

The U.S. Department of Energy's Engineered Nanomaterial Worker Registry: Policy and Challenges

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Office of Worker Safety and Health Policy
(EHSS - AU-11)



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Today's Talk:

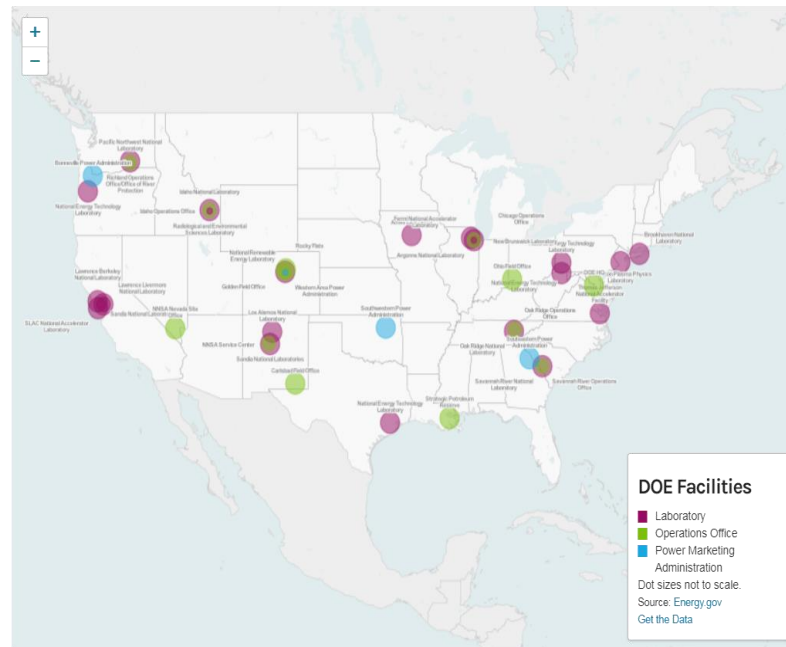
- DOE/DOE's Nanotechnology Safety and Health Policies
- Key Points in DOE's Engineered Nanomaterial Order
- The DOE Nano Worker Registry
- Challenges



DEPARTMENT OF ENERGY



Advanced technologies/nanotechnology research takes place in most of DOE's National Labs & 5 Nanoscale Science Research Centers



DOE's Nanoscale Science Research Centers



Center for Functional Nanomaterials

at Brookhaven National Laboratory, New York

Center for Integrated Nanotechnologies

at Los Alamos & Sandia National Laboratories, New Mexico

Center for Nanophase Materials Sciences

at Oak Ridge National Laboratory, Tennessee

Center for Nanoscale Materials

at Argonne National Laboratory, Illinois

The Molecular Foundry

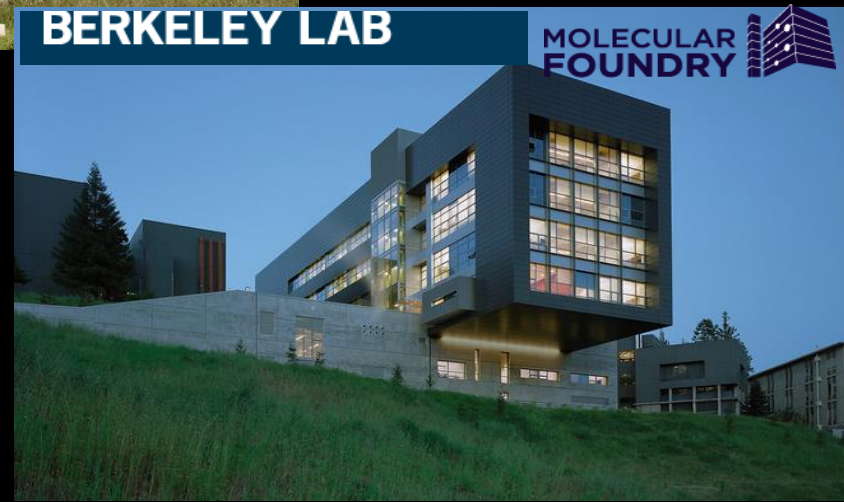
at Lawrence Berkeley National Laboratory, California



<https://science.energy.gov/bes/suf/user-facilities/nanoscale-science-research-centers/>



DOE has Five Nanoscale Science Research Centers



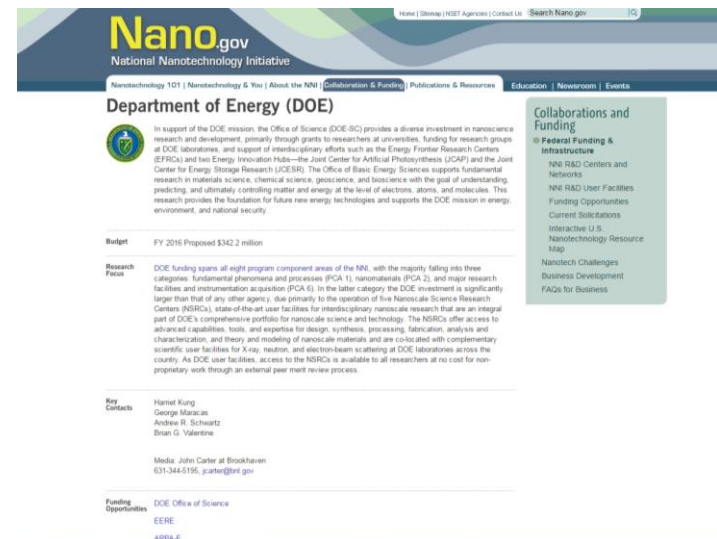
DOE's Nano Research Budget

FY 2019: \$324 million



FY 2000: \$47 million

DOE is 3rd largest contributor to NNI budget



The screenshot shows the Nano.gov website with the following content:

- Nano.gov** National Nanotechnology Initiative
- Department of Energy (DOE)**
- Budget:** FY 2016 Proposed \$342.2 million
- Research Focus:** DOE funding spans all eight program component areas of the NNI, with the majority falling into three categories: fundamental phenomena and processes (PCA 1), nanomaterials (PCA 2), and major research facilities and instrumentation acquisition (PCA 6). In the latter category, the DOE investment is significantly larger than that of any other agency, due primarily to the operation of five Nanoscale Science Research Centers (NSRCs), state-of-the-art user facilities for interdisciplinary nanoscale research that are an integral part of DOE's comprehensive portfolio for nanoscale science and technology. The NSRCs offer access to advanced capabilities, tools, and expertise for design, synthesis, processing, fabrication, analysis and characterization, and theory and modeling of nanoscale materials and are co-located with complementary scientific user facilities for X-ray, neutron, and electron-beam scattering at DOE laboratories across the country. As DOE user facilities, access to the NSRCs is available to all researchers at no cost for non-proprietary work through an external peer-review process.
- Key Contacts:** Harriet Kung, George Maracas, Andrew R. Schwartz, Brian G. Valentine, Media: John Carter at Brookhaven, 631-344-6195, jcarter@bnl.gov
- Funding Opportunities:** DOE Office of Science, EERE, NSRF-E
- Collaborations and Funding:** Federal Funding & Infrastructure, NNI R&D Centers and Networks, NNI R&D User Facilities, Funding Opportunities, Current Solicitations, Interactive U.S. Nanotechnology Resource Map, Nanotech Challenges, Business Development, FA2s for Business.

Examples of Nanotech Activities at DOE

- R&D scale research projects with CNTs and CNFs
- Synthesis of nonporous metal forms
- Sample prep of nanomaterials by cutting, slicing, grinding, polishing, etching, etc.
- Growth of palladium nanocatalysts
- Synthesis of CNTs and metal oxide nanowires onto substrates (within a tube furnace)
- Synthesis of aerogels and machining of aerogels for laser target assembly
- Nanocrystal synthesis
- Sample preparation for accelerator beam line exposure
- Vanadium dioxide nanoparticles – windows

DOE Regulates Their Workers' Safety and Health

- Office of Workers Safety and Health Policy is responsible for the development of WS&H policy for the Department
- Federal Rules (e.g., 10 CFR 851)
- DOE Directives (Policies, Orders)



2004: DOE recognized the need to establish some expectations with regard to handling and use of engineered nanomaterials



In 2005:

1. DOE S&H Bulletin, *Good Practices for Handling Nanomaterials*
2. **DOE SECRETARIAL POLICY STATEMENT ON NANOSCALE SAFETY** – DOE must be prudent and follow a cautious approach in the production, use, and disposition of nanomaterials



2006: DOE Publishes NSRCs Guidance Document: Approach to Nanomaterial ES&H

Revision 3a, May 12, 2008

Department of Energy
Nanoscale Science Research Centers

Approach to Nanomaterial ES&H

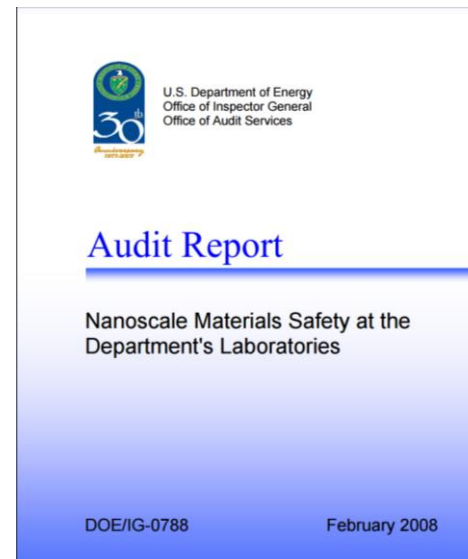
Revision 3a – May 2008



2008: Office of Inspector General Audit Report: DOE labs had not fully adopted nanoscale precautionary measures

The Department should establish clear expectations for precautionary measures and also should establish procedures in:

- Medical surveillance
- Exposure monitoring
- Worker training
- Engineering controls



Consequently DOE published Order 456.1, *The Safe Handling of Unbound Engineered Nanoparticles*



Current Order available at:
<https://www.directives.doe.gov/directives-documents/400-series/0456.1-BOrder-a>

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

ORDER

DOE O 456.1

Approved: 5-31-2011
Admin Chg 1: 2-14-2013

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), activities involving unbound engineered nanoparticles (UNP). This directive ensures that work involving UNP occurs in a safe and secure manner that protects workers, the public, and the environment.
2. **CANCELLATION.** DOE Notice 456.1, *The Safe Handling of Unbound Engineered Nanoparticles*, dated 01-15-09. 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 3d, 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.

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



Order 456.1A: Purpose

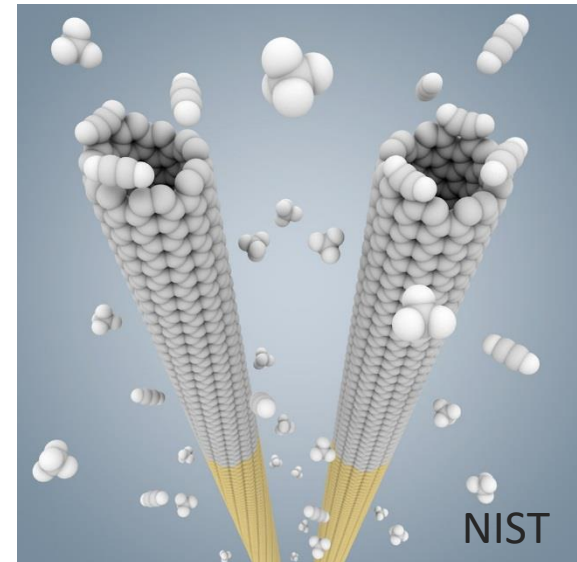
To establish requirements and assign responsibilities for activities involving unbound engineered nanoparticles (UNP).

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.



The Order's Definition of "UNP"

Intentionally created (in contrast with natural or incidentally formed) material with one or more dimensions greater than 1 nanometer and less than 100 nanometers.



The Order's Definition of "UNP"

Nanoscale particles that are **not contained within a matrix under normal temperature and pressure** conditions;

Particles suspended as an aerosol would be "unbound"

Examples: intentionally produced fullerenes, nanotubes, nanowires, nanoropes, nanoribbons, quantum dots, nanoscale metal oxides, nanoplates, nanolayers, and other engineered nanoscale particles



UNP Worker:

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



DOE UNP Registries: Requirements

- **Maintain a registry** of all personnel who meet the Order's definition of an UNP worker
- Use an accessible **electronic format**
- **Provide** the DOE **occupational medicine services provider** with a **copy of or access to the registry**
- **Update the registry annually**, at a minimum



Registry must include:

1. UNP worker **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**
5. The **area** in which the activity is located



A Few Reasons to Have a Registry:

- Identify the at-risk population
- Collect base-line information
- Describe the health status of UNP workers
- Define priorities for prevention and health research
- Evaluate the effectiveness of health and safety programs
- Notify participants of research results



A Brief Look at DOE's UNP Registries

- UNP worker registries are not centralized or collected at HQ for analysis
- Numbers of workers in the registry varies from a few workers (i.e., 10) to many (i.e., 600)
- Some sites break up registries into higher risk and lower risk
- Electronic method of collection varies
- Some variation on additional information included, but most sites only include what is listed in the Order



UNP Workers Offered a Baseline Medical Evaluation

Includes:

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



Medical Surveillance

- At one site – higher risk UNP activities are offered follow-up exams every two years in addition to the baseline exam.
- Some sites – all UNP workers receive baselines - it is mandatory
- Other sites – UNP workers that receive baseline exam as low as 5% for “uniquely UNP workers”



Registry Summary

While there are variations amongst DOE labs that use UNPs, i.e., methods of capturing required information, additional information included in the registry, and making the baseline medical exam mandatory, all DOE Labs maintain an UNP registry, update it regularly, & train their workers.



Past Studies

- DOE's Illness and Injury Surveillance Program (IISP)
- Years: 1990 – 2012
- Program that collected data from occ med departments at 16 DOE sites



Registry Challenges

- Costs/resources
- Increased burden for field sites to report data
- DOE (HQ) not resourced to handle increase in data flow
- Privacy Protections
- Not all workers receive baseline/periodic medical evaluations
- Defining a nanoparticle
- Most exposures are complex
- Limitations on measurement technologies
- Small sample sizes



Analysis of DOE Emergent Technologies Cohort

- Poster in 2012
- Looked at ETW before and after classified as such
- IISP was defunded in 2012
- The IISP was:



More Information & Contacts

Worker Safety and Health Policy:

<http://www.energy.gov/ehss/worker-safety-and-health>

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