U.S. Department of Energy
Washington, D.C.

ORDER

DOE O 456.1A

Approved: 7-15-2016

SUBJECT: THE SAFE HANDLING OF UNBOUND ENGINEERED NANOPARTICLES

1. PURPOSE. To establish requirements and assign responsibilities for the Department of Energy (DOE), including the National Nuclear Security Administration (NNSA), for activities involving unbound engineered nanoparticles (UNP). This directive ensures that a precautionary approach is utilized to manage UNP whose hazards and exposure data have not been well-defined, and that work involving UNP occurs in a safe and secure manner that protects workers, the public, and the environment.

2. CANCELLATION. DOE Order 456.1, Admin Chg 1, *The Safe Handling of Unbound Engineered Nanoparticles*, dated 02-14-13. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual or regulatory obligation to comply with the directive. Contractor Requirements Documents (CRDs) that have been incorporated into a contract remain in effect throughout the term of the contract unless and until the contract or regulatory commitment is modified to either eliminate requirements that are no longer applicable or substitute a new set of requirements.

3. APPLICABILITY.

   a. Departmental Applicability. Except for the exclusion in paragraph 3c, this Order applies to all DOE elements that are engaged in activities involving UNP, including those created after the Order is issued.

      The Administrator of NNSA will assure that NNSA employees comply with their respective responsibilities under this directive. Nothing in this Order 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. Except for the equivalencies/exemptions in paragraph 3.c. the Contractor Requirements Document (CRD) sets forth requirements of this Order that will apply to contracts that include the CRD. The CRD shall be included in contracts requiring activities involving UNP at a DOE facility that include the clause at 48 CFR (DEAR) 970.5204-2, Laws, regulations and DOE directives. For contracts requiring activities involving UNP at a DOE facility that do not include 48 CFR (DEAR) 970.5204-2, the applicable requirements set forth in the CRD shall be included in the contract terms and conditions as appropriate.

   c. Equivalencies/Exemptions for DOE O 456.1. 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 through the joint Navy/DOE Naval Nuclear Propulsion Program, the Deputy Administrator for Naval Reactors (Director) will implement and oversee requirements and practices pertaining to this Directive for activities under the Director's cognizance, as deemed appropriate.

d. The following types of UNP are beyond the scope of this Order:

(1) Biomolecules (proteins, nucleic acids, and carbohydrates);

(2) Nanoscale forms of radiological materials;

(3) Nanoparticles incidentally produced by human activities or natural processes, and

(4) Ultrafine particles such as those produced by diesel engines and forest fires.

4. REQUIREMENTS.

a. DOE elements engaged in 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 activities involving UNP complies with the requirements contained in the Contractor Requirements Document (CRD) or otherwise set forth in the contract, as applicable.

5. RESPONSIBILITIES.

a. Program Secretarial Officers and the Administrator, NNSA. Confirm that DOE field elements engaged in UNP activities comply with this Order.

b. Heads of DOE Field Elements. Notify contracting officers of contracts containing activities involving UNP in order for the contracting officers to incorporate the CRD or its relevant requirements in the identified contract, as appropriate.

c. Contracting Officers. Upon the notification of its applicability by the cognizant head of DOE field element, work to incorporate the CRD or its relevant requirements in DOE contracts that contain activities involving UNP as appropriate.

d. Associate Under Secretary for Environment, Health, Safety and Security. Prior to the cancellation of this Order, in coordination with the PSOs, ensure that appropriate environment, safety and health requirements for activities involving UNP at DOE sites are integrated into existing DOE directives or Rules.

6. REFERENCES.

a. ASTM E2535-07 (Reapproved 2013), Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings.

b. ISO/TR 12885 (2008-10-01), Nanotechnologies - Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies.

c. ASTM E2456-06 (Reapproved 2012), Standard Terminology Relating to Nanotechnology.

d. NIOSH, Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials (NIOSH Publication 2009-125).

e. 10 C.F.R. Part 851, "Worker Safety and Health Program."

f. DOE O 440.1B, Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees, Chg 2, dated 3-14-2013.

g. DOE O 436.1, *Departmental Sustainability*, dated 5-2-2011.

h. DOE P 450.4A, *Integrated Safety Management Policy*, dated 4-25-11.

i. DOE P 456.1, *Secretarial Policy Statement on Nanoscale Safety*, dated 9-15-05, certified 10-2-14.

j. AIHA 2015, "A Strategy for Assessing and Managing Occupational Exposures, 4th edition, American Industrial Hygiene Association," 2015.

k. ISO/TR 13121:2011, Nanotechnologies - Nanomaterial Risk Evaluation.

l. ISO/TS 12901-1 (2012-1-15), Nanotechnologies – Occupational Risk Management Applied to Engineered Nanomaterials – Part 1: Principles and Approaches.

m. ISO/PDTS 12901-2 (2012-09-13), Nanotechnologies – Guidelines for Occupational Risk Management Applied to Engineered Nanomaterials – Part 2: The Use of the Control Banding Approach in Occupational Risk Management.

n. NIOSH, Current Intelligence Bulletin 60, Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles (NIOSH Publication 2009-116).

o. NIOSH, Current Intelligence Bulletin 63, Occupational Exposure to Titanium Dioxide, (NIOSH Publication No. 2011–160).

p. NIOSH, Current Intelligence Bulletin 65, Occupational Exposure to Carbon Nanotubes and Nanofibers (NIOSH Publication 2013-145).

q. NIOSH, Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes (NIOSH Publication 2014-10).

r. NIOSH, General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories (NIOSH Publication 2012-147).

7. DEFINITIONS. Definitions pertaining to work with nanotechnology can be found in Standard Terminology Relating to Nanotechnology, Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings, and Nanotechnologies - Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies (see References).

   a. Engineered nanoparticle means intentionally created (in contrast with natural or incidentally formed) material with one or more dimensions greater than 1 nanometer and less than 100 nanometers.

   b. Unbound Engineered Nanoscale particles (UNP), those nanoscale particles that are not contained within a matrix under normal temperature and pressure conditions that would reasonably be expected to prevent the particles from being separately mobile and a potential source of exposure. An engineered primary nanoscale particle 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 would be "unbound." For example, relevant nanoscale particle types include intentionally produced fullerenes, nanotubes, nanowires, nanoropes, nanoribbons, quantum dots, nanoscale metal oxides, nanoplates, nanolayers, and other engineered nanoscale particles.

   c. UNP worker is a worker who:

      (1) Has the potential for inhalation or dermal exposure to UNP due to performing work with potential exposure to UNP;

      (2) Routinely spends time in an area due to performance of regular duties in which engineered UNP have the potential to become dispersed in the air or onto surfaces; or

      (3) Works on equipment that might contain or bear UNP and that could release UNP during servicing or maintenance.

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

BY ORDER OF THE SECRETARY OF ENERGY:

ELIZABETH SHERWOOD-RANDALL
Deputy Secretary

APPENDIX A. FUNCTIONAL AREA REQUIREMENTS FOR DOE ELEMENTS

1. DOE elements that conduct activities involving UNP must comply with the following functional area requirements and must establish a process to:

   a. Review the recommendations and best practices of the available national standards and guidance for applicability to the work scope

   b. Maintain a registry of all personnel who meet this Order's definition of UNP worker in an accessible electronic format.

      Registry must include as a minimum:

      (1) Name,

      (2) Job title (at the time of being designated an UNP worker),

      (3) A brief description of the UNP,

      (4) A brief description of the UNP activity, and

      (5) The area in which the activity is located.

   c. Provide the DOE occupational medicine services provider with a copy of or access to the registry.

   d. Update the registry annually, at a minimum.

2. NANOTECHNOLOGY POLICIES AND PROCEDURES.

   a. Establish safety and health policies and procedures for activities involving UNP that identify how DOE will comply with the requirements of this Order. These policies and procedures should be an integral part of the Worker Protection Program established in accordance with DOE Order 440.1B, *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*.

3. TRAINING.

   a. At the time of initial assignment, provide all UNP workers and their supervisors with training specific to 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) Exposure routes and transport of UNP within the body;

(4) Limitations on available information, including safety data sheets (SDS), 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 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 -SDSs; and

(9) Site-specific policies, procedures, and hazard controls for UNP.

b. Provide UNP workers and their supervisors with refresher training when new information and changes in requirements, policies or procedures dictate.

4. EXPOSURE ASSESSMENT.

a. Use best available hazard information when conducting an exposure assessment for all activities involving UNP.

b. Establish an air monitoring program for UNP based on preliminary exposure assessments and guidance such as the American Industrial Hygiene Association's "A Strategy for Assessing and Managing Occupational Exposures."

5. MEDICAL SURVEILLANCE. Offer baseline medical evaluations to all UNP workers.

a. Evaluations should include:

- An occupational and medical history update;
- A physical examination with emphasis on the respiratory system; and
- Specific medical tests (e.g., spirometry, chest X-ray) deemed appropriate by the occupational medicine provider.

6. CONTROLS.

a. Control exposures to UNP using a risk-based graded approach that considers the available toxicological and environmental data.

7. POSTING AND LABELING.

a. Post signs indicating hazards, personal protective equipment requirements, and administrative control requirements at entry points into areas where UNP are handled. An area may be an entire laboratory, an area of a laboratory or a containment device such as a laboratory hood or glove box.

b. 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." If affixing a label is impractical, alternative labeling schemes may be used in lieu of affixing labels, as long as the alternative method clearly identifies the containers to which it is applicable, is readily accessible, and provides information to workers regarding potential hazards.

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, when applicable.

8. TRANSPORTATION.

a. 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. 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.

b. Keep an inventory of all UNP waste that is shipped off site that contains a description of the waste, the quantity, and means and location of final disposition.

c. For waste containing UNP, the Site must follow all applicable Federal, State and Local disposal regulations.

d. 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 456.1A, *THE SAFE HANDLING OF UNBOUND ENGINEERED NANOPARTICLES*

Regardless of the performer of the work, the contractor is responsible for complying with the requirements of this CRD. The contractor is responsible for flowing down the requirements of this CRD to 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 the recommendations and best practices of the available national standards and guidance documents for applicability to their work scope.

   b. Maintain a registry of all personnel who meet this Order's definition of UNP worker in an accessible electronic format.

   c. Registry must include as a minimum:

      (1) Name,

      (2) Job title (at the time of being designated an UNP worker),

      (3) A brief description of the UNP,

      (4) A brief description of the UNP activity, and

      (5) The area in which the activity is located.

   d. Provide the DOE occupational medicine services provider with a copy of or access to the registry.

   e. Update the registry annually, at a minimum.

2. NANOTECHNOLOGY POLICIES AND PROCEDURES. The contractor must:

   a. Establish safety and health policies and procedures for activities involving UNP that identify how the contractor will comply with the requirements of this Order.

3. TRAINING.

   a. At the time of initial assignment, the contractor must provide all UNP workers and their supervisors with training specific to 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) Exposure routes and transport of UNP within the body;

(4) Limitations on available information, including safety data sheets (SDS), 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 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 SDSs; and

(9) Site-specific policies, procedures, and hazard controls for UNP.

b. The Contractor must provide UNP 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. Use best available hazard information when conducting exposure assessments for activities involving UNP.

b. Establish an air monitoring program for UNP based on preliminary exposure assessments and guidance such as the American Industrial Hygiene Association's "A Strategy for Assessing and Managing Occupational Exposures."

5. MEDICAL SURVEILLANCE. The contractor must:

a. Offer a baseline medical evaluation to all of their UNP workers;

b. Evaluations should include:

- An occupational and medical history update;
- A physical examination with emphasis on the respiratory system; and

c. Specific medical tests (e.g., spirometry, chest X-ray) deemed appropriate by the occupational medicine provider.

d. Inform any guest worker of the Medical Surveillance portion of this Order to promote awareness of medical surveillance evaluations, but need not apply such

medical surveillance requirements to guest workers. CONTROLS. The contractor must:

e. Control exposures to UNP using a risk-based graded approach that considers the available toxicological and environmental data.

6. POSTING AND LABELING. The contractor must:

a. Post signs indicating hazards, personal protective equipment requirements, and administrative control requirements at entry points into areas where UNP are handled. An area may be an entire laboratory, an area of a laboratory or a containment device such as a laboratory hood or glove box.

b. 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." If affixing a label is impractical, alternative labeling schemes may be used in lieu of affixing labels, as long as the alternative method clearly identifies the containers to which it is applicable, is readily accessible, and provides information to workers regarding potential hazards.

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, when applicable.

7. TRANSPORTATION. The contractor must:

a. Label the innermost receptacle or container with a label that communicates an appropriate level of caution and description of the contents.

8. 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.

b. The contractor must keep an inventory of all UNP waste that is shipped off site that contains a description of the waste, the quantity, and means and location of final disposition.

c. For waste containing UNP, the Site must follow all applicable Federal, State and Local disposal regulations.

d. 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.