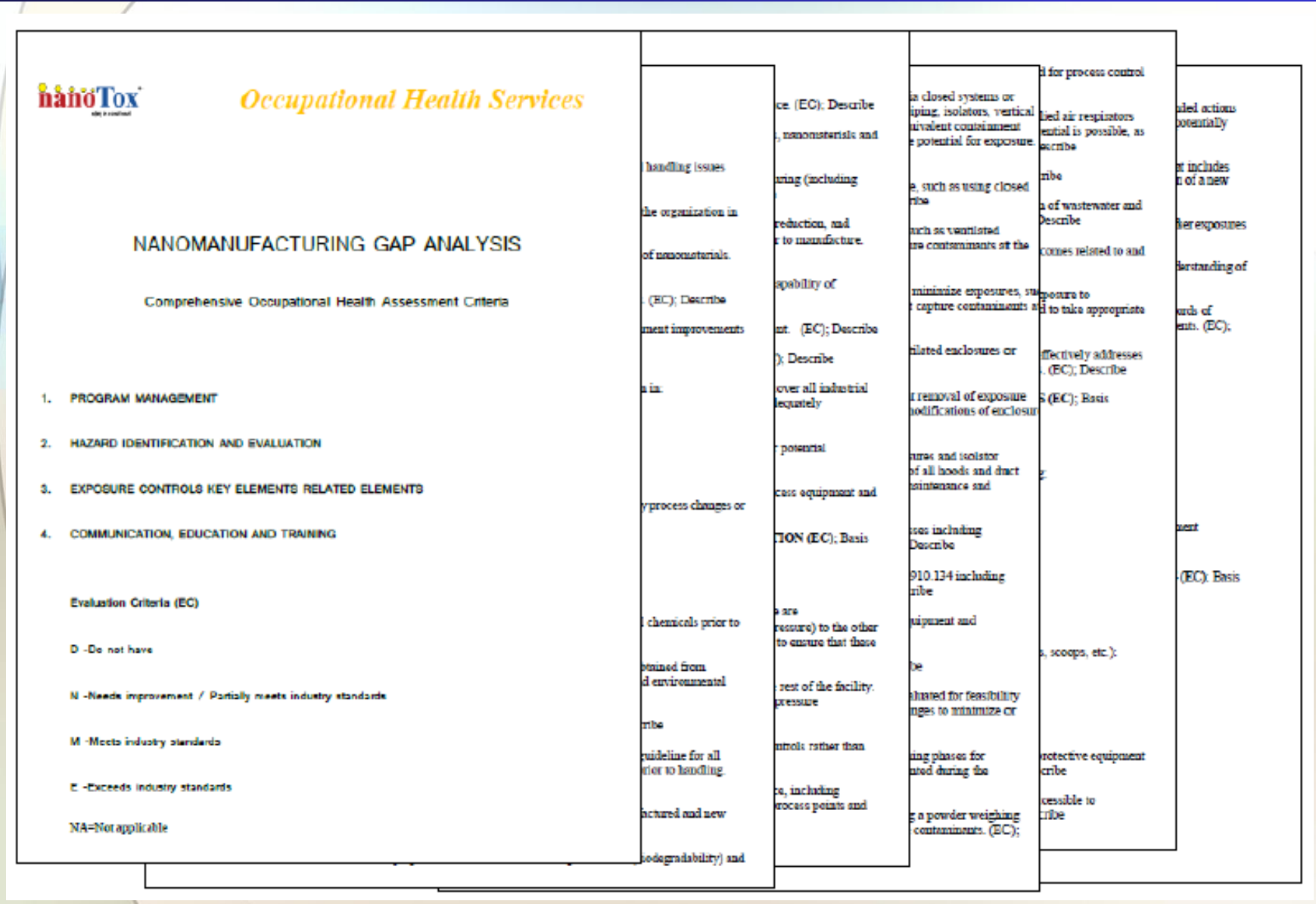

nanoTox
Nanoparticle Manufacturer/Processor/Researcher EHS Review Observation/Improvement Plan
Functional OEHS Program Elements
Anticipate
Recognize
Evaluate
Control

nanoTox OEHS Assessment Services

- Fundamental OEHS Program Elements
  - *Is there a demonstrated commitment to OEHS?*
  - *Does a viable and robust OEHS program exist?*
  - *Is regulatory compliance more than a day-to-day requirement?*
  - *Do OEHS initiatives have senior management participation?*
- Hazard Identification and Evaluation
  - *Does information exists relative to environmental fate & effect?*
  - *Is appropriate technology implemented to minimize exposure?*
  - *Do health surveillance programs exist and are they sufficient?*
  - Are all processes defined by TWA's exposure levels?

nanoTox OEHS Assessment Services

- Exposure Containment & Control
  - *Do exposure controls consistently rely on engineering practices?*
  - *Are facilities in place to contain and control exposures?*
  - *Do preventative maintenance & change control programs exist?*
  - *Are worker exposures continuously monitored and controlled?*
- Communication, Education & Training
  - *Is training at the appropriate levels available and provided?*
  - *Do changes in process controls occur based on exposure?*
  - *Is there employee engagement in OEHS at all levels?*
  - *Are exposure and medical monitoring results communicated?*



nanoTox

Occupational Health Services

NANOMANUFACTURING GAP ANALYSIS

Comprehensive Occupational Health Assessment Criteria

1. PROGRAM MANAGEMENT
2. HAZARD IDENTIFICATION AND EVALUATION
3. EXPOSURE CONTROLS KEY ELEMENTS RELATED ELEMENTS
4. COMMUNICATION, EDUCATION AND TRAINING

Evaluation Criteria (EC)

D -Do not have

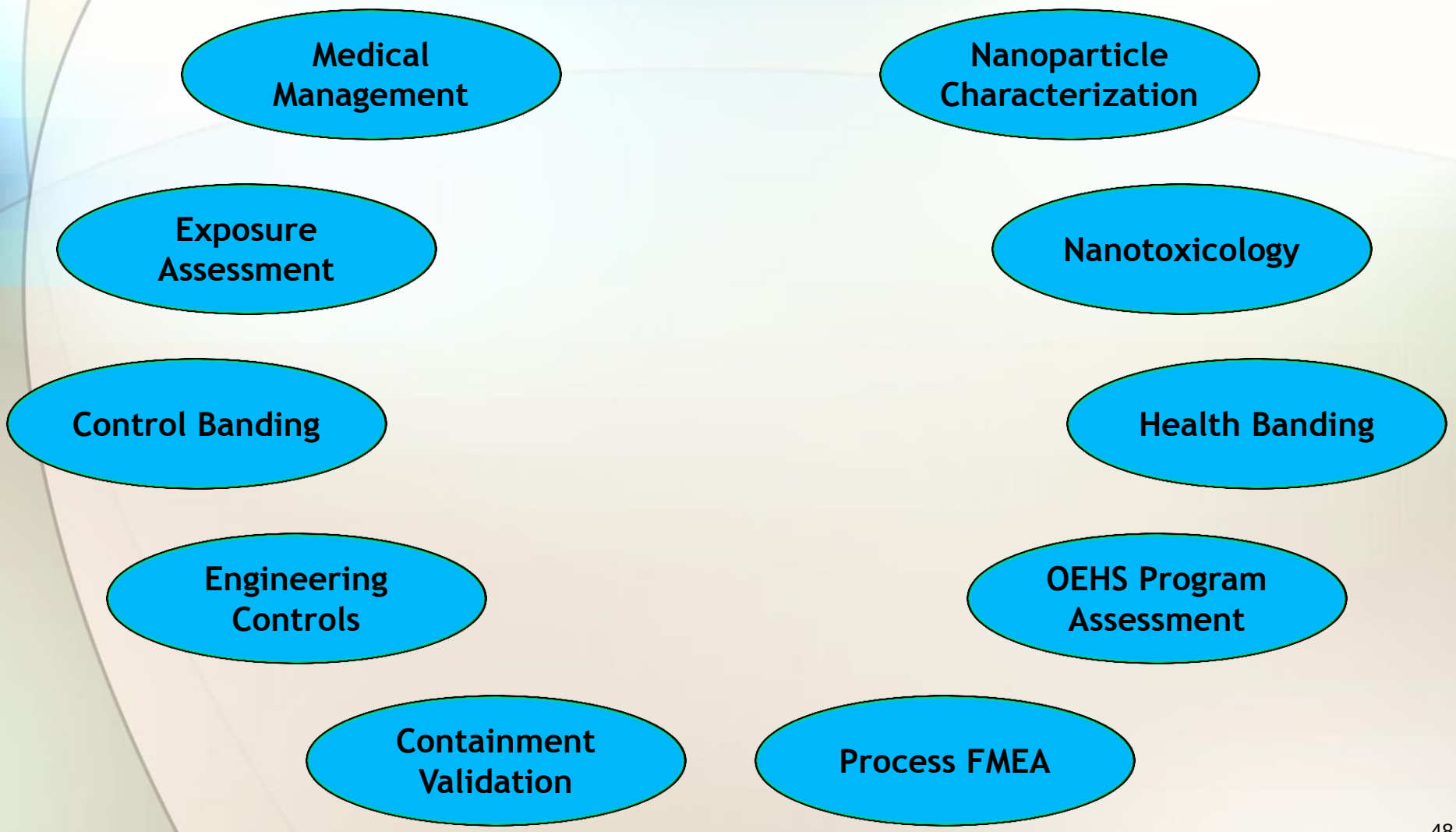
N -Needs improvement / Partially meets industry standards

M -Meets industry standards

E -Exceeds industry standards

NA=Not applicable

Nanomaterial OEHS Lifecycle



Process Characteristics that Affect Exposure

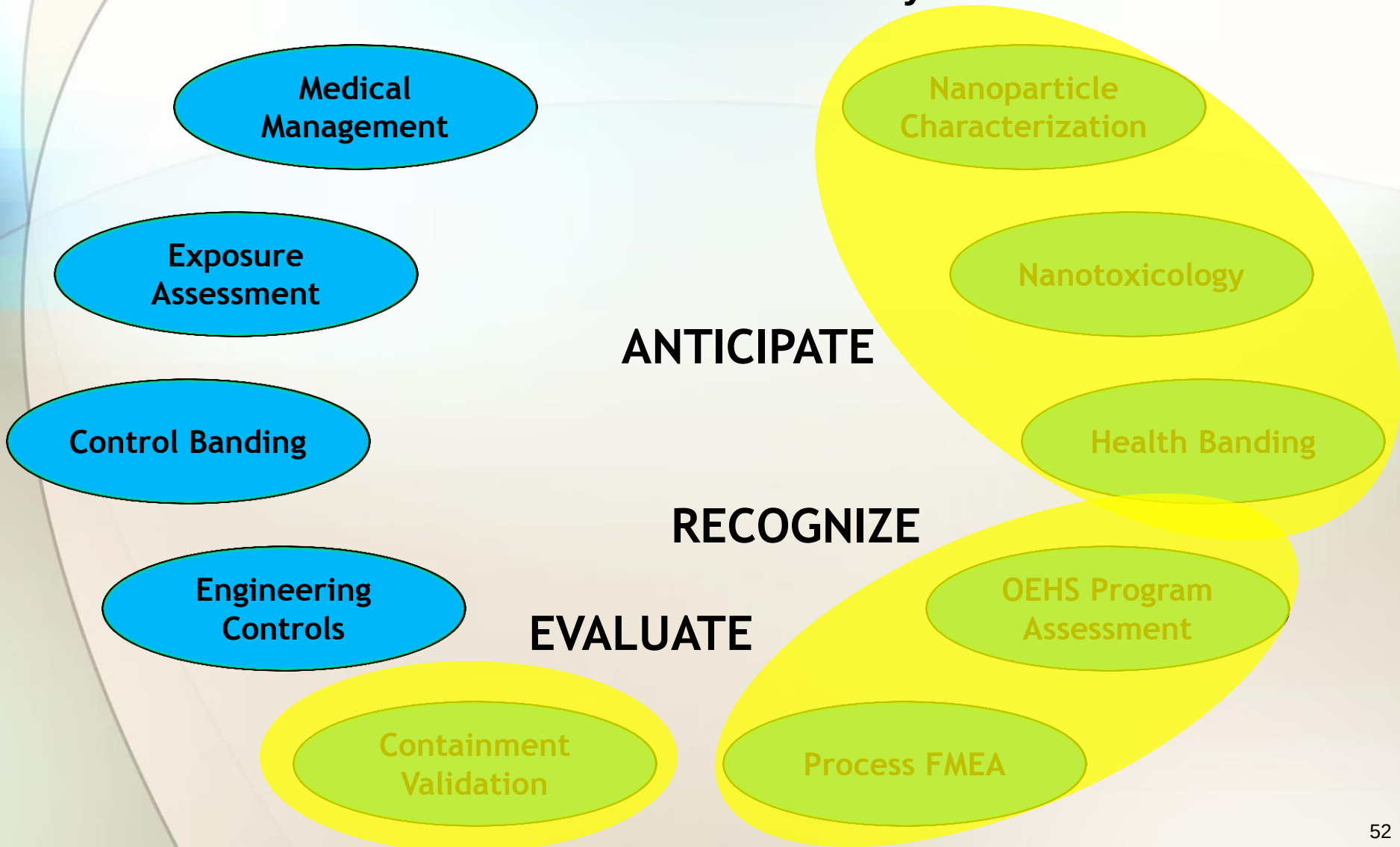
Less	Action	More
Closed	Operation	Open
Low Energy / Velocity	Process	High Energy / Velocity
Low Δ p/ Temp	Pressure	High Δp/Temp
None	Transfers	Multiple
Well	Training	Poorly
None Required	Operator Skill	Highly Dependent
Routine	Task Type	Non Routine
Short	Duration	Long
One Operation	Frequency	Multiple Operation

Sèvres - Cité de la céramique *(Founded in 1738)*

Facility Characteristics that Affect Exposure

Better	Feature	Worse
- Ve to Corridor	Pressure	+ Ve to Corridor
Two stage + Ve buffer	Airlock	Single stage no buffer
Isolator	ECM	LEV
HEPA Terminals	Filtration	No HEPA
Away from Access	Airflow	Towards Access

Nanomaterial OEHS Lifecycle



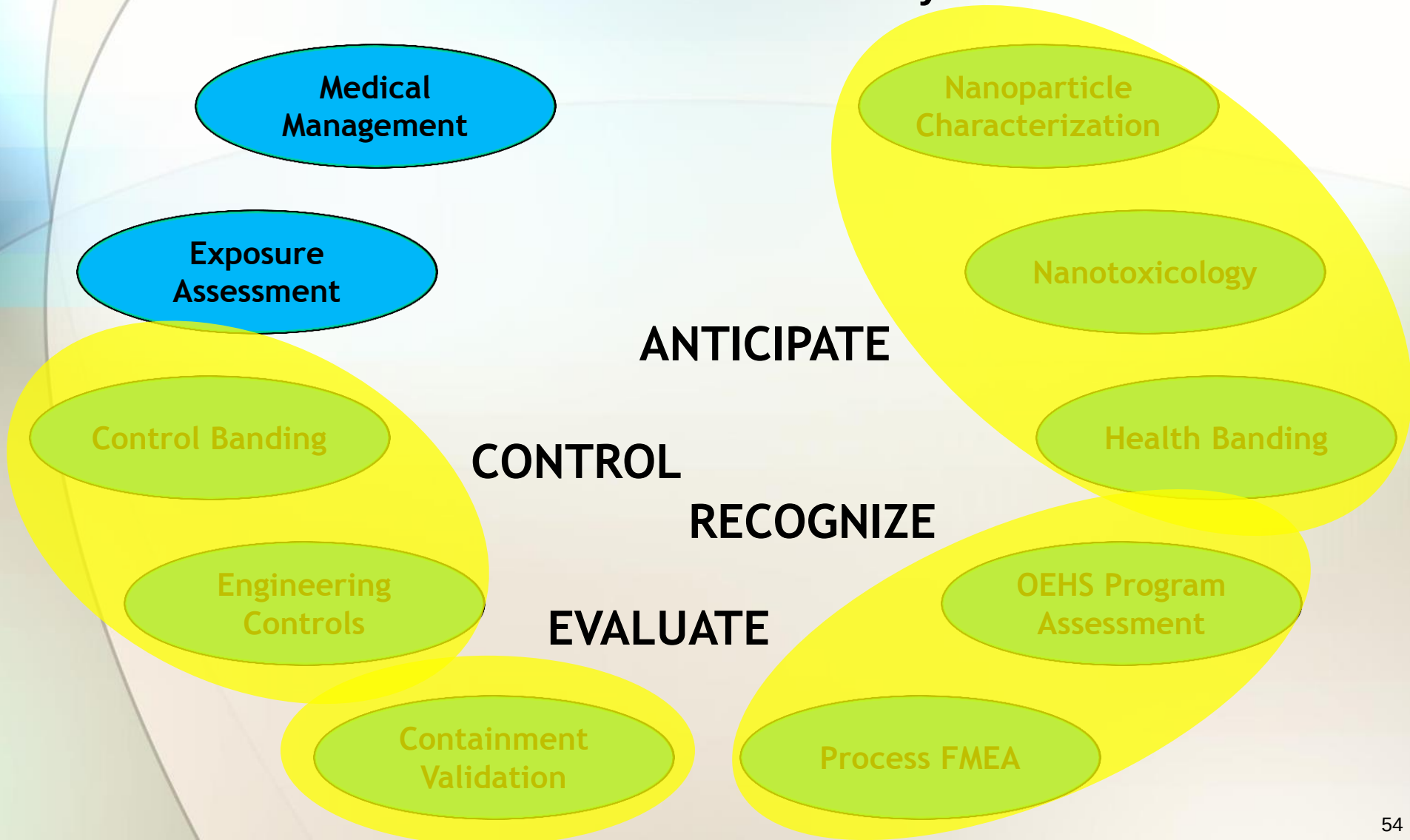
Containment Validation

Validation refers to establishing documented evidence that a process or system, when operated within established parameters, can contain contaminants effectively and reproducibly to assure the protection of workers who may interact with the system.

Containment, by definition, is the action of preventing a hostile force from expanding into other areas. In the nanotechnology arena, this takes on significant proportions, particularly in processing and laboratory environments, extending to the very fundamentals of building design, validation and process management, and determining the success of pivotal research and development (R&D) projects.

Containment encompasses the procedural steps required to manage nanomaterials within a known and fixed parameter; this includes the measures employed to prevent both the release of these agents, which often present a hazard to the surrounding environment, and the ingress of contaminants into a sensitive and controlled process.

Nanomaterial OEHS Lifecycle



Protecting your laboratory environment
LABCONCO

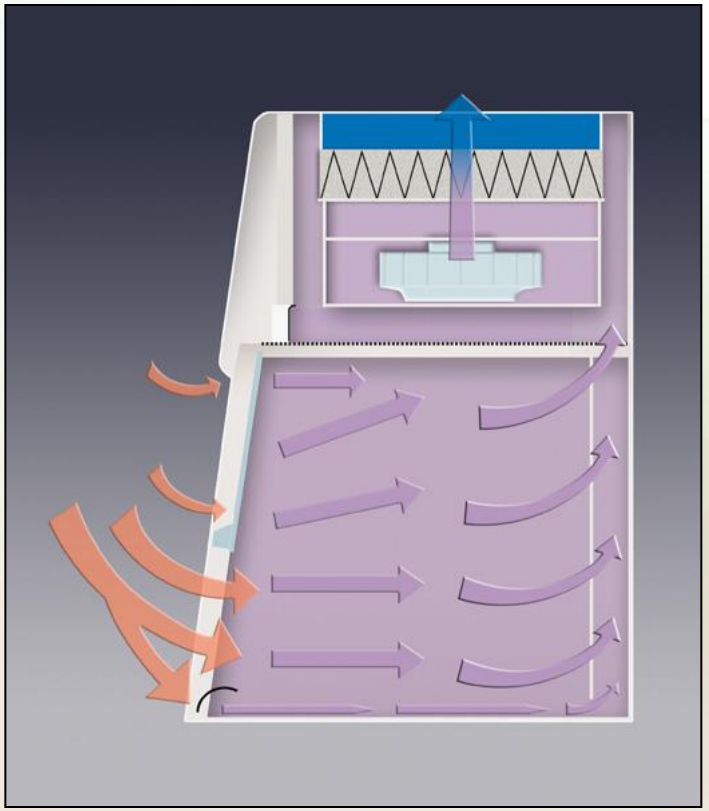
nanoTox
safety in a small world

Low-Flow Ventilated Balance Enclosure *(XPert® Nano)*

- Provides user protection
- Safe containment of hazardous powders, particulates and materials during nanomaterial manipulation
- Completely stainless interior is used for static dissipating properties.
- Optional Ionizer for static dissipation on instruments, utensils, etc placed inside of the unit

Common Functionality

- Turbulence is the ***enemy*** of containment
- Performance enhancing features
  - Upper Air Dilution
  - Side entry air foils
  - Clean-Sweep™ Air Foil
  - Upper containment sash foil
  - Patented Rear Baffle
- Interfering Air currents
  - Placement of the equipment
  - Alternate sources (humans)



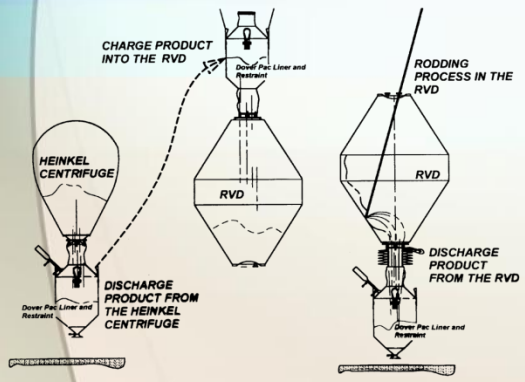
Engineering Controls:

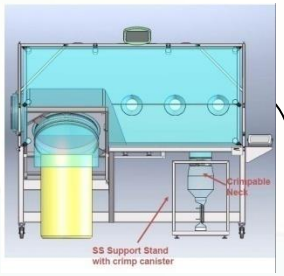
Courtesy of Laura Hodson, MSPH, CIH; NIOSH, 2010
"Engineering Case Studies: Nanomaterials"

The Role Of Flexible Technologies In Absolute Containment

Toxicology, Industrial Hygiene & Medical Management

Evolution of Engineered Controls



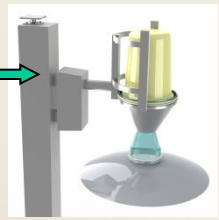


Pharma

Nano

1997 — 2006 — Today

BioPharm



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Flexible Technologies may be new to Nanotech but, it has been in use for decades in other industries:

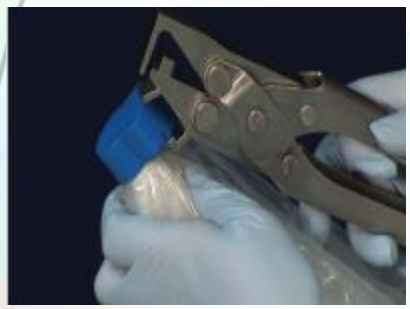
Semiconductor – Used for small scale development

Space Program/Military/CDC – Space Suit, landing systems, inflatable solar collection grids, field collection and isolation systems, fuel tanks, dismantling chemical and biological weapons

Asbestos/Mold Abatement & HAZMAT– Flexible systems to isolate and remove.

Nuclear - Flexible systems to allow maintenance and removal.

Crimp Removal Tool in Action



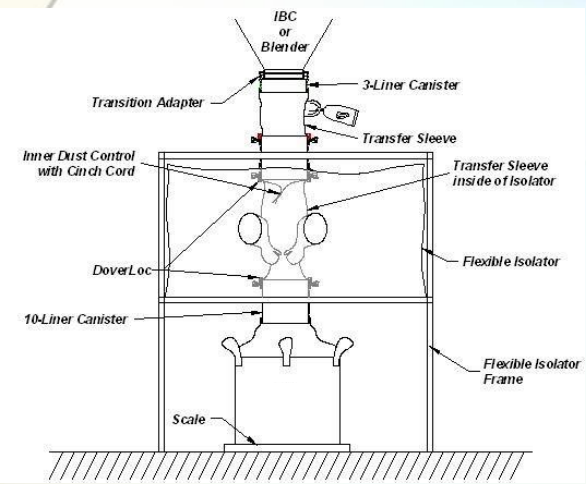
Flexible Containment Performance – Pharma Industry Experience

Method	Operation	Personal (micrograms/m³)	Area (micrograms/m³)
ILC Dover Pac & Crimp System	Reactor Charging	0.8 - 23 Mean 4.6	0.01- 0.9
Continuous Liner (ILC Crimp System)	Blender Discharge in a Pack Out Booth	0.4 + 0.3	0.42 + 0.08
Continuous Liner (ILC Crimp System)	Conical Dryer Discharge in a Pack Out Booth	0.12 + 0.08	0.10 + 0.04
Continuous Liner (ILC Crimp System)	Discharging and Sampling from Cone Mill a Pack Out Booth with Door fitted with Glove Ports	> 0.05	> 0.05
Bagging in/out (ILC Crimp System)	Loading Isolator, Milling, and Sampling	> 0.05*	> 0.05

Airborne Concentrations (TWA / Time of Operation)

Courtesy of ISPE; The Role Of Flexible Technologies In Containment; *Presented by Hari Floura, President; Floura, LLC*

Process Containment



Dual Neck FIBC Vessel Offload

Isolator Offload

Lab Enclosures

Enclosure and
Continuous Liner offload

Enclosed Granulator

Fluid Bed Processor

63

Containment Results (SMEPAC Protocols)

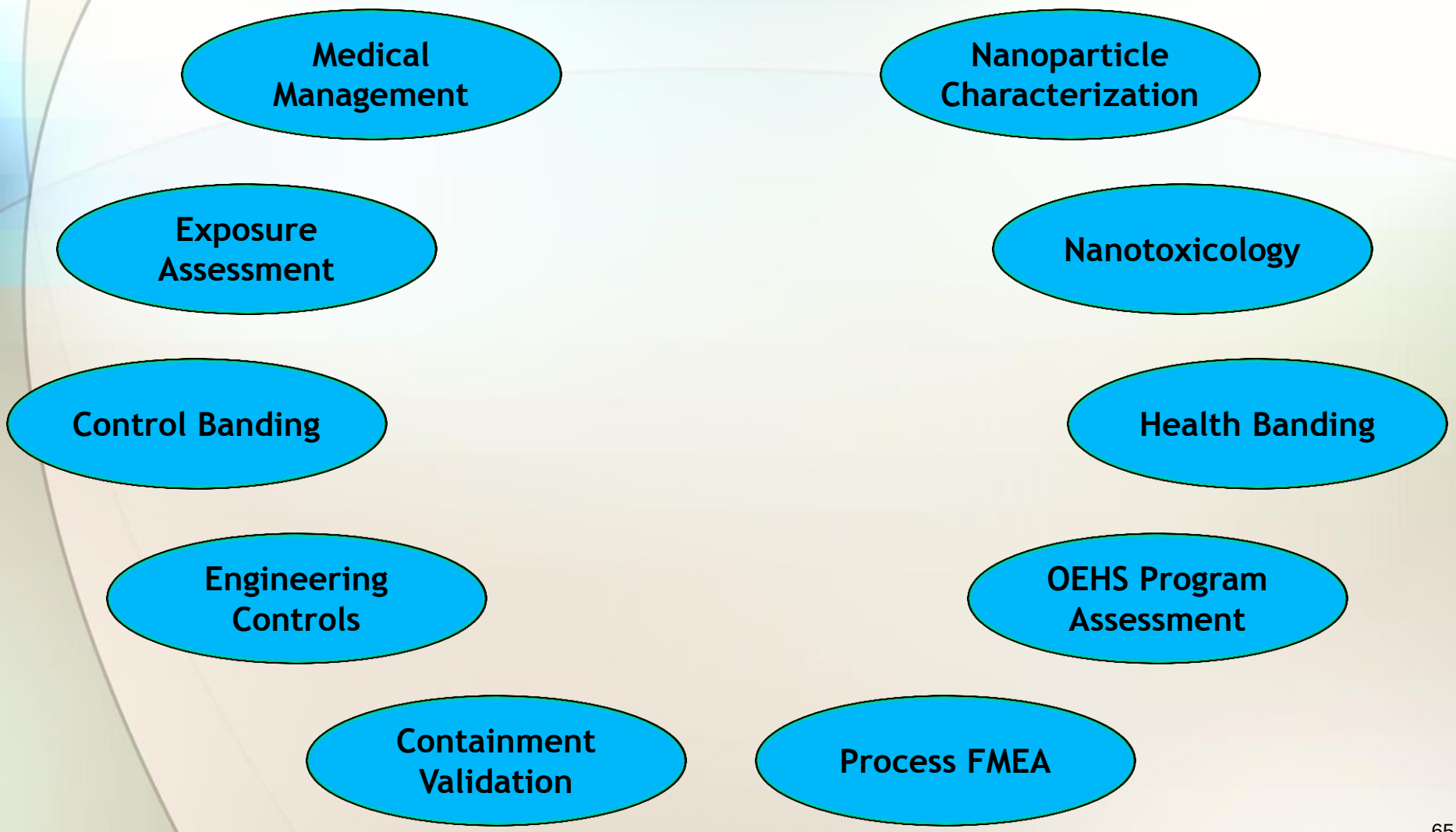
ILC Dover Enclosure System	Test Material	OBZ	*OBZ-TWA ($\mu g/m^3$)	Comment (No. of operators)
Granulator	Lactose	0.1120-0.0108	0.0026-0.0027	Operation (2)
Granulator	Lactose	0.0247-0.3000	0.0027-0.0331	Cleaning (2)
Drying Oven	Lactose	0.0395-0.0416	0.0026-0.0028	Operation (2)
Drying Oven	Lactose	0.0142-0.0630	0.0026-0.0037	Cleaning (3)

Granulator

Tray Dryer

64

Nanomaterial OEHS Lifecycle



Control Banding:

* *Control Banding is a complementary approach to protecting worker health by focusing resources on exposure controls.* Since it is not possible to assign a specific Occupational Exposure Limit to every chemical in use, a chemical is assigned to a "band" for control measures, based on its health hazard categorization, the amount of chemical in use, and its volatility/dustiness.

* *The outcome is one of four recommended control strategies:*
  - *Employ good industrial hygiene practice*
  - *Use local exhaust ventilation*
  - *Enclose the process*
  - *Seek the advice of a specialist*

* *Industrial hygiene expertise is not replaced - specific operating knowledge and professional judgment are required for implementation of the best "reasonably practicable" combination of controls to minimize risks to workers.*

Traditional "Control Banding" Systems

	Low Dustiness	Medium Dustiness	High Dustiness
Hazard Group A			
Small	1	1	1
Medium	1	1	2
Large	1	2	2
Hazard Group B			
Small	1	1	1
Medium	1	2	2
Large	1	3	3
Hazard Group C			
Small	1	1	2
Medium	2	3	3
Large	2	4	4
Hazard Group D			
Small	2	2	3
Medium	3	4	4
Large	3	4	4
Hazard Group E			
For all hazard group E substances, choose control approach 4			

Parameters

Amount Used

Dustiness

Hazard Group (R-Phrase)

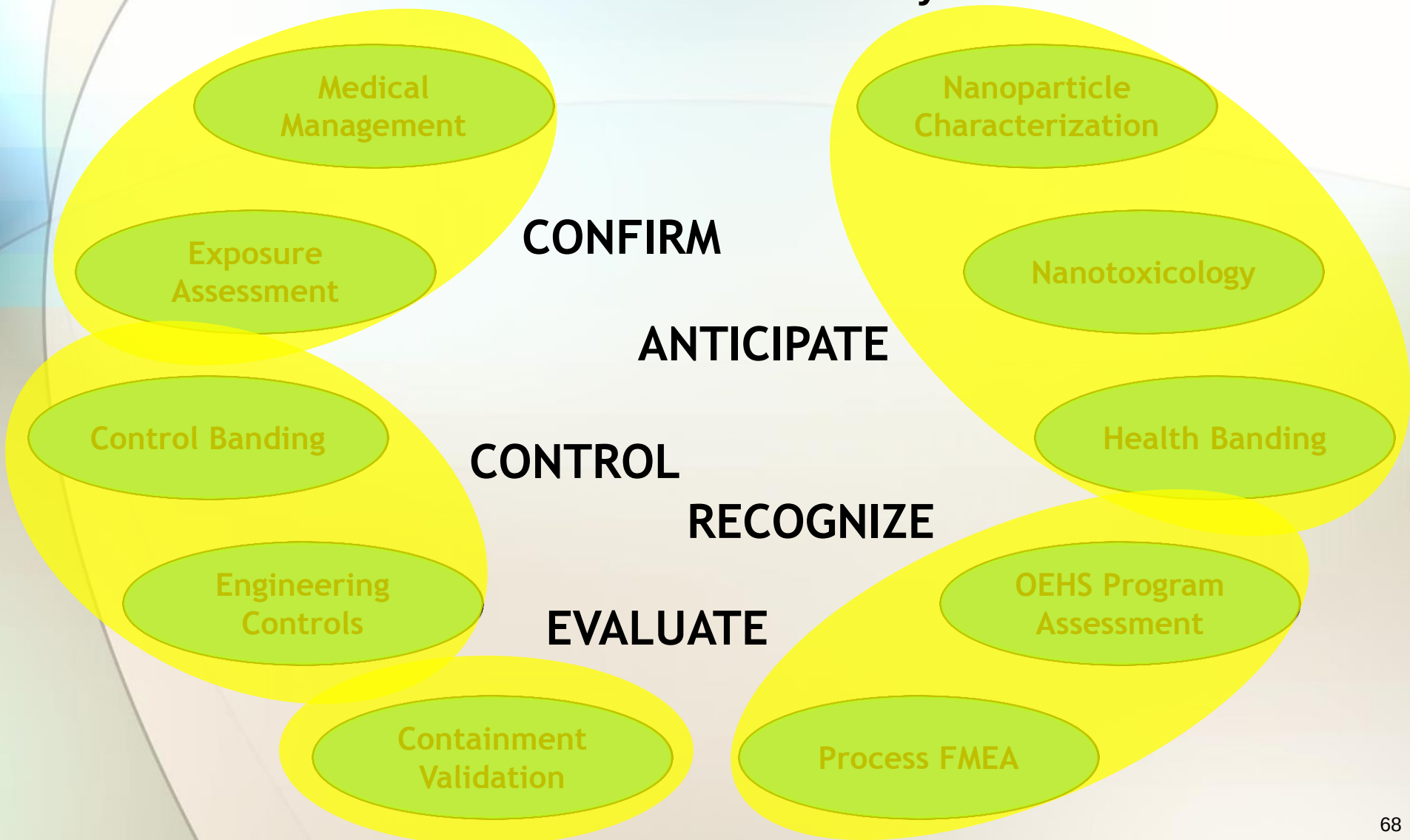
Control Approach

1. General Ventilation
2. Engineering Control
3. Containment
4. Specialist Advice

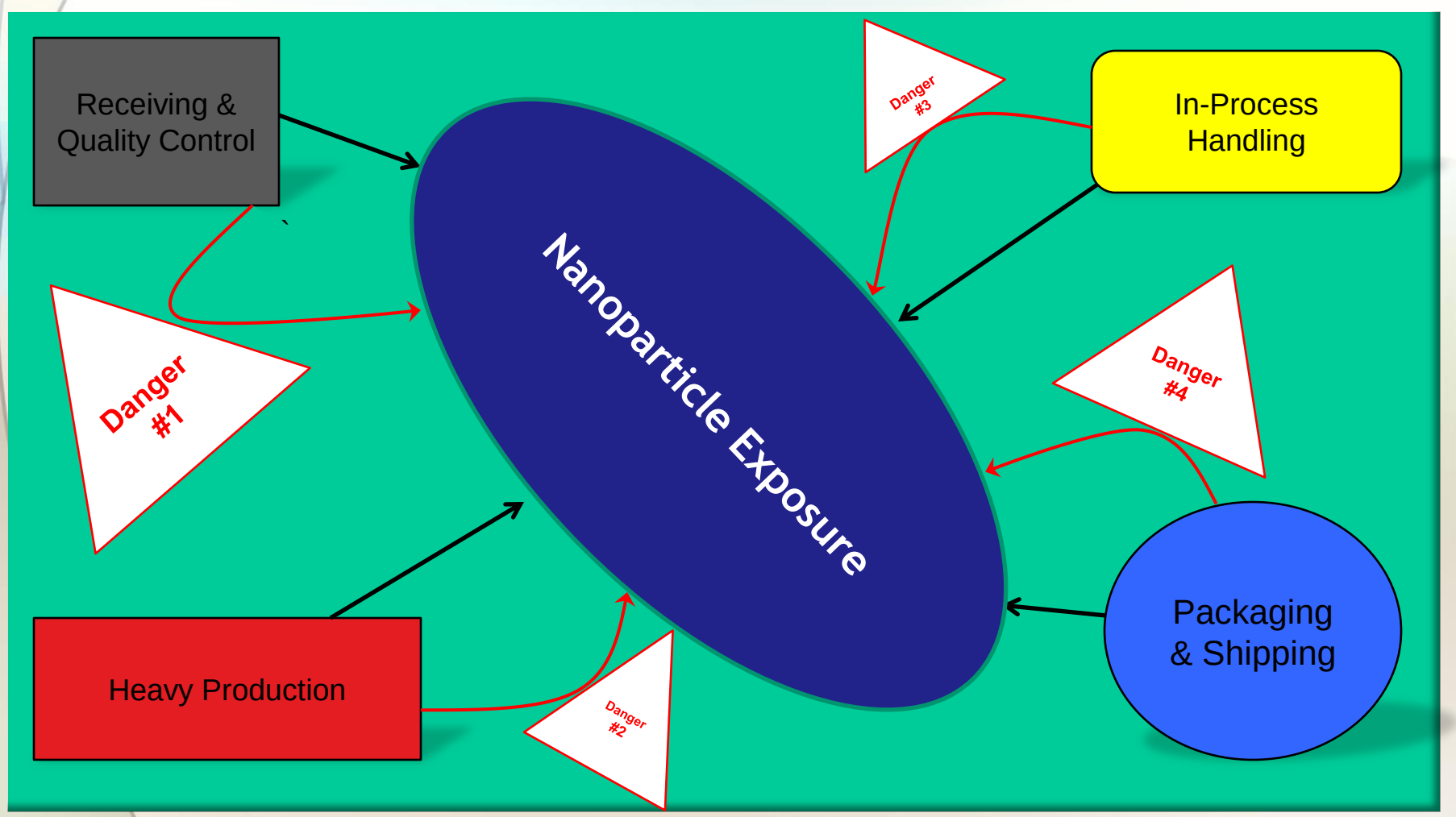
NIOSH

Adapted from ILO

Nanomaterial OEHS Lifecycle



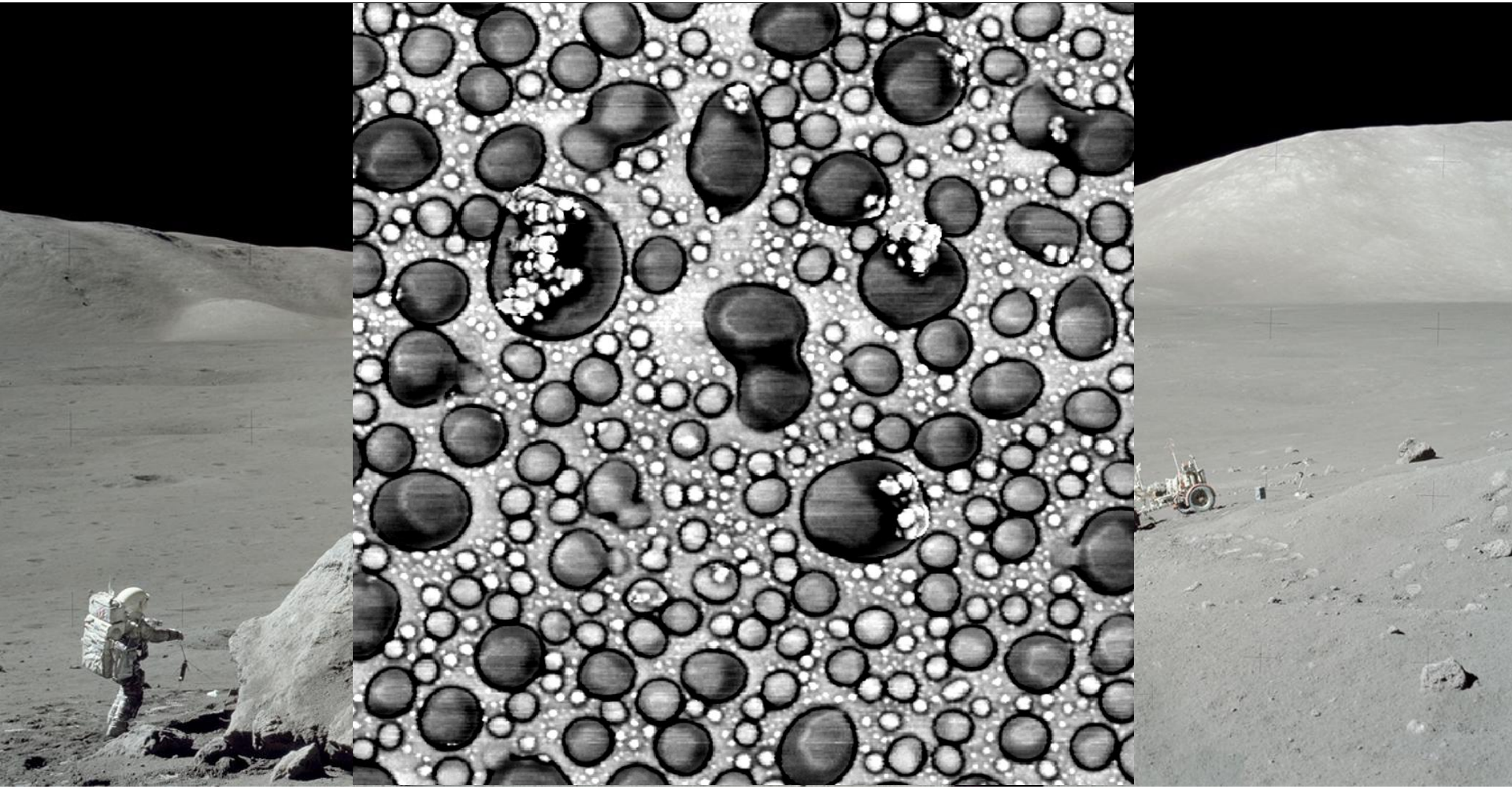
Exposure Assessment



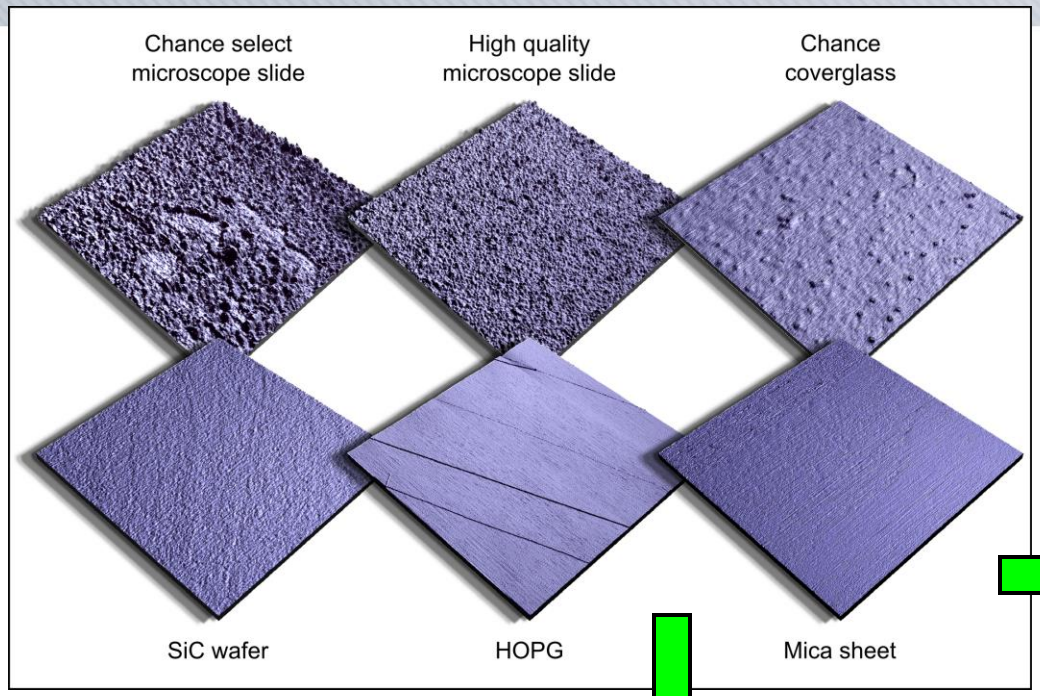
What to Measure? To Measure is to Compare!

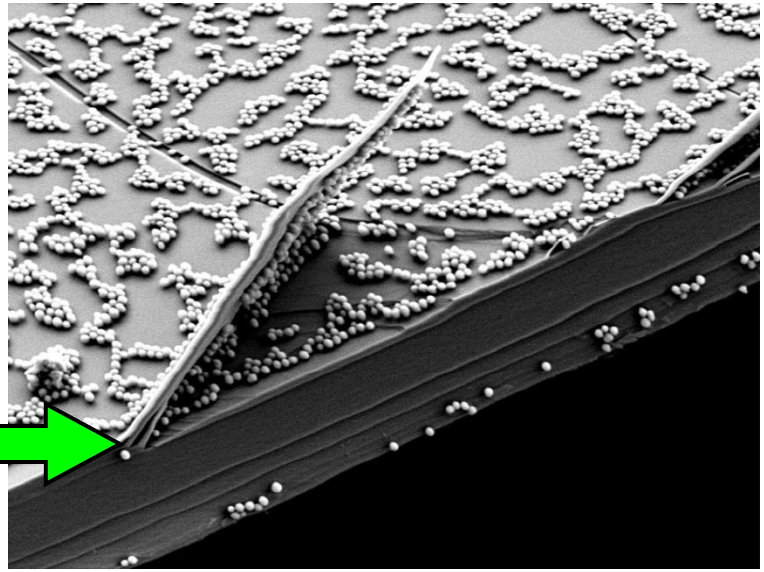
What to Measure? To Measure is to Compare!

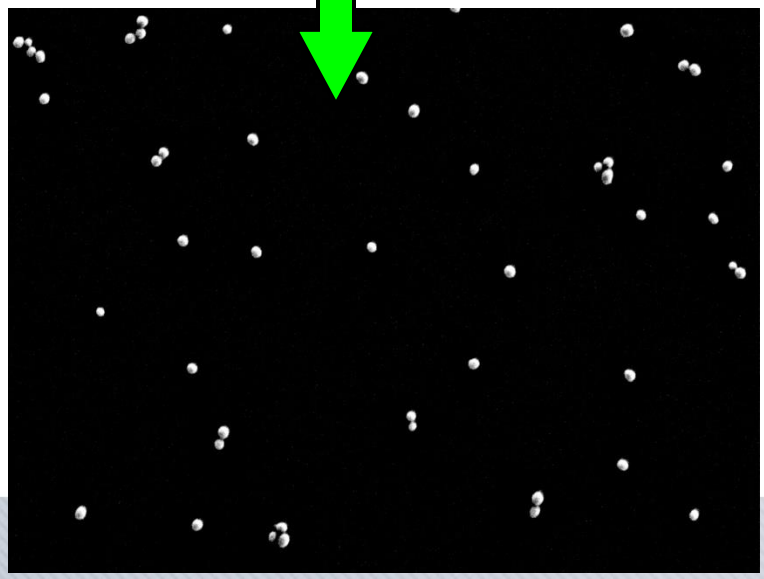
What to Measure? To Measure is to Compare!



Sample Preparation



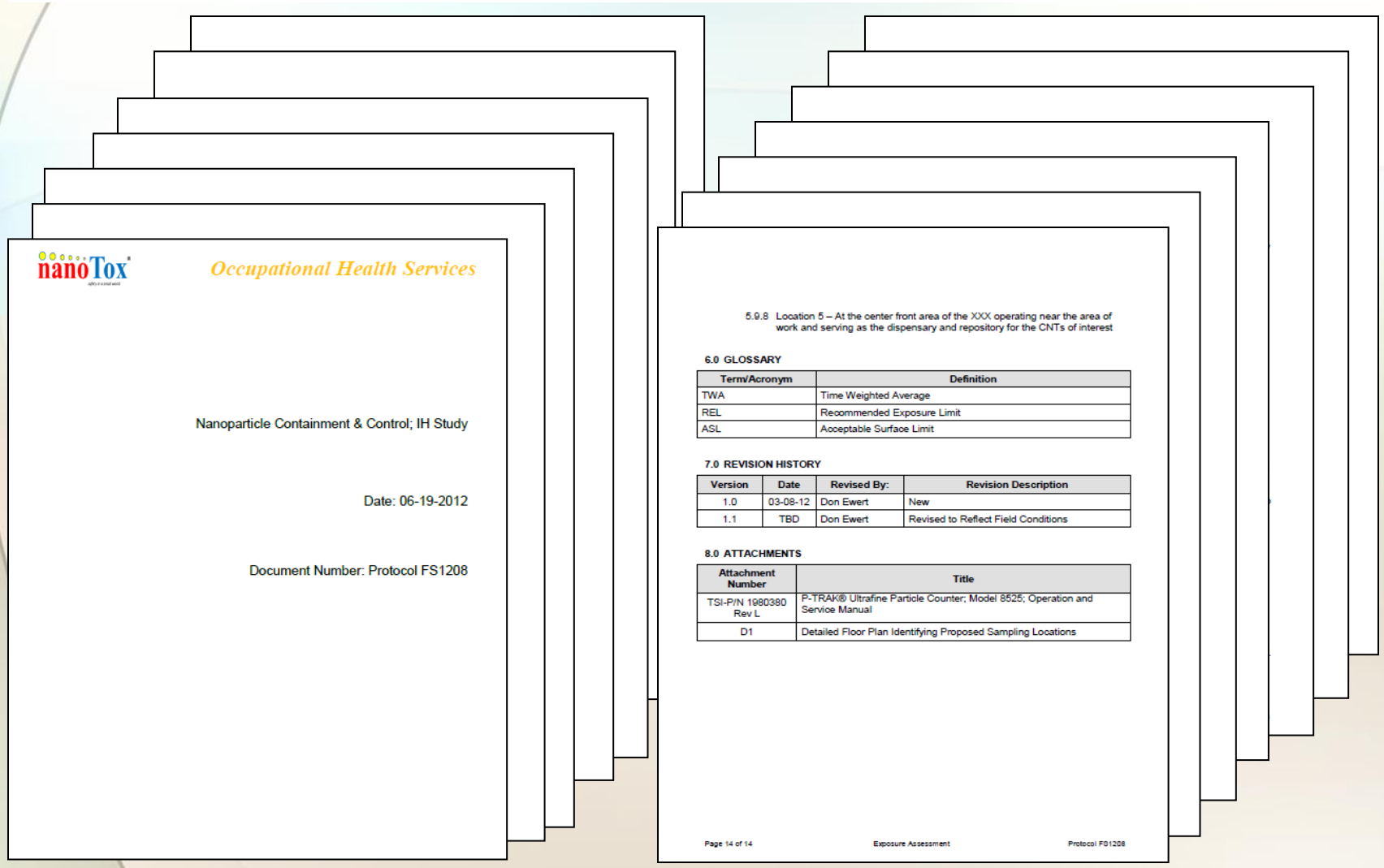




- Method of Collection and Deposition
- Choice of substrate
- Surface quality
- Surface chemistry
- Surface concentration of particles…

❑ Collaboration ENSTA / School of Mines (JF Hochepied)

Establishing a Written Assessment Protocol



nanoTox — Occupational Health Services

Nanoparticle Containment & Control; IH Study

Date: 06-19-2012

Document Number: Protocol FS1208

5.9.8 Location 5 – At the center front area of the XXX operating near the area of work and serving as the dispensary and repository for the CNTs of interest

6.0 GLOSSARY

Term/Acronym	Definition
TWA	Time Weighted Average
REL	Recommended Exposure Limit
ASL	Acceptable Surface Limit

7.0 REVISION HISTORY

Version	Date	Revised By:	Revision Description
1.0	03-08-12	Don Ewert	New
1.1	TBD	Don Ewert	Revised to Reflect Field Conditions

8.0 ATTACHMENTS

Attachment Number	Title
TSI-P/N 1980380 Rev L	P-TRAK® Ultrafine Particle Counter; Model 8525; Operation and Service Manual
D1	Detailed Floor Plan Identifying Proposed Sampling Locations

Page 14 of 14 Exposure Assessment Protocol FS1208

Nanomaterial OEHS Lifecycle

- Medical Management
- Nanoparticle Characterization
- Exposure Assessment
- Nanotoxicology
- Control Banding
- Health Banding
- Engineering Controls
- OEHS Program Assessment
- Containment Validation
- Process FMEA

Aerasense

PHILIPS

NanoMonitor

Continuous and accurate measurement of ultra-fine and nano-particles

"When based in a big city, as our building is, ultra-fine particles have to be on your agenda. Aerasense showed me that some of our filtration systems weren't working according to the guidelines and important changes were made. We are now much more proactive about improving our indoor air quality."

Facility Manager of a large bank office in Amsterdam, the Netherlands

Accurate and thorough

- Detects ultra-fine airborne particles (10 to 300 nm)
- Carries out continuous, real-time measurement
- Measures particle concentration
- Patented technology
- Independently-validated accuracy (by the German Institut für Gefahrstoff-Forschung)

IGF

Convenient

- Compact
- Simple operation
- No addition of liquids required
- Minimal maintenance requirements for the user
- Silent operation

NanoReporter software

The NanoMonitor is supplied together with the specially-developed NanoReporter software, which gives you easy yet powerful analysis, comparison and archiving of measurement data. You can view both on-line and saved measurement data in either graphical or numerical format.

Other benefits include:

- Real-time display of measurements from NanoMonitor
- Intuitive, straightforward user interface
- One-click report generation
- Comparison of up to four different measurements
- Export of data for further post-processing

TRUST. SCIENCE. INNOVATION.

CONTAMINATION CONTROL

Remote Particle Counters

Features and Benefits

- AeroTrak 7201-A2F: 0.2 to 10 µm
- AeroTrak 7301-A2F: 0.3 to 25 µm
- AeroTrak 7501-A2F: 0.5 to 25 µm
- 0.1 CFM (2.83 L/min) flow rate
- 2 Channel 4-20 mA output
- 1 Channel 4-20 mA output for laser and flow status
- 4-20 mA linear and log scaling – user selectable
- ISO 21501-4 compliant
- 24 VDC power
- Configuration via web browser and DIP switches
- Low outgassing and ionics using 3M™ Adhesive Technology
- Stainless steel enclosure
- External alarm output
- Smallest remote particle counter in the market (0.3 µm @ 0.1 CFM)

AeroTrak™ Remote Particle Counters Models 7201-A2F, 7301-A2F & 7501-A2F

The AeroTrak Remote Particle Counters with 2-Channel 4-20 mA output offer the most features and flexibility of any remote particle counters on the market today. These instruments are easy to install, configure and integrate into your systems. High quality connectors are used to make wiring straightforward. Once wired, users can select either Log or Linear 4-20 mA output signals, as well as which of the four standard supplied size channels are configured for the output. Additional remote configuration is easily completed via a web browser. And, a third 4-20 mA output provides Laser status and flow information. Each Remote Particle Counter with Analog Output includes an alarm output that can be wired directly into a PLC.

The TSI AeroTrak Remote Particle Counters with Analog Outputs are a great choice to tie directly into a Building Management System (BMS) or into a PLC.

These particle counters are calibrated with NIST traceable PSL spheres using TSI's world-class Classifier and Condensation Particle Counters, the recognized standard for particle measurements. Backed with a standard two-year warranty and TSI's long-standing reputation for high quality, there are no other particle counters like it on market today.

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Optical Particle Counter

AeroTrak™ Portable Particle Counter Model

9310

A 1cfm flowrate optical particle counter (OPC) to measure airborne particles from 0.3 to 25 micron.

The Model 9310 AeroTrak™ Optical Particle Counter is routinely used to measure airborne contamination in process environments, providing precise count and size distributions in real time. Designed for certification testing and monitoring of controlled environments, this instrument can help ensure areas meet particle regulation requirements.

- 6 user-selectable and adjustable bin sizes
- TrakPro™ Lite Software
- Easy to use, touch screen interface
- Meets ISO and JIS standards

nanoTox OEHS Management System (nOMS) Certification

"Setting the Standard in Risk Management"

Measuring & Reporting OEHS Performance

International Organization for Standardization

International Organization for Standardization (ISO)

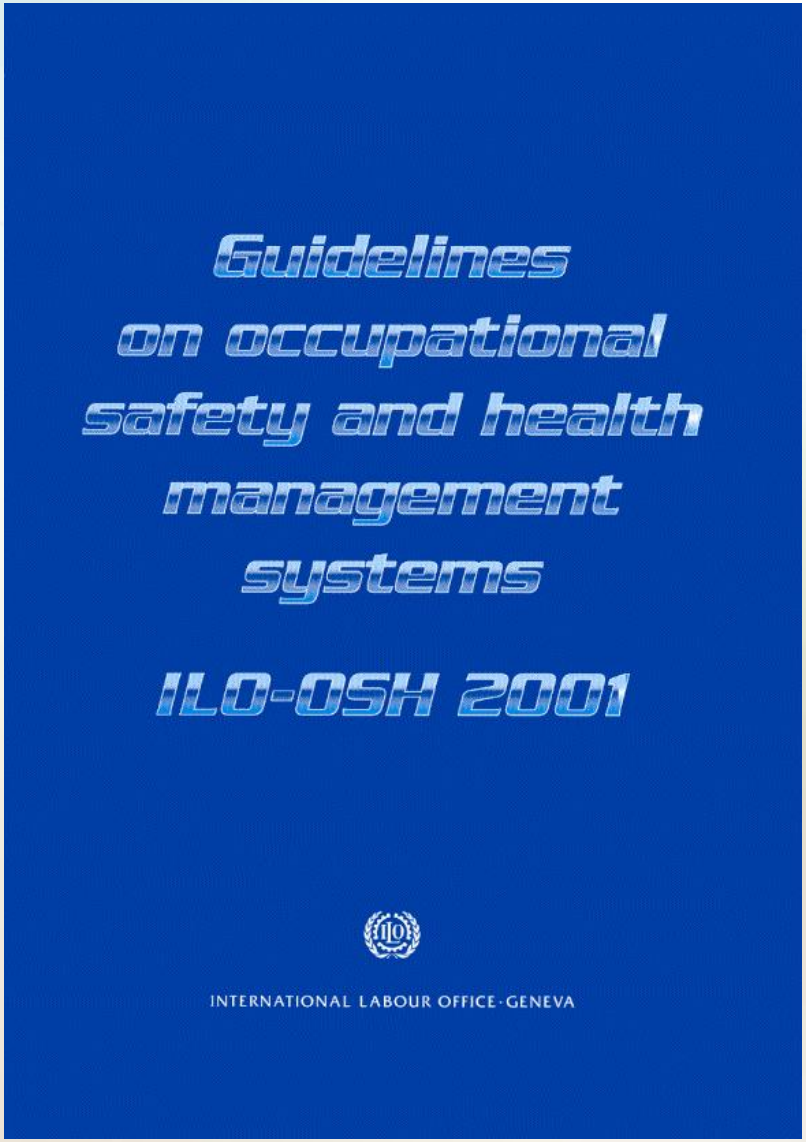
OHSAS 18001 is the internationally recognized assessment specification for occupational health and safety management systems. It was developed by a selection of leading trade bodies, international standards and certification bodies to address a gap where no third-party certifiable international standard exists. OHSAS 18001 has been designed to be compatible with ISO 9001 and ISO 14001, to help your organization meet their health and safety obligations in an efficient manner.

Planning for hazard identification, risk assessment and risk control
OHSAS management program
Structure and responsibility
Training, awareness and competence
Consultation and communication
Operational control
Emergency preparedness and response
Performance measuring, monitoring and improvement

This standard does not establish OH&S performance criteria, nor does it provide detailed specifications for the design of an OHSAS management system

International Labour Organization

The International Labour Organization (ILO): published a standard in 2001 titled ILO-OSH 2001, which is similar to OHSAS 18001. The system is based on five steps Policy, Organizing, Planning & Implementation, Evaluation, and Action for improvement. This is supported by auditing with an emphasis on continuous improvement. The ILO management system was created to assist employers to keep pace with rapidly shifting and competitive industrial environments. The ILO recognizes that national legislation is essential, but sometimes insufficient on its own to address the challenges faced by industry, and therefore elected to ensure free and open distribution of administrative tools in the form of occupational health and safety management system guidance.



AFNOR Certification offers a joint certification solution on Occupational Health & Safety management working to standard OHSAS 18001: and standard ILO-OSH 2001. This approach ultimately rewards you with dual certification.

We were the first certification body in France to deliver OH&S management system certification, to OHSAS 18001 in 2000 and to ILO-OSH in 2005. Backed by this key experience, we are the only certification body to offer dual OHSAS-ILO OSH certification. AFNOR Certification auditors may well be qualified specifically for these benchmark frameworks, but more than that, they are specialists in your business lines and core activities, and therefore fully in tune with your expectations.

OH&S management system certification is phased in through a series of steps:

Audit step 1: analysis on the key OH&S management system components (risk analysis, regulatory intelligence, internal audit, management review, definition and design of the audit schedule...),

Audit step 2: auditing rollout of the OH&S management system (interviews,..),

Decision to award certification taken by qualified AFNOR Certification Experts (based on the audit report), Certificate issued,

12-month routine surveillance audit: sustainability of the OH&S management system,

At three years on: certificate renewal (contract).

The Sponsors

US Agencies and EC services working on modalities for cooperation: Workshops, networking, Communities of Research, joint calls for research proposals

- **E.U. FP7 & H2020 – Framework Programme** - for research projects in Nanotechnologies, materials and production technologies (NMP) - http://ec.europa.eu/research/industrial_technologies
- **U.S. 18 Federal Agencies and Departments** – see individual websites
- **White House Office of Science and Technology Policy (OSTP**) provides advice on R&D budget, shapes priorities across agencies, and coordinates interagency research initiatives - http://www.whitehouse.gov/administration/eop/ostp
- **National Nanotechnology Initiative & NNCO** - http://www.nano.gov/
- **Nanotechnology Signature Initiatives** - http://nano.gov/signatureinitiatives

US-EU bridging nanoEHS research efforts – CoR Chairs

Government of the Netherlands

Tom van Teunenbroek;
Ministry of Infrastructure and Environment

STANFORD UNIVERSITY

Lawrence Gibbs;
Stanford University

RUC Roskilde Universitet

Henriette Selck;
Roskilde University

ihcp Institute for Health and Consumer Protection

Dr. Hubert Rauscher;
European Commission

Pacific Northwest NATIONAL LABORATORY

Nathan A. Baker
Pacific Northwest National Laboratory

CLEMSON UNIVERSITY

Steve Klaine,
Clemson University

TNO innovation for life

Dr Derk Brouwer
TNO, The Netherlands

CEINT Center for the Environmental Implications of NanoTechnology

Mark R. Wiesner;
Duke University

ILSI Risk Science Innovation and Application

Richard Canady, ILSI Research Foundation

IOM

Martie van Tongeren, Institute of Occupational Medicine

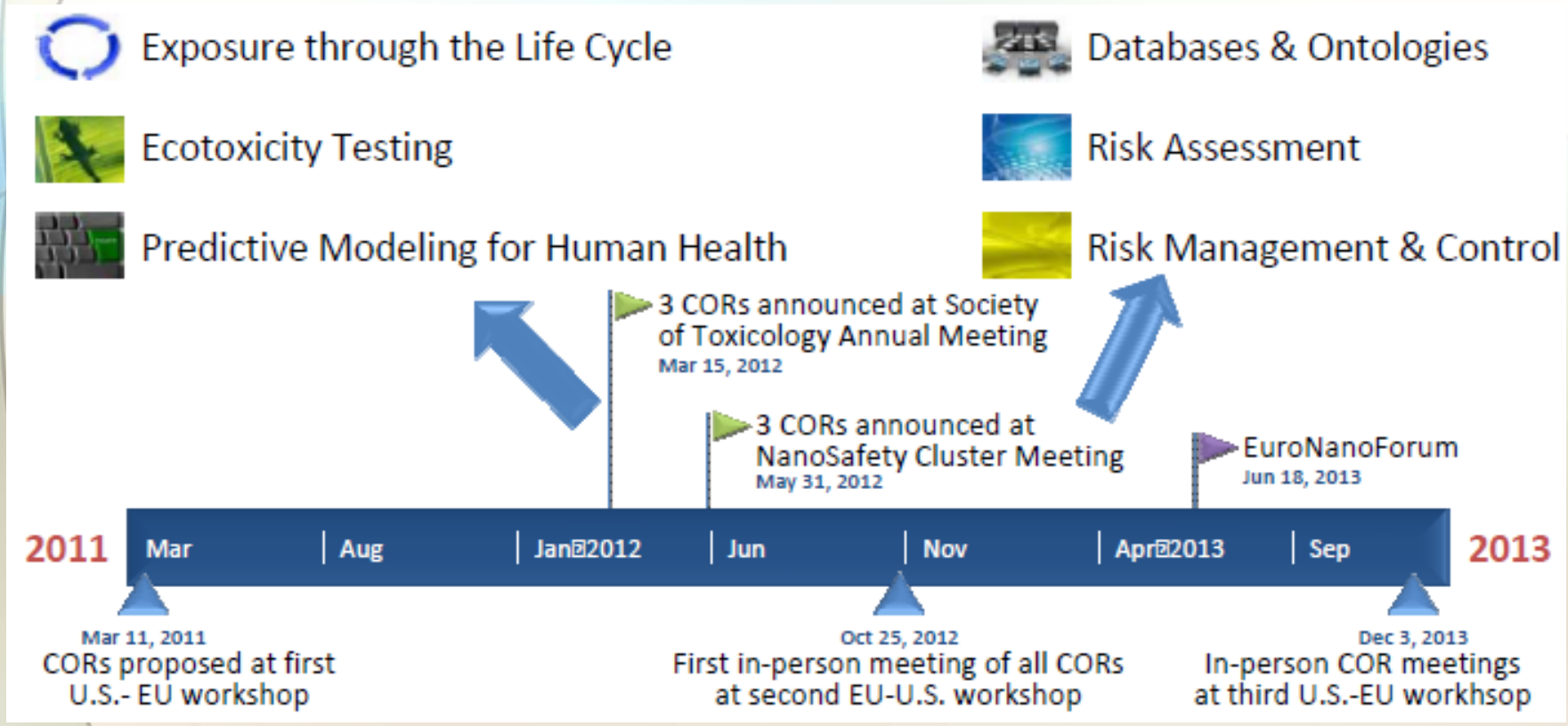
Karolinska Institutet

Bengt Fadeel;
Karolinska Institutet

KANSAS STATE UNIVERSITY

Jim E. Reviere;
Kansas State University

Communities of Research (CORs)



Risk Management & Control

The co-chairs for this CoR are Tom van Teunenbroek and Lawrence Gibbs.

Risk management and controls for nanotechnology identifies and implements strategies to address and manage potential nanosafety related hazards. This involves standardizing a range of approaches to better inform and understand potential risk factors and integrate them into an effective risk management and control scheme. Areas of potential research and collaboration include:

- Identification and incorporation of relevant risk characterization information, hazard identification, exposure science, and risk modeling and methods into the safety evaluation of nanomaterials
- Understanding, characterizing, and controlling of workplace exposure to nanomaterials
- Integration of risk and exposure assessments into decision-making frameworks for risk management, including possible regulatory actions
- Integration and standardization of risk communication within the risk management framework

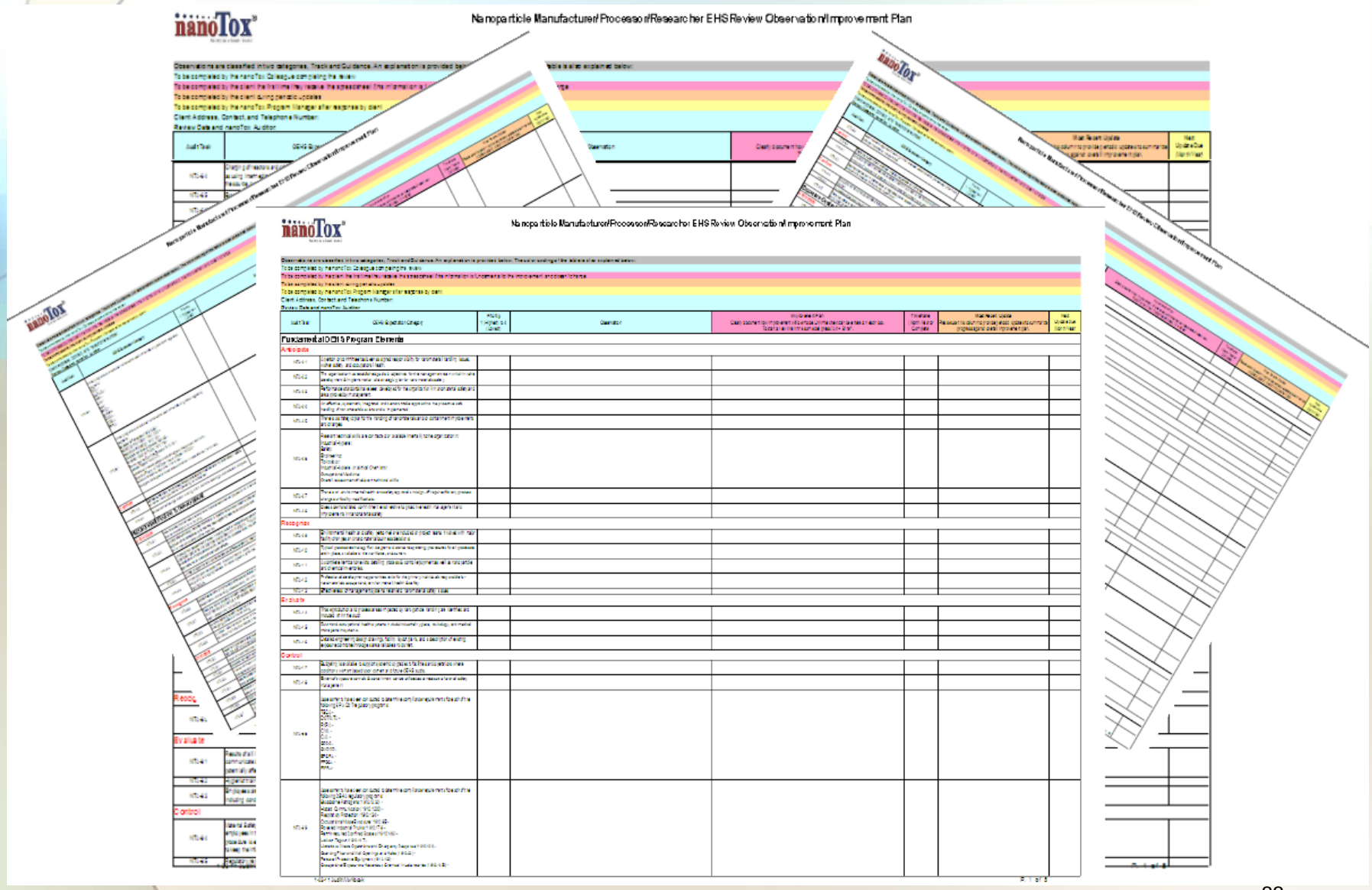
The focus of the Community of Research: Risk Management and Controls is to engage scientists and nanosafety professionals in identifying and sharing methodologies, control strategies and demonstrated effective solutions for the common purpose of reducing and preventing adverse health, safety and environmental exposures to nanomaterials. Through participation in active exchange of interested and knowledgeable scientists and professionals, development of best practices can emerge that can be widely shared. Also, the CoR will identify specific research needs to improve risk management decision-making where gaps are found in the fundamental risk management variables

nanoTox OEHS Management System Certification

- Implementation of the Certification Program is typically scheduled over a six month time span beginning with issuance of the Field Assessment Model and ending with successful completion of the audit.
- Level of customer resources necessary to achieve nOHMS certification depends upon both the degree to which OEHS is integrated into business processes and the size and type of organization
  - Small versus large business
  - Research versus manufacturing
- Only those records and processes needed to demonstrate nOHMS certification are required

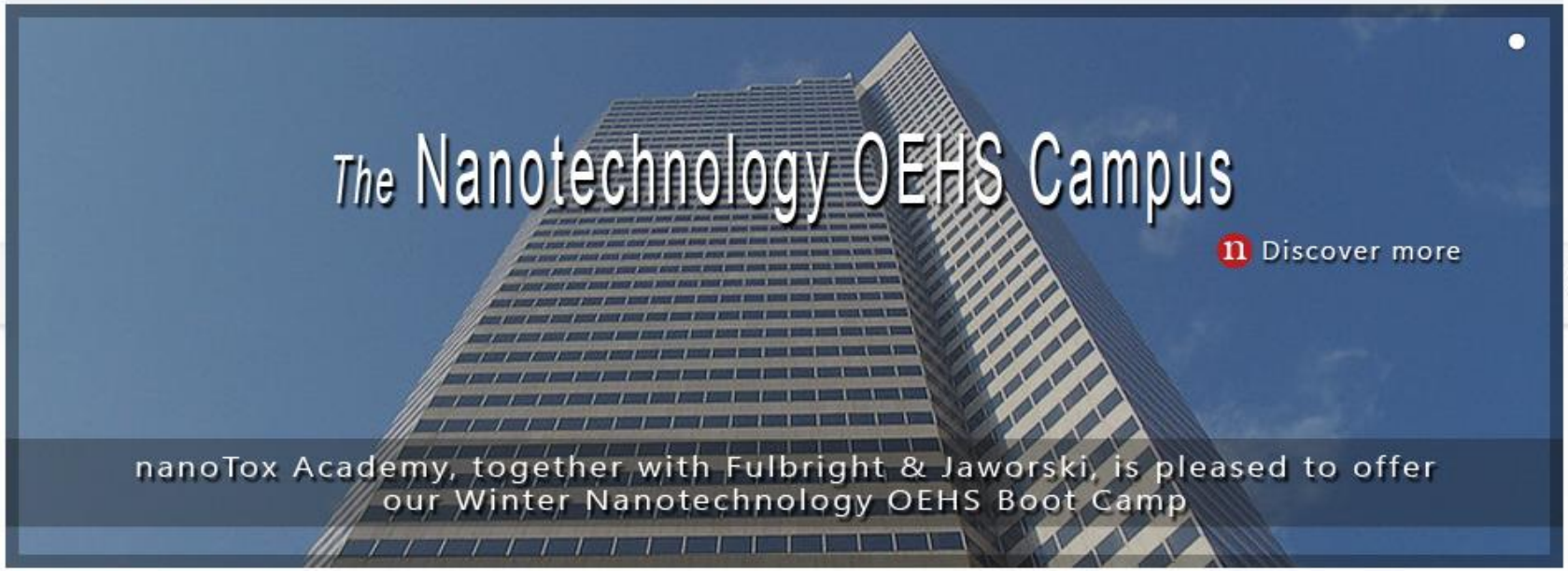
nanoTox OEHS Management System Certification

- Once an organization has completed the certification implementation process, a Certification Audit will be scheduled and carried out.
- Biennually thereafter the organization will receive an on-site compliance audit to ensure adherence to continuous improvement.
- During years in which the on-site audit is not conducted, the organization will be required to conduct a self-audit and to self-certify the results.


nanoTox
Nanoparticle Manufacturer/Processor/Researcher EHS Review Observation/Improvement Plan
Audit Task
OEHS Program Category
Priority
Observation
Improvement Plan
Timeframe
Risk Reduction Update
Visit Update Due
Functional OEHS Program Elements
Anticipate
Recognize
Evaluate
Control

nanoTox Academy
safety in a small world

HOME | BOOT CAMPS | SEMINAR SERIES | SPOTLIGHT TRAINING | WEBINARS | ON-DEMAND EDUCATION | ABOUT | CONTACT



"Training Tomorrows OEHS Professionals Today"

www.nanotoxacademy.com

nanoTox Academy Programs

Nanotechnology OEHS Seminar Series

No Charge to Attendees*

THIS EVENT INTRODUCES THE COMPONENTS OF A SUCCESSFUL NANOTECHNOLOGY OEHS PROGRAM

- Occupational, Environmental, Health, & Safety
- State of the Nanotechnology Industry
- Guidance and Available Resources
- Regulatory Criteria (OSHA, EPA, REACH)
- Product Safety and Corporate Stewardship
- Path Forward and Best Practices

THOMPSON HINE

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3900 Key Center
127 Public Square
Cleveland, OH

LNE
Sharing a passion for progress

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nanoTox Academy Programs

Nanotechnology OEHS Mini Boot Camps

Discover more

THIS EVENT DETAILS THE COMPONENTS OF A SUCCESSFUL NANOTECHNOLOGY OEHS PROGRAM

- Program Fundamentals and Creation of a HASP
- OEL Derivation and Control Banding Criteria
- Developing Audit Systems and Validating Processes
- Process Validation and Exposure Monitoring
- Medical Management and Health Surveillance Systems
- Nanotoxicology Health Banding & Categorization
- Conducting the FMEA and Prioritizing Risks
- Surrogate Monitoring and Sampling Protocols
- Selection and Design of Engineering Controls
- Product Stewardship and Corporate Sustainability

ILC DOVER
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DUBLIN, IRELAND
DECEMBER, 2013

nanoTox Academy Programs

Nanotechnology OEHS Full Boot Camps

Professional Development Course

(ABIH - Contact Hours = 24, BCSP - COC = 1.5)

THIS EVENT PROVIDES HAND ON EXPERIENCE BUILDING A SUCCESSFUL NANOTECHNOLOGY EHS PROGRAM

* Fundamentals of Building a Nanotechnology OEHS Program
* Methods for Assigning Health Bands to Nanomaterials
* Audit Systems to Assess OEHS Program Capabilities
* Development of Company-Specific Control Banding Criteria
* Surrogate Monitoring Techniques & Containment Validation
* Process Validation and Exposure Monitoring Methods
* Medical Management and Health Surveillance Systems
* Tools to Determine the Toxicology of Your Nanomaterials
* Instructions for Deriving Nanomaterial OEL's
* Cataloging Process Inventories and Prioritizing Risks
* Selection of Engineering Controls and Protection Factors
* Method Development Criteria and Sampling Protocols
* Crisis Management Scenarios and Contingency Planning
* Product Stewardship and Corporate Sustainability Issues

October 28 - 30, 2013

St. Edward's University
Professional Education Center
Austin, Texas

nanoTox Academy Programs

Other Nanotechnology Venues & Events

Featuring Presentations From nanoTox Academy SME's

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION
TEXAS HILL COUNTRY
www.texashillcountryaiha.org

Texas Hill Country ESH for High Technology

2013 TEXAS HILL COUNTRY SYMPOSIUM
CHALLENGES AND LESSONS LEARNED FOR EMERGING EHS ISSUES

November 1, 2013
Freescale - Parmer
Austin, TX

WATER INNOVATIONS ALLIANCE

November 13-14, 2013
Rice University, Shell Auditorium
Houston, TX

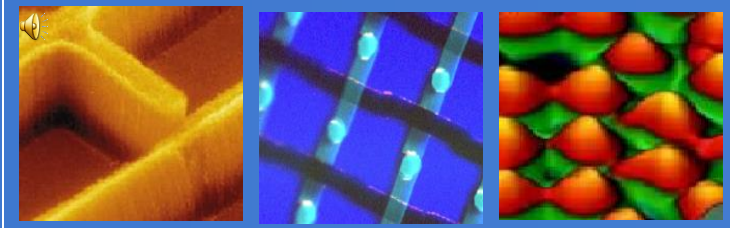
American Industrial Hygiene Association
Upper Midwest Section

AIHA-UMS Professional Development Conference

MCOHS Midwest Center for Occupational Health and Safety

November 21, 2013
Town and Country Club
Saint Paul, MN

AIHA
Protecting Worker Health



Thank You For Participating

Please Complete Your Evaluation Forms
(Check Your Badge for a Prize)

nanoTox, Inc. Service Capabilities

- GLP Nanoparticle Characterization & Toxicology Testing
- nanoTox Categorization & Health Based Control Banding
- Fast-Track OEHS Performance & Program Assessments
  - **Fundamental OEHS Program Elements**
  - **Hazard Identification & Development**
  - **Exposure Containment & Control**
  - **Communication, Education & Training**
- Comprehensive Industrial & Occupational Hygiene Services
- Medical Management – Bio-Monitoring & Surveillance Programs
- Bi-Annual nanoTox Academy & Design-Build Training Programs
- Global Provider of AssuredNano OEHS Program Accreditation