

SUBJECT: THE SAFE HANDLING OF UNBOUND ENGINEERED NANOPARTICLES

1. OBJECTIVES.

- a. To establish requirements and assign responsibilities for the Department of Energy (DOE), including the National Nuclear Security Administration (NNSA), activities involving unbound engineered nanoparticles (UNP) activities.
- b. To ensure that work involving unbound engineered nanoparticles occurs in a safe and secure manner that protects workers, the public, and the environment.

2. CANCELLATION. None.

3. APPLICABILITY.

- a. DOE Elements. Except for the exclusion in paragraph 3c, this Notice applies to all DOE elements that are engaged in nanotechnology activities involving UNP, including those created after the Notice is issued. (Go to www.directives.doe.gov for the current listing of Departmental elements.)

The Administrator of NNSA will assure that NNSA employees and contractors comply with their respective responsibilities under this directive. Nothing in this Notice will be construed to interfere with the NNSA Administrator's authority under section 3212(d) of Public Law (P.L.) 106-65 to establish Administration-specific policies, unless disapproved by the Secretary.

- b. DOE Contractors. Except for the equivalencies/exemptions in paragraph 3c the Contractor Requirements Document (CRD) sets forth requirements of this Notice that will apply to contracts that include the CRD. The CRD must be included in all contracts that contain nanotechnology activities involving UNP at a DOE facility.
- c. Exclusion. In accordance with the responsibilities and authorities assigned by Executive Order 12344, codified at 50 U.S.C. Sections 2406 and 2511, and to ensure consistency throughout the joint Navy/DOE Naval Propulsion Program, the Deputy Administrator for Naval Reactors (Director) will implement and oversee the requirements and practices to this Directive for activities under the Director's cognizance, as appropriate.

4. REQUIREMENTS.

- a. DOE elements engaged in nanotechnology activities involving UNP must comply with the requirements set forth in the Attached Functional Area Requirements for DOE elements (Appendix A).

- b. DOE field elements must confirm that all contractor work with nanotechnology activities involving UNP complies with the requirements contained in the Contractor Requirements Document (CRD).
- c. DOE field elements must maintain a listing of all nanotechnology activities involving UNP at their DOE sites in an accessible electronic format.

5. RESPONSIBILITIES.

a. Program Secretarial Officers and the Administrator, NNSA.

- (1) Confirm that DOE field elements are complying with this Notice.
- (2) Direct the DOE field elements to have contracting officers incorporate the CRD and any amendments to the CRD into DOE contracts that undertake nanotechnology activities involving UNP.

b. Chief, Health Safety and Security. Prior to the cancellation of this Notice, in coordination with the PSOs ensure that appropriate environment, safety and health requirements for nanotechnology activities involving UNP at DOE sites are integrated into existing DOE directives.

c. Contracting Officers. Incorporate the CRD and any amendments to the CRD into DOE contracts that contain nanotechnology activities involving UNP as directed by the appropriate head DOE field element.

6. DEFINITIONS. Definitions pertaining to work with nanotechnology can be found in *Terminology for Nanotechnology* and *Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings* (see References).

a. Engineered nanoparticle means intentionally created (in contrast with natural or incidentally formed) particle with one or more dimensions greater than 1 nanometer and less than 100 nanometers. The following types of nanoparticles are beyond the scope of this definition:

- (1) Biomolecules (proteins, nucleic acids, and carbohydrates);
- (2) Materials for which an occupational exposure limit (OEL) or national consensus or regulatory standards exists for the nanoscale particles;
- (3) UNP incapable of becoming airborne or not expected to be generated or released;
- (4) Nanoscale forms of radiological materials; and

- (5) Nanoparticles incidentally produced by human activities or natural processes, such as diesel engines and forest fires.
- b. Unbound engineered nanoparticle (UNP) means those engineered nanoparticles that, under reasonably foreseeable conditions encountered in the work, are not contained within a matrix that would be expected to prevent the nanoparticles from being separately mobile and a potential source of exposure.

An engineered nanoparticle dispersed and fixed within a polymer matrix, incapable, as a practical matter, of becoming airborne, would be “bound,” while such a particle suspended as an aerosol or in a liquid would be “unbound.”

- c. Nanomaterial worker is a worker who performs any of the following activities: handles UNP and has the potential for inhalation or dermal exposure to UNP; routinely spends time in an area in which engineered UNP have the potential to become dispersed in the air; works on equipment that might contain or bear UNP and that could release UNP during servicing or maintenance.

7. REFERENCES.

- a. Department of Energy Nanoscale Science Research Centers, *Approach to Nanomaterial ES&H* (5-12-08, Rev 3a).
- b. ASTM E2535-2007, *Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*.
- c. ISO/TR 12885 (2008-10-01), *Nanotechnologies- Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*.
- d. ASTM E2456-06, *Terminology for Nanotechnology*.
- e. NIOSH, *Approaches to Safety Nanotechnology: An Information Exchange with NIOSH*, July 2006.
- f. 10 CFR 851, “Worker Safety and Health Program.”
- g. DOE O 440.1B, *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*, dated 5-17-07.
- h. DOE O 450.1A, *Environmental Protection Program*, dated 6-4-08.
- i. DOE P 450.4, *Safety Management System Policy*, dated 10-15-96.
- j. DOE P 456.1, *Policy on Nanoscale Materials*, dated 9-15-05.

8. CONTACT. Questions concerning this Notice should be addressed to the Office of Worker Safety and Health Policy at 301-903-6061.

BY ORDER OF THE SECRETARY OF ENERGY:



JEFFREY F. KUPFER
Acting Deputy Secretary

FUNCTIONAL AREA REQUIREMENTS FOR DOE ELEMENTS

DOE elements which conduct activities involving UNP must comply with the following functional area requirements:

1. DOE PROCESS. DOE must establish a process to:
 - a. Review all References in this Notice to identify applicable approaches to working with UNP.
 - b. Maintain inventories of nanotechnology activities involving UNP at DOE sites in an accessible electronic format.
 - c. Maintain registries of all personnel designated as nanomaterial workers.

Provide the DOE occupational medical services provider with a copy of the registry.
2. NANOTECHNOLOGY POLICIES AND PROCEDURES.
 - a. Establish safety and health policies and procedures for nanotechnology activities involving UNP as part of the Federal Employee Occupational Safety and Health Program.
 - b. Review nanotechnology plans for compliance with and inclusion in the site safeguards and security plans, facility security plans, and emergency management programs.
 - c. Develop an annual status report describing the safety and health status of the nanotechnology activities involving UNP.
 - d. Conduct annual self-assessments of compliance with nanotechnology policies and procedures.
3. TRAINING.
 - a. At the time of initial assignment, provide all nanomaterial workers and their supervisors with training specific to nanotechnology activities involving UNP. This training must include, as a minimum, the following topics:
 - (1) Uncertainties of properties and hazards of UNP;
 - (2) Differences in reactivity and toxic potential of nanoscale and macro forms of the same materials;
 - (3) Unusual exposure routes and transport within the body;

- (4) Limitations on evaluating the significance of exposures and environmental releases;
 - (5) The importance of minimizing exposure to UNP and their release into the environment;
 - (6) Hazard controls including the limitations on their effectiveness;
 - (7) Permissible and recommended exposure limits for UNP;
 - (8) The location and availability of reliable reference material on the hazards, safe handling, storage and disposal of UNP; including material safety data sheets (MSDSs); and
 - (9) Site-specific policies, procedures, and hazard controls for UNP.
- b. Provide nanomaterial workers and their supervisors with refresher training when new information and changes in requirements, policies or procedures dictate.
4. EXPOSURE ASSESSMENT.
- a. Using best available hazard information, conduct exposure assessment for all nanotechnology activities involving UNP.

Exposure assessment must assess the need for use of HEPA exhaust filtration.
 - b. Establish an air monitoring program for UNP based on preliminary exposure assessments and guidance provided in *Department of Energy Nanoscale Science Research Centers Approach to Nanomaterial ES&H* document.
5. MEDICAL SURVEILLANCE. Offer baseline medical evaluations to all nanomaterial workers. The baseline medical evaluations must include:
- a. General physical exam;
 - b. Pulmonary function test;
 - c. General blood work; and
 - d. Other tests or exams as determined by the DOE occupational medical provider.
6. CONTROLS.
- a. Control exposures to UNP using a risk-based graded approach that considers the toxicological and environmental data for all UNP.

- b. Conduct work that could generate airborne UNP in a ventilated full or partial enclosure designed to protect workers from airborne contaminants such as an exhaust ventilation hood, glove bag, or glove box.
- c. If the operation cannot be enclosed, use alternate controls such as local exhaust ventilation (“snorkels”) to capture fugitive UNP, at the source.
 - (1) Ventilation systems that can produce “blow back” such as laminar flow hoods are not acceptable for the control of UNP.
 - (2) Enclosed systems under positive pressure must be used in a negative pressure enclosure and exhausted prior to opening.
- d. Assure appropriate controls are in place to exclude UNP from any exhaust air entering the work space.
- e. Regularly test and maintain all ventilation systems, used to control worker exposure to UNP, according to prescribed procedures or the manufacturers’ recommendations.

7. POSTING AND LABELING.

- a. Post signs indicating hazards, personal protective equipment requirements, and administrative control requirements at entry points into designated areas where UNP are handled. A designated area may be an entire laboratory, an area of a laboratory or a containment device such as a laboratory hood or glove box.
- b. Where appropriate, label storage and transfer containers to plainly indicate the contents include UNP, e.g., nanoscale zinc oxide particles or other identifier instead of just zinc oxide.
- c. When UNP are being moved or transferred outside of the laboratory, include label text indicating that the material may be unusually reactive and vary in toxic potential, quantitatively and qualitatively, from macro size forms of the same material.

8. TRANSPORTATION.

- a. Properly package, label, and provide safety information for the transport of all UNP.
- b. When multiple layers of packaging are used, label the innermost receptacle or container with a label that communicates an appropriate level of caution and description of the contents.

9. WASTE MANAGEMENT.

- a. Sites must have a documented procedure for managing UNP waste that includes the proper storage and tracking of the waste as it is moved across the site and eventually dispositioned. To the extent possible, UNP waste shall be segregated from other waste during management and disposition. The site must keep an inventory of all UNP waste that is shipped off site that maintains a description of the waste, the quantity, and means and location of final disposition. Where final disposition is off-site, the documented procedure shall include notification of any appropriate environmental regulatory agency.
- b. For waste containing UNP, the Site must follow all applicable Federal, State, and Local disposal regulations.
- c. If information on UNP hazards suggests that additional protective measures should be taken for their disposal then those measures will be identified and put into place.

CONTRACTOR REQUIREMENTS DOCUMENT
DOE O 456.1, THE SAFE HANDLING OF
UNBOUND ENGINEERED NANOPARTICLES

The contractor is responsible for compliance with this Contractor Requirements Document (CRD) after it is incorporated into the contract. The contractor is responsible for coordinating the requirements of this CRD with subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements.

1. CONTRACTOR PROCESS. The contractor must:
 - a. Review all References in this Notice to identify applicable approaches to working with UNP.
 - b. Maintain registries of all personnel designated as nanomaterial workers.

Provide the contractor occupational medical services provider with a copy of the registry.
 - c. Maintain inventories of activities involving UNP in an accessible electronic format.
 - d. Provide to the head of DOE field element an annual review of activities involving UNP.
 - e. Report compliance with the requirements of this Notice in a written statement to the head of DOE field element within 60 days of incorporation of this CRD into the contract.
 - f. Give labor organizations timely notice of the development and implementation of procedures under this CRD, and of any changes to those procedures, when contractor employees are represented for collective bargaining by a labor organization. The requirements of the CRD do not supersede contractor's obligation to bargain with labor organizations consistent with Federal labor laws.

2. NANOTECHNOLOGY POLICIES AND PROCEDURES. The contractor must:
 - a. Establish safety and health policies and procedures for activities involving UNP as part of the DOE-approved Worker Safety and Health Program document, required by 10 C.F.R. §851.11 "Development and approval of the worker safety and health program."
 - b. Review Nanotechnology policies and procedures for compliance with and inclusion in the site safeguards and security plans, facility security plans, and emergency management programs.
 - c. Conduct an annual self-assessment of compliance with nanotechnology policies and procedures.

3. TRAINING.

- a. At the time of initial assignment, the contractor must provide all nanomaterial workers and their supervisors with training specific to nanotechnology activities involving UNP. This training must include as a minimum the following topics:
- (1) Uncertainties of properties and hazards of UNP;
 - (2) Differences in reactivity and toxic potential of nanoscale and macro forms of the same materials;
 - (3) Unusual exposure routes and transport within the body;
 - (4) Limitations on available information, including MSDS, for evaluating the significance of exposures and environmental releases;
 - (5) The importance of minimizing exposure to UNP and their release into the environment;
 - (6) Hazard controls including their limitations on the effectiveness;
 - (7) Permissible and recommended exposure limits for UNP;
 - (8) The location and availability of reliable reference material on the hazards, safe handling, storage and disposal of UNP, including material safety data sheets (MSDSs); and
 - (9) Site-specific policies, procedures, and hazard controls for UNP.
- b. The Contractor must provide nanomaterial workers and their supervisors with refresher training when new information and changes in requirements, policies or procedures dictate.

4. EXPOSURE ASSESSMENT. The contractor must:

- a. Using best available hazard information, conduct an exposure assessment for all activities involving UNP.
- b. Exposure assessment must assess the need for use of HEPA exhaust filtration.
- c. Establish an air monitoring program for UNP based on preliminary exposure assessments and guidance provided in Department of Energy Nanoscale Science Research Centers Approach to Nanomaterial ES&H (5/12/08, Rev 3a).

5. MEDICAL SURVEILLANCE. The contractor must offer a baseline medical evaluation to all of their nanomaterial workers.

- a. The contractor must inform any guest worker of the requirements of the Medical Surveillance portion of this Notice but need not apply such requirements to guest workers.
 - b. The baseline medical evaluation must include:
 - (1) A general physical exam;
 - (2) Pulmonary function test;
 - (3) General blood work; and
 - (4) Other tests or exams as determined by the contractor's occupational medical service provider.
6. CONTROLS. The contractor must:
- a. Control exposures to UNP using a risk-based graded approach that considers the toxicological and environmental data for all UNP.
 - b. Conduct work that could generate airborne UNP in a ventilated full or partial enclosure designed to protect workers from airborne contaminants such as an exhaust ventilation hood, glove bag, or glove box.
 - c. If the operation cannot be enclosed, use alternate controls such as local exhaust ventilation ("snorkels") to capture fugitive UNP, at the source.
 - (1) Ventilation systems that can produce "blow back" such as laminar flow hoods are not acceptable for the control of UNP.
 - (2) Enclosed systems under positive pressure must be used in a negative pressure enclosure and exhausted prior to opening.
 - d. Assure appropriate controls are in place to exclude UNP from any exhaust air entering the work space.
 - e. Regularly test and maintain all ventilation systems used to control worker exposure to UNP, according to prescribed procedures or the manufacturers' recommendations.
7. POSTING AND LABELING. The contractor must:
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- b. Where appropriate, label storage and transfer containers to plainly indicate the contents include UNP, e.g., nanoscale zinc oxide particles or other identifier instead of just zinc oxide.
 - c. When UNP are being moved or transferred outside of the laboratory, include label text indicating that the material may be unusually reactive and vary in toxic potential, quantitatively and qualitatively, from macro size forms of the same material.
8. TRANSPORTATION. The contractor must:
 - a. Properly package, label, and provide safety information for the transport of all UNP.
 - b. When multiple layers of packaging are used, label the innermost receptacle or container with a label that communicates an appropriate level of caution and description of the contents.
9. WASTE MANAGEMENT.
 - a. The contractor must have a documented procedure for managing UNP waste that includes the proper storage and tracking of the waste as it is moved across the site and eventually dispositioned. To the extent possible, UNP waste shall be segregated from other waste during management and disposition. The contractor must keep an inventory of all UNP waste that is shipped off site that maintains a description of the waste, the quantity, and means and location of final disposition. Where final disposition is off-site, the documented procedure shall include notification of any appropriate environmental regulatory agency.
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