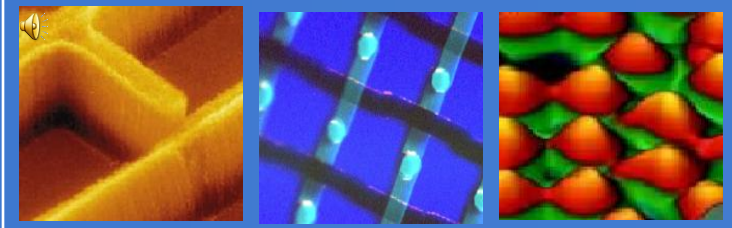


Assessing the Risks of Emerging Nanomaterials

Nanotechnology Risk Management & Control

OEHS Program Certification - *A Due Diligence Approach*

Donald Ewert, IH
VP – Field Services
Past-Chair; AIHA-Nanotechnology Working Group

US-EU: Bridging NanoEHS Research Efforts - Webinar
(November 7, 2013)

nanoTox OEHS Management Program Certification

- Implementation of the Certification Program is typically scheduled over a six month time span beginning with issuance of the Nanotechnology OEHS Program Model and ending with successful completion of the audit.
- Level of customer resources necessary to achieve nOMS Certification depends on both the degree to which Nanotechnology OEHS has been integrated into business practices and the size/type of organization.
- Only those records and/or processes needed to demonstrate nOMS Certification are required. The audit does not evaluate quality.
- Once an organization has attested that is prepared for assessment, a Certification Audit is scheduled and carried out.
- Biannually, thereafter the organization receives an on-site compliance audit to ensure adherence to continuous improvement and globally harmonized Nanotechnology OEHS Program tenets.
- 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.

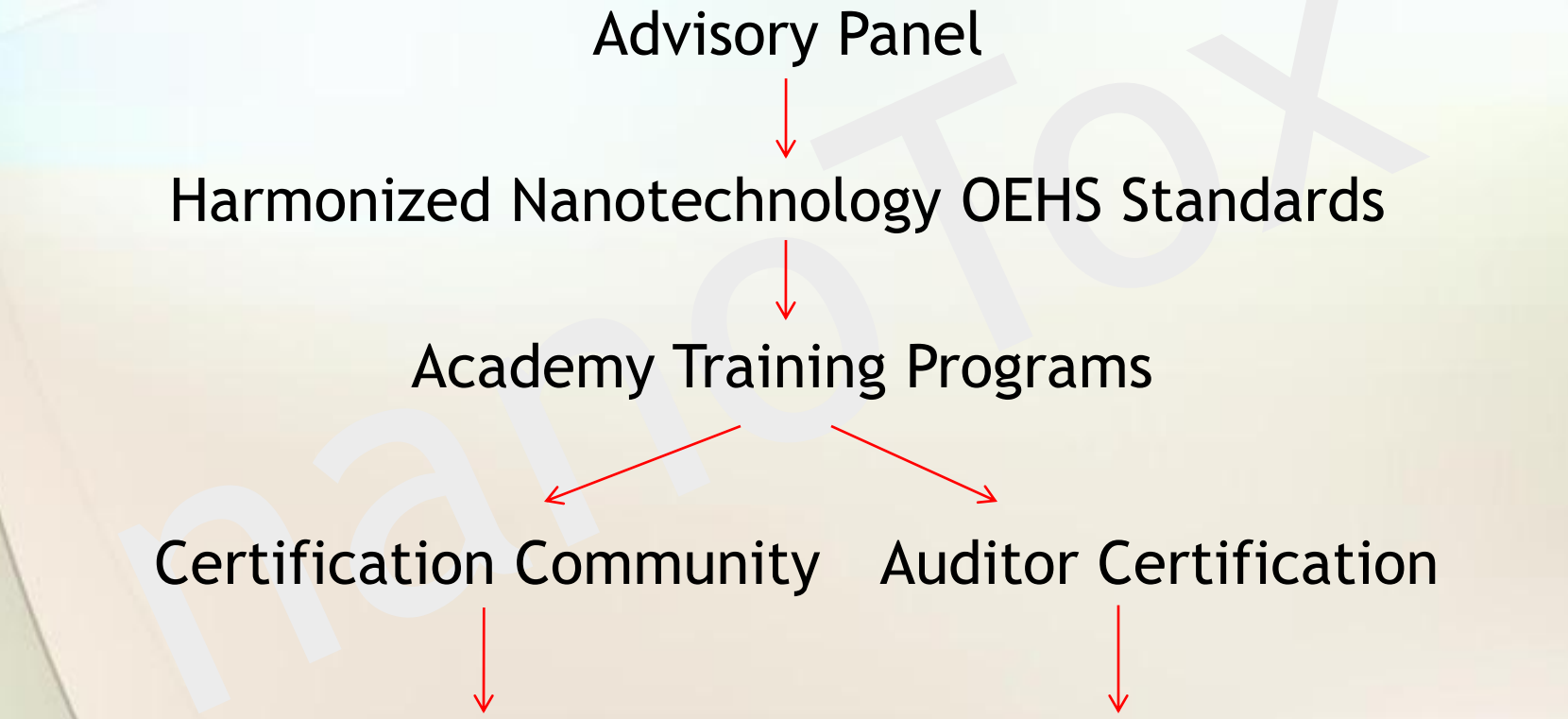
The **Functional Model**
(nOMS Certification)

"Setting the Standard in Risk Management"

Measuring & Reporting OEHS Performance

nOMS Certification Program

Executive Overview



nOMS - Advisory Panel Model

Membership in the Advisory Panel is voluntary with members solicited based on their knowledge, experience and contribution to Nanotechnology OEHS. Contributing individuals represent a balance in perspectives from across commerce, institutions, scientific communities, regulatory affairs, medical practice, and worker environs.

1. **Responsibilities:**
   a. Collection and collation of current Nanotechnology OEHS good practices from across international boundaries.
   b. Determination, selection and documentation describing minimum and maximum Nanotechnology OEHS good practices.
   c. Preparation of clear and concise guidance describing the scope of Nanotechnology OEHS good practices.
   d. Development of criteria and audit systems capable of fairly assessing Nanotechnology OEHS Programs against existing industry standard good practices.

nOMS - Advisory Panel Model (Cont'd)

2. Purpose:

a. To serve as the primary body in collating a comprehensive standard which harmonizes diverging and converging international approaches to Nanotechnology OEHS good practices.
b. To advocate for Certification of Nanotechnology OEHS Programs against the standards it establishes for harmonization of Nanotechnology OEHS good practices.
c. To establish clear and concise criteria by which Nanotechnology OEHS Programs can be audited for conformance to the current good practices is establishes.
d. To develop policies and procedures appropriate to the informatics and auditing processes involved with Certification of Nanotechnology OEHS Programs.

nOMS - Advisory Panel Model (Cont'd)

3. Structure:

a. Membership status modeled after the American Industrial Hygiene Association – Nanotechnology Working Group.
b. All qualified individuals are invited to participate in the Advisory Panel at no cost to participants.
c. Members will be solicited for participation based upon their engagement in the Nanotechnology OEHS community of practice.
d. Membership within the Advisory Panel is separated according to the activity level of individual participants.

I. Individuals who actively contribute to the development of standards in Nanotechnology OEHS good practices retain full membership.
II. Members who wish to participate but, who are unable to actively contribute to the development of standards, retain corresponding membership.

nOMS Certification Program

Program Administrator

AP Member

AP Member

EU Co-Chair

Advisory Panel

US Co-Chair

AP Member

AP Member

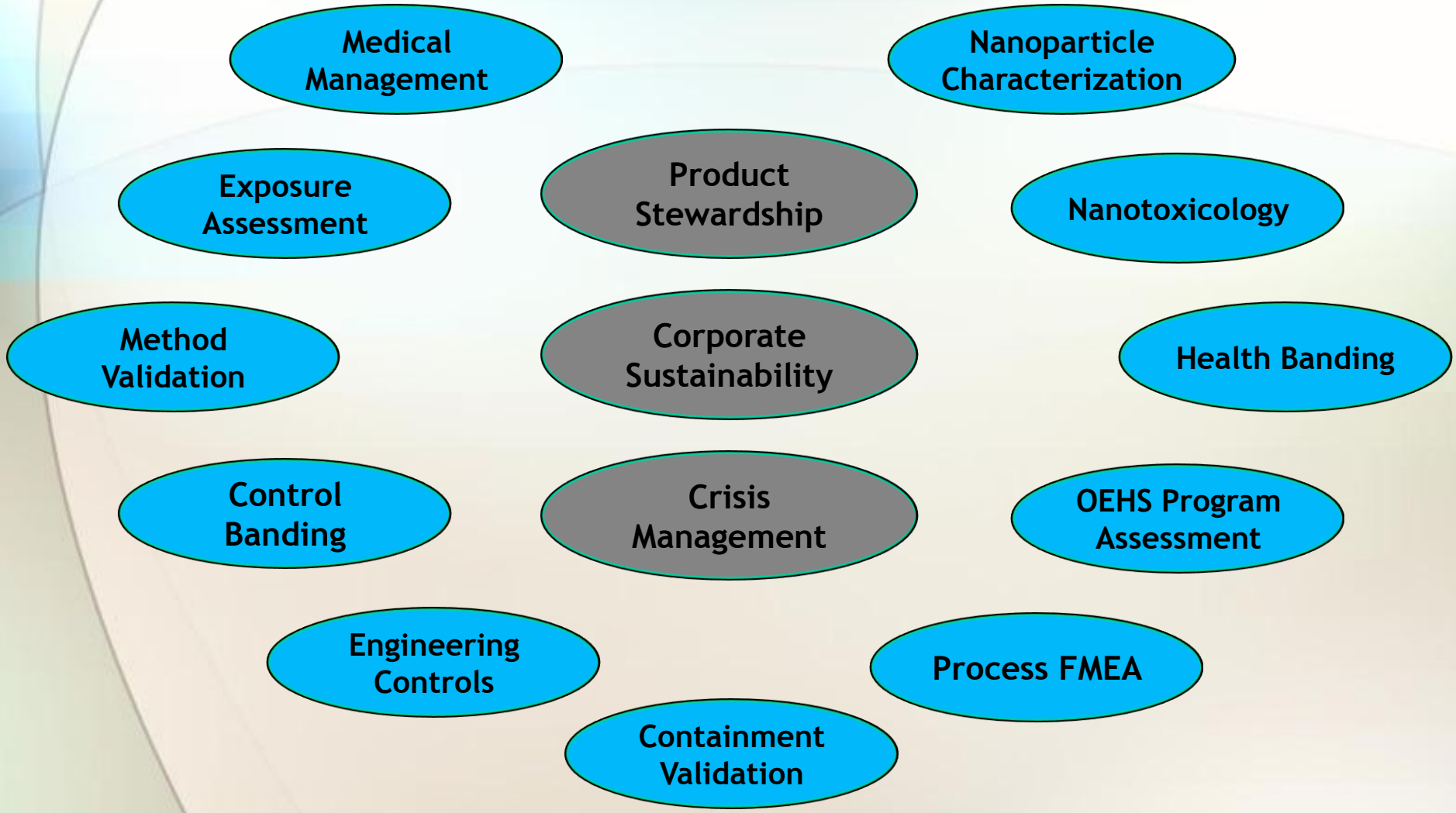
AP Coordinator – Program Liaison

A Nanotechnology OEHS Program
(nOMS Certification)

"Setting the Standard in Risk Management"

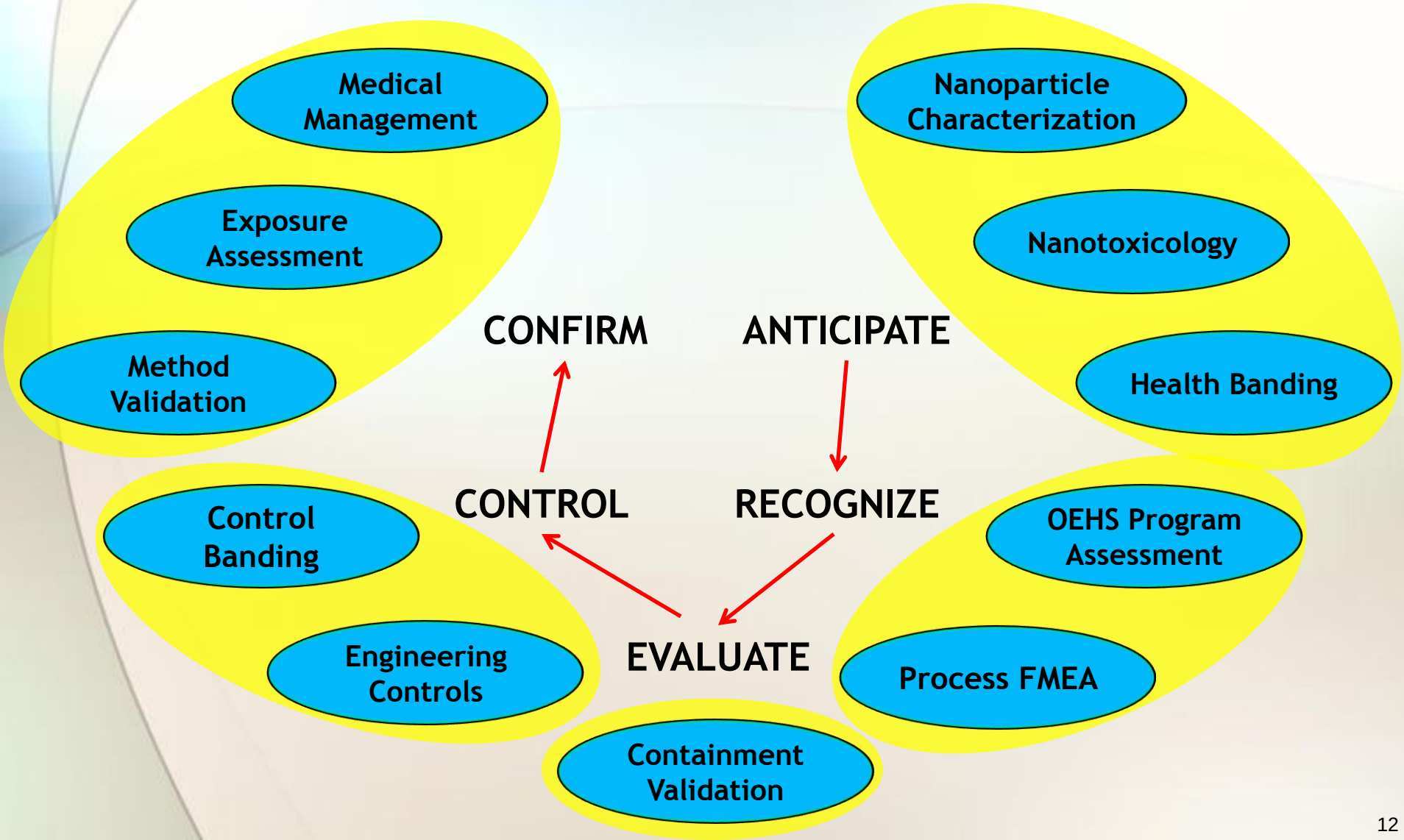
Measuring & Reporting OEHS Performance

Nanomaterial OEHS Lifecycle

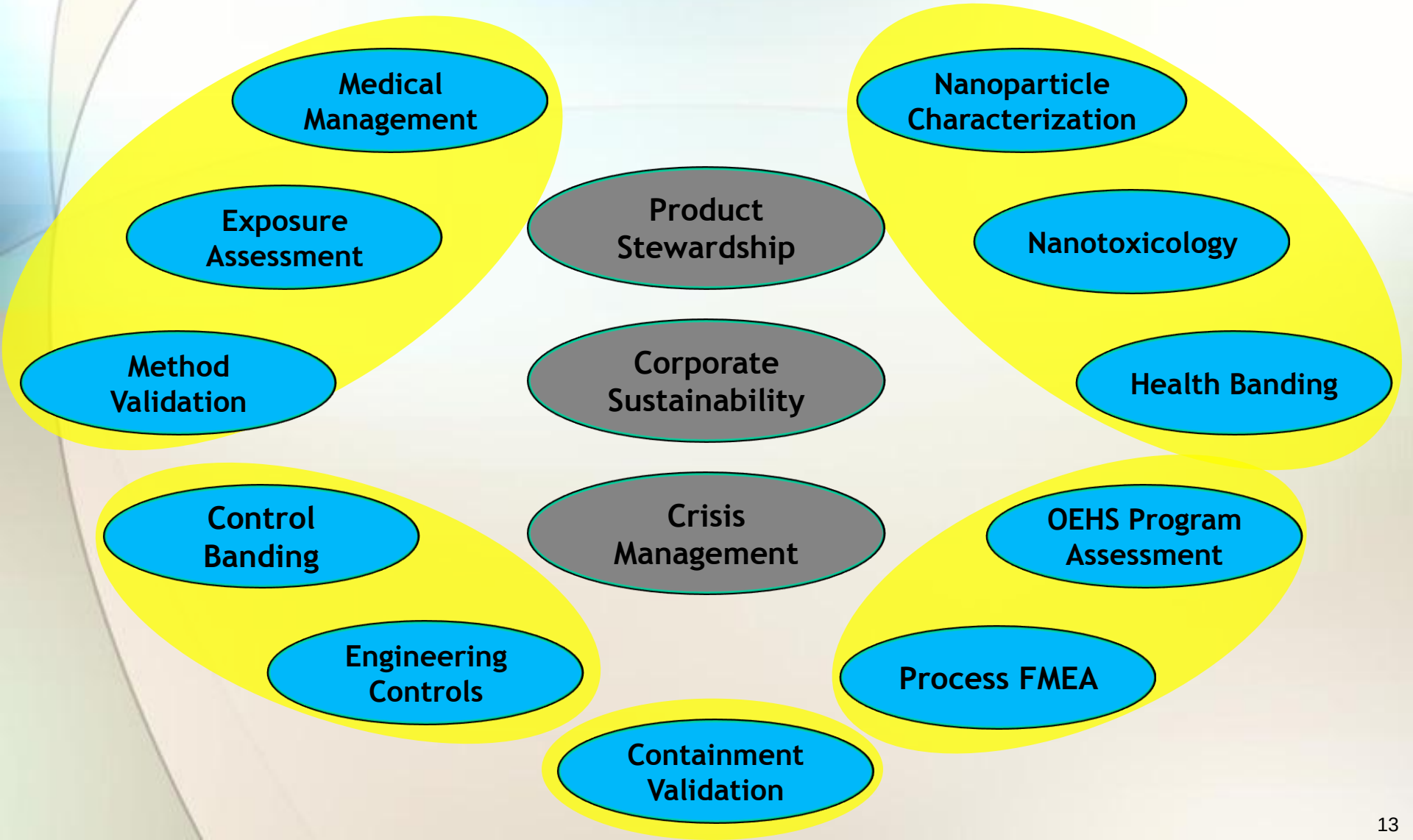



THE Synergist
1/11
www.aiha.org
Sound the Alarm
SHOULD WE BE WORRIED ABOUT WOOD DUST EXPOSURES?
10 Confirming Our IH Decision-Making Framework
22 Frank Mirer on the Precautionary Principle
27 Secure Your Smart Phone
29 The State of the OEHS Profession
COLUMN | LEADERSHIP PERSPECTIVE
Leadership Perspective
Confirming Our IH Decision-Making Framework
BY MARK D. HOOVER, TOM ARMSTRONG, TIM BLODGETT, ALLAN K. FLEEGER, PERRY W. LOGAN, BILL MCARTHUR, AND PAUL J. MIDDENDORF
Confirm
Anticipate
Control
Recognize
Evaluate
Risk Management Decision-Making Framework
Documentation and Improvement
Rationale for "Confirm"
A Community Opportunity
10
The Synergist ■ January 2011

Nanomaterial OEHS Lifecycle



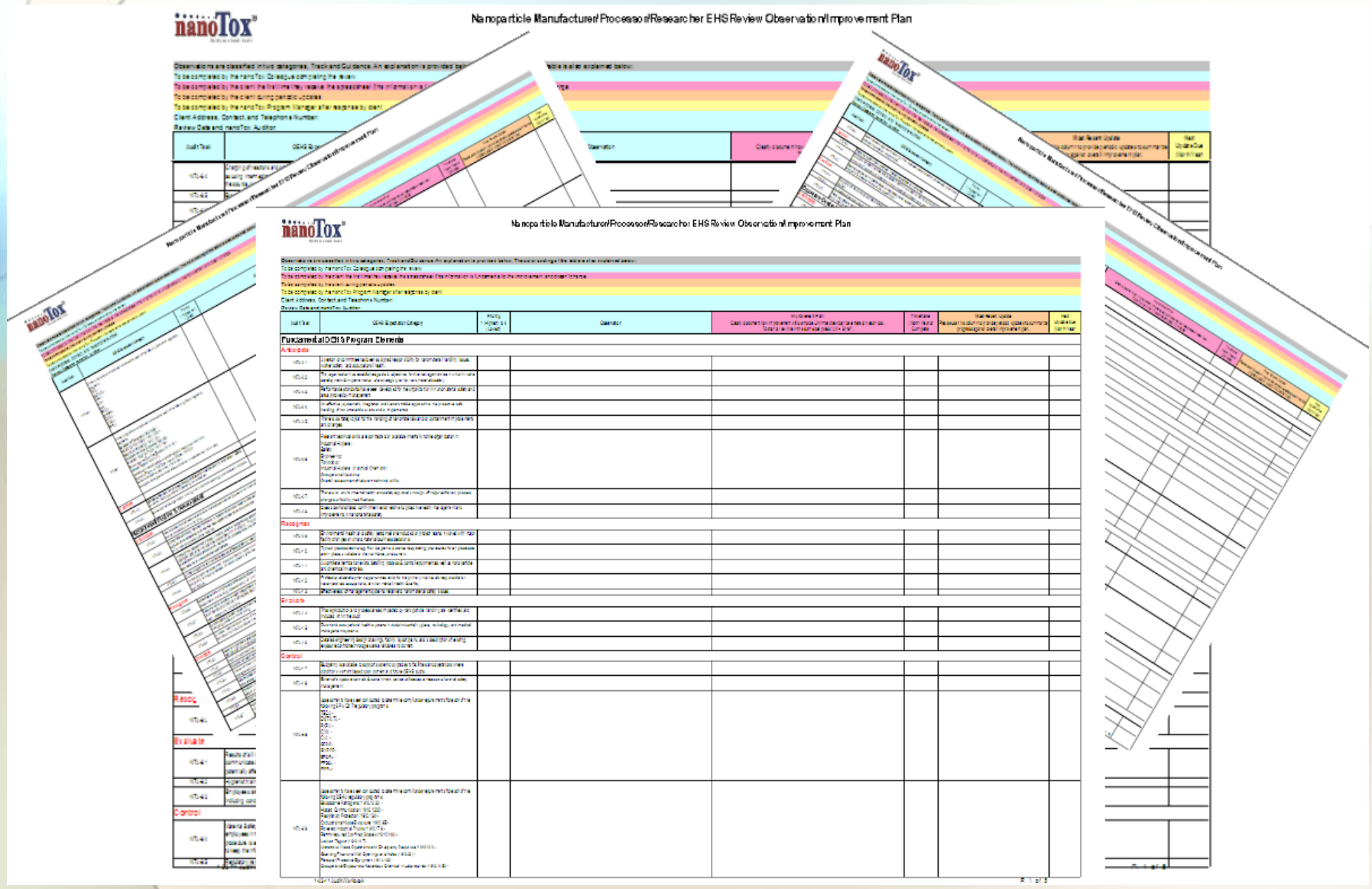
Nanomaterial OEHS Lifecycle



An Audit & Accreditation Model
(nOMS Certification)

"Setting the Standard in Risk Management"

Measuring & Reporting OEHS Performance


nanoTox
Nanoparticle Manufacturer/Processor/Researcher EHS Review Observation/Improvement Plan
Fundamental 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 exist 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 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?*

OEHS Assessment and Evaluation Criteria (EC)

(5 Points) NA - Not available for assessment

When the entity attests to having a program element but, is unable to provide any substantiation or evidence of activity.

(4 Points) D - Do not have

When the entity has not established the program element.

(3 Points) N - Needs improvement/Partially meets industry standards

When the program element exists but, isn't robust or capable of meeting the expectation.

(2 Points) M - Meets industry standards

When the program element exists and satisfies the expectation in accordance with industry standards.

(1 Points) E - Exceeds industry standards

When the program element not only exists and satisfies the expectation but also, exceeds industry standards and establishes a new threshold for performance.

The Risk Product Number (RPN)

(nOMS Certification)

"Setting the Standard in Risk Management"

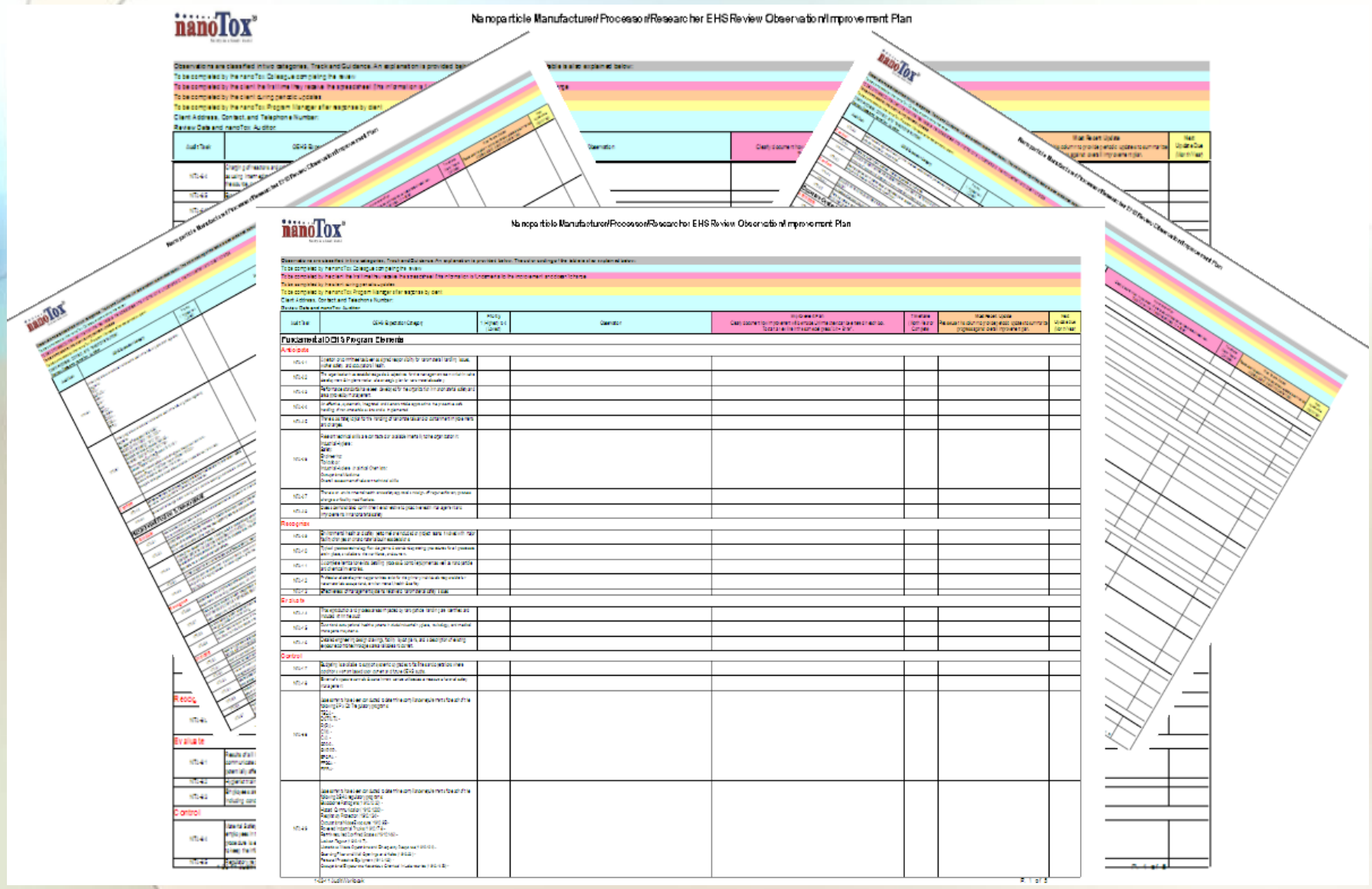
Measuring & Reporting OEHS Performance

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	

nanoTox Categorization – GHS Compliant

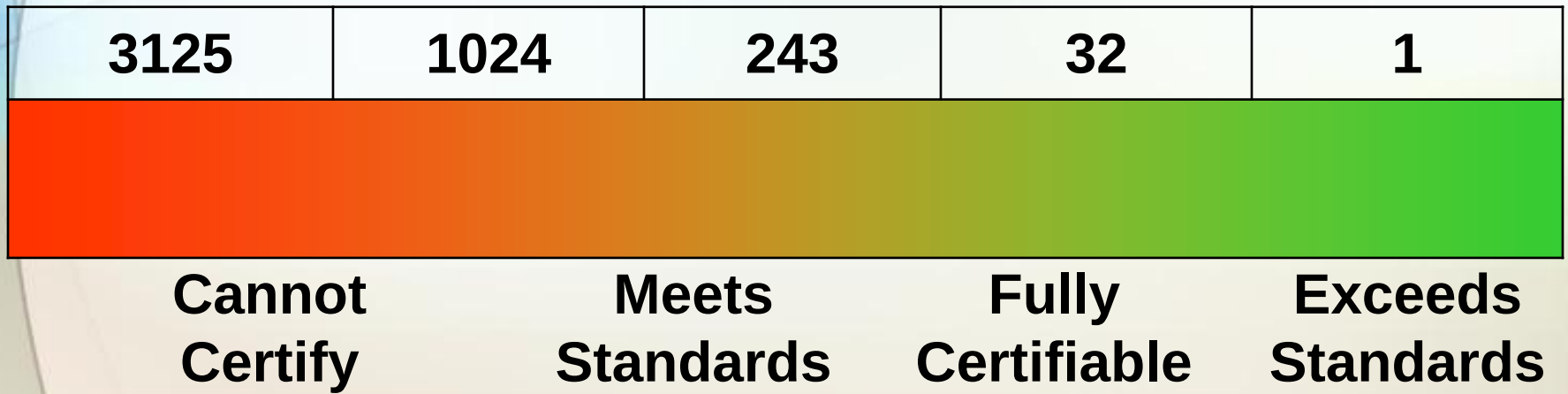
Criteria	Nanomaterial Categorization				
	E (5)	D (4)	C (3)	B (2)	A (1)
REL	< 1 µg/m³	1 to < 10 µg/m³	10 to <100 µg/m³	0.10 to <1 mg/m³	>1 mg/m³
Acute Toxicity - Oral	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Acute Toxicity - Dermal	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Acute Toxicity - Inhalation	Super Toxic	Extremely Toxic	Highly Toxic	Moderately Toxic	Slightly Toxic
Aspiration Hazard	5	4	3	2	1
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	


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

Categorization x nOMS Assessment Values = RPN

Categorization	E	D	C	B	A
	5	4	3	2	1
Site Assessment	**Not Available for Assessment**	**Doesn't Exist or Needs Improvement**	**Meets Standards**	**Fully Certifiable**	**Exceeds Standards**
Fundamentals	5	4	3	2	1
Toxicity Analysis	5	4	3	2	1
Exposure Controls	5	4	3	2	1
Training & Education	5	4	3	2	1
Total Score (RPN)	**3125**	**1024**	**243**	**32**	**1**

Health Band x OEHS Program Maturity = RPN



nanoTox Academy
safety in a small world

"Training Tomorrows OEHS Professionals Today"

www.nanotoxacademy.com

nanoTox Academy Programs - Intermediate

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

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

nanoTox Academy Programs - Advanced

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

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

nOMS Certification - Training & Licensing Curriculum

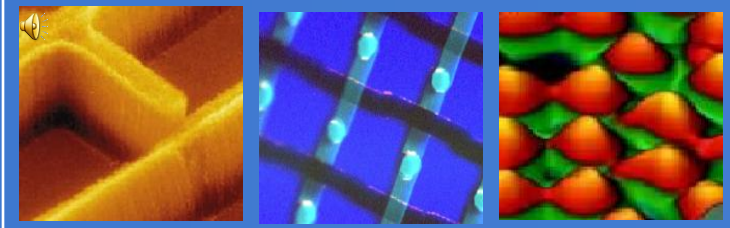
2-Hour, Introductory Seminar Program; General Attendance

1-Day, Intermediate nOMS Training; General Attendance

2- Day, Advanced nOMS Training; General Attendance

+ 1-Day, Hands On Field Practicum (General Attendance)

+ 1-Day, Auditor Certification (Auditor Attendance)



Thank You For Participating

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