Volume I
Summary Report

Environment, Safety, and Health Special Review of Work Practices for

Nanoscale Material Activities at Department of Energy Laboratories

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Office of Independent Oversight
Office of Health, Safety and Security
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HSS
Office of Health, Safety and Security

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Abbreviations Used in This Report

ANL	*Argonne National Laboratory*
ANSI	*American National Standards Institute*
BNL	*Brookhaven National Laboratory*
CDC	*Centers for Disease Control and Prevention*
CFR	*Code of Federal Regulations*
CINT	*SNL Center for Integrated Nanotechnology*
CNM	*ANL Center for Nanoscience Materials*
DOE	*U.S. Department of Energy*
DOT	*Department of Transportation*
EM	*Office of Environmental Management*
ES&H	*Environment, Safety, and Health*
FY	*Fiscal Year*
HEPA	*High Efficiency Particulate Air*
HSS	*DOE Office of Health, Safety and Security*
IG	*Office of the Inspector General*
ISM	*Integrated Safety Management*
LBNL	*Lawrence Berkeley National Laboratory*
LSM	*ORNL Laboratory Space Manager*
MSDS	*Material Safety Data Sheet*
NIOSH	*National Institute for Occupational Safety and Health*
NNSA	*National Nuclear Security Administration*
NREL	*National Renewable Energy Laboratory*
NSRC	*Nanoscale Science Research Center*
ORNL	*Oak Ridge National Laboratory*
OSHA	*Occupational Safety and Health Administration*
PPE	*Personal Protective Equipment*
R&D	*Research and Development*
RCRA	*Resource Conservation and Recovery Act*
SBMS	*Standards Based Management System*
SC	*Office of Science*
SME	*Subject Matter Expert*
SNL	*Sandia National Laboratories*
SOP	*Standard Operating Procedures*
SRNL	*Savannah River National Laboratory*
TJNAF	*Thomas Jefferson National Accelerator Facility*
ULPA	*Ultra Low Penetration Air*

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Executive Summary

At the direction of the Secretary of Energy, the U.S Department of Energy (DOE) Office of Independent Oversight, within the Office of Health, Safety and Security (HSS), performed a Special Review of work practices for nanoscale material activities at DOE Laboratories. Staff from the Office of Science and the National Nuclear Security Administration and nanomaterial safety subject matter experts from DOE Laboratories also participated in this review. The primary focus of this Special Review was to compare selected DOE site operations to the approach outlined in *Department of Energy Nanoscale Science Research Centers Approach to Nanoscale ES&H* (NSRC Approach Document) and other applicable requirements including 10 CFR 851 and the DOE integrated safety management (ISM) policy.

The Special Review included onsite field reviews of work practices at eight of the 16 laboratories currently performing nanoscale activities. Nanomaterial work performed at the reviewed sites consisted primarily of research projects and involved milligram or microgram quantities of nanomaterials. The amount of nanomaterial work activities varied considerably across the sites, ranging from one project to over 75 projects. In most cases, the relevant work was conducted with nanomaterials in solution or embedded in a matrix, although some researchers worked with particulate or dry powder forms of nanomaterials, some of which was in a dispersible form.

Current DOE requirements do not provide sufficient direction to ensure that the DOE contractors that manage and operate National Laboratories adequately address the unique aspects of nanomaterial safety (e.g., unknown and uncertain health and toxicological impacts, lack of exposure standards, limited sampling and monitoring technological capability). DOE established a policy, over two years ago, that establishes DOE's broad goal of protecting workers from the uncertain hazards associated with working with nanomaterials. Other DOE requirements (e.g., 10 CFR 851, *Worker Safety and Health Program*, and the ISM requirements) are intended to establish safety management processes that encompass all site hazards; however, these processes often rely on the existence of established consensus standards for controlling hazards (e.g., occupational exposure limits), and such standards often do not exist for controlling uncertain hazards associated with novel materials such as nanomaterials. DOE plans to develop additional requirements (e.g., a currently reserved section in 10 CFR 851) that specifically address potential nanomaterial hazards but has deferred that effort.

As an interim measure, pending development of nanomaterial-specific requirements, the Under Secretary for Science has established expectations that National Laboratories implement the NSRC Approach Document. All DOE National Laboratories committed to implement the NSRC Approach Document in principle, as indicated in letters provided to the Secretary of Energy and Under Secretary for Science through the National Laboratory Directors' Council.

The results of this Special Review indicate that the Under Secretary for Science's expectations for and the National Laboratories' commitment to implementing the NSRC Approach Document have led to a number of significant improvements and are continuing to have a positive impact. There are many instances of recent actions that DOE sites have taken to meet the NSRC Approach Document, and other actions are planned as a result of recent internal reviews and this Independent Oversight Special Review. In addition, several DOE sites have taken significant actions to institutionalize nanomaterial safety requirements.

However, Independent Oversight identified concerns with policy and direction in three general areas. First, although sites agreed to implement the NSRC Approach Document, the expectations were not consistently understood and communicated within the site organizational elements or by researchers and support personnel who work with nanomaterials. Second, the NSRC Approach Document was originally intended only to suggest approaches for managing the safety of nanoscale activities and has some shortcomings when it is used by DOE line management as a mechanism to delineate DOE expectations and guidance. Third, despite the active engagement of senior DOE management in deciding to use the NSRC Approach Document as an interim requirements document, DOE line management's approach essentially established an informal guidance document that does not have a foundation within the DOE directives system.

For the sites that were reviewed, the effectiveness of site programs in implementing the recommendations of the NSRC Approach Document and other applicable requirements varies considerably. A few sites have devoted significant and sustained management attention and resources to implementing comprehensive and systematic nanomaterial safety protocols. In addition, all sites have effectively applied some safety practices for nanoscale activities and have developed one or more particularly effective or innovative practices in specific aspects of nanomaterial safety.

Notwithstanding the progress, successes, and initiatives, at most sites there are a number of weaknesses in implementing the NSRC Approach Document recommendations at the activity level. Several sites have not systematically applied the NSRC Approach Document recommendations, and the observed practices were not adequate. In addition, site management at one site decided to suspend nanomaterial operations to address weaknesses identified during the Independent Oversight review. Implementation weaknesses were prevalent in a number of important aspects of nanomaterial safety practices including chemical management, medical surveillance, contamination control practices, ventilation controls, communication of hazards to workers, use/control of personal protective equipment, shipment packaging and labeling, transport of shipments, and management of waste streams. The cause of the implementation deficiencies varied from site to site and across organizations within the various sites but often stemmed from a failure to clearly establish and communicate requirements in accordance with the DOE management systems. At some sites, implementation weaknesses were more prevalent for nanomaterial work activities that received less management attention and safety specialist support. For example, at sites with designated Research Centers, the activities within the Research Centers often received higher levels of safety support and management attention and had newer facilities and equipment that were designed specifically for nanomaterial activites; these Research Center activities typically had fewer implementation deficiencies than research projects at the same site that were not performed within the Research Centers. DOE oversight and contractor assessments have not been sufficient to identify many of the implementation weaknesses.

Some actions are under way to address process and implementation weaknesses. In some cases, the individual sites that were reviewed have initiated corrective actions for site-specific weaknesses identified by this Special Review. Other appropriate actions, such as independent assessments of each site, have already been directed by DOE and scheduled by site contractors (although some are not scheduled until late 2009). Further, the DOE Under Secretary for Science has recently taken action (including a July 21, 2008, memorandum to the National Laboratory Directors' Council emphasizing the importance of effective implementation of the NSRC Approach Document) to reinforce his expectations and to prompt DOE sites to increase their efforts to ensure worker safety, recognizing the uncertain nature of nanomaterial hazards. The National Laboratory Directors' Council, representing the DOE Laboratories, has responded to the Under Secretary for Science memorandum and the draft results of the Special Review in an August 8, 2008, letter to the Secretary. This letter confirmed the commitment to effective nanosafety practices, acknowledged the unevenness in implementation of nanomaterial safety controls, and expressed their perspective that DOE requirements for nanomaterial safety need to be flexible.

The ongoing actions are appropriate but do not fully address the current implementation weaknesses or resolve the issues associated with the current lack of DOE requirements. The following recommendations are provided for DOE line management and contractor site management consideration:

- **HSS, in coordination with DOE line management at Headquarters, should utilize the DOE directives management system to ensure that clear requirements and expectations are established and communicated.** Timely direction (e.g., a DOE notice) is needed to replace the current unofficial direction (i.e., informal direction to conform with the NSRC Approach Document), with interim direction that complies with DOE directive system requirements and references the NSRC Approach Document.

- **DOE site offices and contractors should use the results of this Special Review to refine and improve current site nanosafety programs.** DOE sites should systematically evaluate the weaknesses and challenges identified in this Special Review to determine applicability and extent of condition, and develop corrective actions as needed, with particular emphasis on improving site work planning and control processes, site requirements documents (e.g., Environment, Safety, and Health Manuals), contamination control methods, and methods used to identify nanomaterial work being performed at each site, as well as all workers who may be exposed to nanomaterials.

- **DOE and contractors should increase and/or accelerate assessment activities that focus on nanomaterial safety.** DOE site offices and contractors should ensure that oversight processes and contractor assurance systems include nanomaterial safety as a specific focus area and perform targeted, performance-based reviews of nanomaterial safety practices.

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1 Introduction

At the request of the Secretary of Energy, the U.S. Department of Energy (DOE) Office of Independent Oversight, within the Office of Health, Safety and Security (HSS), performed a Special Review of work practices for nanoscale material activities at DOE Laboratories. Representatives from DOE line management organizations – the Office of Science (SC) and the National Nuclear Security Administration (NNSA) – as well as nanoscale science subject matter experts from national laboratories and representatives from the HSS Office of Health and Safety, contributed to the Special Review.

Background

A number of DOE Laboratories work with engineered nanomaterials. Some DOE Laboratories and other organizations define nanoscale nanomaterials as having one or more dimensions on the order of one to one hundred nanometers. Nanoscale particles exhibit unique properties that often differ from the properties of larger particles of the same material. Research and development (R&D) with nanomaterials is expected to yield advances in numerous fields including electronics, medicine, and materials sciences.

Nanoscale materials are expected to result in health and healthcare advances, such as more targeted methods of delivering drugs, new cancer therapies, and methods of early detection of diseases. However, they also may have unwanted health effects, and their health effects may be uncertain and not well understood with the current state of science and technology. One of the main concerns associated with manufactured nanoparticles is the potential for increased toxicity which can result from the higher reactivity of nanoparticles (compared to larger materials). These more reactive particles can enter the body through the lungs or digestive tract, and nanomaterials may also enter the body through absorption through the skin (the significance of skin exposure pathways is a matter of current scientific debate and research). Once in the body, because of their small size, nanoscale particles can penetrate deep into the lungs and may translocate to other organs following pathways that are not common in studies with larger particles and can cause inflammation and damage to the lungs, as well as other organs. Additionally, animal studies indicate that low-solubility ultra-fine particles might be more toxic than larger ones on a mass-for-mass basis. Further, the effects of nanoscale materials on the human body are not well known, and exposure limits have not been established. DOE and various other organizations, such as Centers for Disease Control and Prevention (CDC), the National Institute for Occupational Safety and Health (NIOSH), and the American Society of Mechanical Engineers, have established guidance that encourages conservative controls to maintain exposures as low as practicable until health effects are better understood.

Worldwide R&D in the use of nanoscale materials is increasing rapidly. SC supports R&D of nanoscale materials through its materials sciences subprogram. Various other DOE program offices and various non-DOE organizations (e.g., other U.S. government agencies, such as the Department of Defense and National Aeronautics and Space Administration, other countries, educational institutions, and commercial industry) also support nanomaterial R&D at DOE sites and/or perform experiments that use DOE facilities. In addition, experienced DOE and contractor personnel have made significant contributions to the development of national and international guidelines for nanomaterial safety.

DOE recently established Nanoscale Science Research Centers at five DOE sites. At each site, the Center consists of a facility (or set of facilities) where significant research activities involving nanomaterials are performed by site staff and/or visiting researchers. Although these Centers are a focal point for nanomaterial research, significant DOE mission-related nanomaterial research activities are also performed at DOE sites and facilities other than the five Centers.

Nanomaterial Policy. DOE nanomaterial environment, safety, and health (ES&H) policy is defined in DOE Policy 456.1, *Secretarial Policy Statement on Nanoscale Safety*. Key provisions of that policy include:

- Existing DOE directives and standards that contain provisions that are relevant to nanotechnology work must be appropriately applied.
- DOE and its contractors will identify and manage potential health and safety hazards and potential environmental impacts at sites through the use of existing integrated safety management (ISM) systems, including environmental management systems.
- DOE organizations working with nanoscale materials will stay abreast of current research and guidance relating to the potential hazards and impacts of nanoscale materials and will ensure that this best current knowledge is reflected in the identification and control of the potential hazards and impacts at their facilities.

Like all DOE policies, Policy 456.1 applies only to DOE Federal organizations. According to DOE Order 251.1B, *Department Directives Program*, contractor requirements must be provided in a separate corresponding Contractor Requirements Document and incorporated into the site contract. DOE has not developed or issued such a Contractor Requirements Document for DOE Policy 456.1.

Other Requirements. Another relevant policy is the DOE ISM policy. This policy addressed all site hazards, including nanoscale materials, and requires a systematic process for identifying, analyzing, and controlling hazards. Although the policy applies to Federal organizations, the contracts for DOE site operations include a contract clause that invokes ISM as a requirement at DOE sites.

Research Center at Sandia National Laboratories

DOE sites must also comply with 10 CFR 851, *Worker Safety and Health Program*, which requires a comprehensive program for protecting worker health and safety. This regulation requires various processes and controls, such as workplace assessments and monitoring, to be performed in accordance with a site-specific worker safety and health plan. Paragraph 11 of Appendix A to 10 CFR 851, *Nanotechnology Safety*, has been reserved by DOE to address nanomaterial safety requirements; the requirements for that paragraph have not yet been developed.

NSRC Approach Document. To provide best practices and guidance, the Nanoscale Science Research Centers Safety Committee developed a document entitled the *Department of Energy Nanoscale Science Research Centers Approach to Nanoscale ES&H* (NSRC Approach Document). This document was originally developed in March 2006 and was originally intended only for use by the five Research Centers. The document has undergone several revisions. Revision 1 was issued in April 2007. Revision 2 of the NSRC Approach Document was issued in June 2007; this version was in effect at the time Independent Oversight planned and initiated the Special Review. Revisions 3 and 3a were issued in May 2008, after the Special Review was initiated. These revisions included refinements of certain provisions but no major changes that would change the results of this Special Review.

The NSRC Approach Document provides recommendations for implementing a nanomaterial safety program and is consistent with similar guidance developed by other organizations, including ASTM International and the CDC. However, the NSRC document is a guidance document and is intended to change with emerging technology. The continual development and revision of this guidance document is consistent with DOE Policy 456.1, which states that "Much of the scientific information on the safety, health and environmental hazards of working with these materials is yet to be determined." The development of the NSRC Approach Document was an example of line management proactively developing safety information as a part of the ISM process to address an area where no national standard existed.

Office of Inspector General Investigation. The DOE Office of the Inspector General (IG) performed a review of nanomaterial safety at DOE sites and issued a report in February 2008. The report identified inconsistencies and weaknesses in DOE implementation of safety controls for nanomaterials. The IG report included a recommendation addressed to HSS, indicating that DOE should adopt and disseminate the NSRC Approach Document as a requirement document. (Note: This Special Review confirmed many of the implementation deficiencies identified by the IG report.)

DOE and Contractor Response to the Investigation and Subsequent Action. DOE responded that it did not fully agree with the IG recommendation about the need for additional requirements, but indicated that a number of actions would be taken to enhance nanomaterial safety. Specifically, the DOE SC requested in March 2007, through the DOE National Laboratory Directors' Council, that DOE sites that work with nanomaterials (1) provide assurance of compliance with the DOE nanomaterial policy and implementation of the NSRC Approach Document, and (2) perform independent assessments to confirm compliance/implementation.

In response, the various laboratories developed individual letters describing their approach to conformance with the policy, implementation of the NSRC Approach Document, and independent assessments. These letters were delivered to the Under Secretary for Science under a cover memorandum from the National Laboratory Directors' Council on May 5, 2008.

In a related effort, on May 30, 2007, a letter was sent to the Secretary of Energy on behalf of the National Laboratory Directors' Council about the approach to nanomaterial safety at the DOE Laboratories. The letter recommended a new approach to working together in that DOE would focus on establishing limited high-level requirements to establish the "what" and that the contractors and the Laboratories would define "how" the requirements were to be accomplished. Specifically, the Laboratory Directors proposed that they would implement the NSRC Approach Document in lieu of DOE establishing specific and mandatory direction in the area of nanomaterial safety. While the letter is consistent with the Secretary of Energy's principle of "what" versus "how," it does not discuss other parameters of the Secretary's principles, such as the need for well-defined requirements in certain critical areas, such as ES&H and security. In addition, the letter did not address specific target dates for full implementation or define an approach for tracking and evaluating implementation progress.

Independent Oversight Special Review

To implement the Secretary of Energy's direction to perform a Special Review, the DOE Chief Health, Safety and Security Officer consulted with various DOE senior managers to define the scope of the review, coordinated with various DOE program office managers and Laboratory Directors to invite participation by DOE line management personnel and experts from the Research Centers in all phases of the Special Review, and provided direction to the HSS Office of Independent Oversight with regard to the scope and conduct of the Special Review.

Scope of the Special Review. The primary focus of this Special Review was to compare selected DOE site operations against the approach outlined in the NSRC Approach Document (Revision 2, June 2007). The Special Review also considered applicable DOE policies, including DOE Policy 456.1, *DOE Secretarial Policy Statement on Nanoscale Safety*; DOE Policy 450.4, *Safety Management System*, which applies to all site hazards, including nanoscale materials, and requires a systematic process for identifying, analyzing, and controlling hazards; and 10 CFR 851, *Worker Safety and Health Program*, which requires a comprehensive program for protecting worker health and safety.

Field Reviews. The Special Review included onsite field reviews of work practices at eight of the 16 laboratories currently performing nanoscale activities. The onsite field reviews were performed during May-July 2008 and included the eight sites shown below.

SITE	RESPONSIBLE PROGRAM OFFICE
Argonne National Laboratory* (ANL)	SC
Brookhaven National Laboratory* (BNL)	SC
Lawrence Berkeley National Laboratory* (LBNL)	SC
National Renewable Energy Laboratory (NREL)	Office of Energy Efficiency and Renewable Energy
Oak Ridge National Laboratory* (ORNL)	SC
Sandia National Laboratories* (SNL)	NNSA
Savannah River National Laboratory (SRNL)	Office of Environmental Management (EM)
Thomas Jefferson National Accelerator Facility (TJNAF)	SC
"*" Indicates the site as one of DOE's five Nanoscale Science Resource Centers	

The field reviews focused on collecting data by reviewing nanomaterial program documents, observing activities involving nanomaterials, conducting facility walkthroughs, and interviewing personnel. Independent Oversight analyzed the data and developed a field report for each site, which was reviewed by an internal HSS quality review board. Reports were validated with site representatives and revised, as appropriate, to ensure factual accuracy, and are included in Volume II. Close-out meetings were conducted with DOE site office and site contractor management to discuss results.

Organization of Report. This Summary Report is organized to provide DOE management with useful feedback about the status of work practices for nanomaterial activities across DOE based on the sample of eight sites as follows:

Research Center at Oak Ridge National Laboratory

- Section 2, Notable Practices, lists a number of special or innovative practices that were evident at one or more sites and that could be considered for applicability by other DOE sites.
- Section 3, Successes in Implementing the NSRC Approach Document, identifies instances of successful and/or effective implementation.
- Section 4, Challenges in Implementing the NSRC Approach Document, identifies instances where DOE sites have not effectively implemented the recommendations of the NSRC Approach Document, or where policies and guidance need to be further defined or refined to facilitate site implementation of the recommendations.
- Section 5, Assessment, provides an overall summary of the status of site implementation of the NSRC Approach Document and other applicable policies.
- Section 6, Conclusions and Recommendations, provides Independent Oversight's conclusions and recommendations for improvement.

Research Center at Brookhaven National Laboratory

Appendix A of this report provides information about the Special Review, including a list of participants. Appendix B of this Report, *Summary of Field Implementation of the NSRC Approach*, provides a consolidated summary of the results of the eight field reviews in each of the 13 elements of the NSRC Approach Document. Volume II of this report provides the results of the field reviews at each of the eight sites.

2 Notable Practices

During the course of this review, the Independent Oversight team identified a number of notably effective practices that can provide useful information to DOE line management and other DOE sites that work with nanomaterials. These notable practices included proactive efforts to address challenging problems, innovative efforts to better use technology, particularly effective practices, and/or notable management initiatives. Other DOE sites should consider gathering additional information about the notable practices (e.g., contacting the applicable sites) and determining whether the notable practice should be further evaluated and, if determined to be beneficial, applied or adapted to site-specific needs. The following paragraphs identify a number of notable practices that were evident at specific sites.

Nanomaterial Worker Identification and Tracking. Three sites – ANL, BNL, and ORNL – have developed systems to identify nanomaterial workers and to enhance the capability to track worker training, provide effective medical surveillance, and monitor potential exposures. Such processes are effective steps in establishing a registry of nanomaterial workers.

- ANL developed an electronic job hazard questionnaire that is used to identify nanomaterial associated workers and ensure that training and medical surveillance requirements are met. The questionnaire is given to employees annually and when they change jobs. It flags individuals as nanomaterial workers and informs appropriate site personnel that the individual is a nanomaterial worker, as appropriate. For example, personnel in the medical department would be made aware that the individual is a nanomaterial worker and thus could consider the work conditions in evaluating medical conditions.

Vacuum System

- BNL developed an electronic job assessment form to identify workers classified as needing medical baseline evaluations.
- ORNL has completed its identification of nanoparticle workers as part of the implementation of the ORNL medical surveillance program. This information will allow tracking of nanoparticle workers for such purposes as training, exposure assessments, hazard analysis, and hazard controls. This information can also supply information to a nanoparticle worker registry if DOE establishes one in the future.

Ventilation. Four sites – NREL, TJNAF, BNL, and ORNL – have developed and implemented some innovative and effective applications of filtered ventilation controls.

- NREL has procured ultra-low penetration air (ULPA) vacuums for some laboratories. These vacuums are rated for filtration of smaller particle sizes than standard high efficiency particulate air (HEPA) filters and thus may have the potential to be more effective in certain situations. (The Special Review team recognizes that ULPA systems cost significantly more and do not necessarily enhance protection in all situations, and that HEPA systems have been tested for nanomaterial penetration and found suitable, whereas ULPA systems have had limited testing and validation. Nevertheless, the use of ULPAs is a notable concept that DOE sites should be aware of and consider during site-specific evaluations of potential engineering controls.)

- At TJNAF, the laboratory ventilation for a project was specifically modified for nanotube work to minimize exposure to any type of airborne contamination. Modifications to the areas where nanomaterials are produced and handled included installation of a separate local ventilation system for the laser production table (laser hutch) and modification of an existing laboratory chemical hood exhaust system to have a dedicated HEPA-filtered exhaust system routed directly through the roof to the outside.

- Because of the unknown characteristics of the nanomaterials, TJNAF made the proactive decision to conservatively require the local exhaust systems to be cleaned annually using asbestos-like cleaning techniques, including an annual requirement to change out the HEPA filters before they become a large exposure hazard. TJNAF has deemed this practice to be a conservative approach and consistent with a good safety practice of regular maintenance of filters; however, the Special Review team acknowledges that some personnel from other DOE Research Centers did not concur with the annual cleaning approach (indicating that its effectiveness is debatable and has not been demonstrated to reduce overall nanomaterial exposure).

- At ORNL and BNL, ventilation and HEPA filters are used extensively to control the spread of nanomaterial contamination into work areas and to reduce environmental emissions. Glove boxes, glove bags, and chemical hoods were also used extensively for research activities involving nanoscale particulate materials. ORNL has designed some containment systems and ventilation systems in their newer facilities in a manner that allows HEPA filters to be added readily where needed (based on an analysis of the hazards of the materials being used).

Engineering Containment. Three sites – ANL, SRNL, and LBNL – have developed and implemented examples of unique state-of-the-art engineering controls or procured equipment to provide for more effective containment of nanomaterials.

Glovebox Containment System

- At the ANL Center for Nanomaterials (CNM) and at SRNL, centrifuges with engineered controls designed for use with nanoparticles have been installed and used. These organizations performed detailed research of available laboratory equipment and selected the equipment that provided the most conservative controls. At SRNL, the principal investigator for the Zero Interface, Catalyst-Impregnated Ionomer Membrane for Fuel Cell Applications project identified and procured a centrifuge that has features to prevent dispersion and provide for effective containment of excess nanomaterials while spinning layers of particles on a substrate. At CNM, ANL researchers are using a proprietary, patented technology for HEPA-filtering the exhaust from centrifuges and for providing biosafety containment for the centrifuges. The unique HEPA filtering and biosafety containment technical features of the proprietary products are ideally suited to prevent exposure to and ensure safe handling of the nanomaterials.

- One laboratory at the LBNL Molecular Foundry has designated a glovebox line as a designated nanoparticle work area. This glovebox line is utilized for metal organic chemical vapor deposition of nanomaterials onto a substrate. This process is computer controlled and totally enclosed, and includes scrubbing of the gaseous effluent stream.

- The Center for Nanomaterials at ANL has obtained and dedicated a special low-face-velocity HEPA-filtered enclosure for working with dispersible nanoparticles. CNM, the Argonne Industrial Hygiene group, and the vendor have been working to establish that this is an effective mechanism for handling dry, dispersible nanoparticles.

- Several state-of-the art ultra-fine particle filtration systems for nanoparticles were incorporated into the design of ANL Center for Nanomaterials. For example, there is a biobay in the clean room, which HEPA filters all exhaust, incorporates a glove box, and can be used for handling nanoparticulates as well as biologicals. In addition, the CNM clean room is all ULPA-filtered to capture nanoscale particles, and thus facilitates monitoring of nanoparticulates generated or released during processes or tasks.

Exposure Monitoring/Sampling. Five sites – ANL, SNL, BNL, ORNL, and LBNL – have taken proactive actions to address the difficult challenges associated with performing measurements in support of exposure monitoring and sampling programs for nanomaterials.

- ANL has performed quantitative exposure assessment monitoring/sampling for three nanomaterial projects and sampled ultrafine particles at some additional locations (e.g., wafer dicer saws and an auto shredder pilot plant).

- ANL has procured three direct reading particle measuring devices for conducting exposure surveys and has developed an Industrial Hygiene Operating Procedure for Nanoparticle and Ultrafine Particle Measurements.

- ANL is developing and prototyping exposure monitoring methods, such as electrostatic precipitation sampling.

- At SNL, one Center for Integrated Nanotechnology (CINT) laboratory uses an ultraviolet light source to scan for quantum nanodot (a particular type of nanomaterial that fluoresces under ultraviolet radiation) contamination in their hood and workspace.

- BNL conducted a baseline monitoring program prior to use of the new Center for Functional Nanomaterials.

- ORNL has been instrumental in developing industrial hygiene monitoring protocols for nanomaterials, culminating in the development of the Example Industrial Hygiene Protocol

Nanoparticle Counter

included with the NSRC Approach Document. ORNL has also conducted more monitoring of nanomaterial work activity than any other reviewed DOE site.

- At LBNL, the Molecular Foundry has developed a portable clean room that can be attached to the face of a chemical fume hood. The clean room provides HEPA-filtered makeup air to the hood, significantly reducing background particle counts and improving the ability to detect possible releases of nanoscale particulates during monitoring. The portable clean room configuration is being modified to accommodate various hood designs at other LBNL laboratories.

Workplace Hazard Controls. Several sites, including SNL, NREL, TJNAF, and ORNL, have demonstrated proactive and/or innovative mechanisms for controlling potential nanomaterial hazards.

- In one CINT laboratory at SNL, researchers wore disposable gloves under the glove box gloves as an added layer of protection. The contrasting colors of the two gloves allowed the researchers to readily detect small tears. The effectiveness of this practice was demonstrated in one recent event; a breach in one of the gloves on a glove box was discovered by this method. In addition, this laboratory sometimes uses cover gloves on top of the glove box gloves to prevent degradation of the gloves.

- In some situations, NREL has consolidated work locations to minimize the potential for employee exposures and contamination. For example, sample preparation work was moved to the same laboratory that generates the sample.

- TJNAF has established conservative personal protective equipment (PPE) requirements that are more stringent than the NSRC Approach Document for nanomaterial handling. For example, all nanomaterials are required to be in enclosed containers at all times except during a few defined operations, and nanomaterial work outside of the chemical fume hood (including sample recovery, transfer of the sample to the fume hood, and cleaning activities) requires respiratory protection in addition to the skin protection required for all hands-on nanomaterial work.

- TJNAF developed a material safety data sheet (MSDS) specifically for boron nitride nanotubes produced as a result of the current research project. The MSDS is comprehensive and easy to understand, and it addresses all MSDS subject areas required by Occupational Safety and Health Administration (OSHA) Standard 29 CFR 1910.1200(g).

- ORNL has established the Laboratory Space Managers (LSMs) to ensure proper control of such matters as access to the laboratory, protection of co-located workers, and maintenance and housekeeping activities. LSMs are an integral element of the control of nanomaterial use in the research laboratories and were found to be knowledgeable and accountable for the control of potential nanomaterial hazards and work within their laboratories. The LSMs are also effective mentors to the large group of users at ORNL involved with nanomaterial.

Chemical Inventory Management. Two sites – LBNL and NREL – have modified their chemical management processes and tools to facilitate chemical inventory management during the procurement process to incorporate nanomaterials.

- LBNL is planning to pilot a program to better identify nanomaterials at the time of procurement. The pilot program is currently planned to be tested at the Material Science Division and then expanded to cover all divisions. When a procurement request is made to purchase a material identified in the system as containing nanomaterials, the system will notify appropriate ES&H personnel. Purchase requests for materials that are not pre-evaluated will trigger Procurement to contact a subject matter expert to make a determination whether the material contains nanomaterials.

- NREL has established procedures to ensure that chemicals (including nanomaterials) obtained from outside research partners are identified for inclusion in the inventory as part of shipping and receiving processes. In addition, nanomaterials procured by NREL are bar-coded and entered into the Chemical Management System inventory by Shipping and Receiving when they are received.

Nanomaterial Waste Streams. Two sites – TJNAF and BNL – have implemented conservative processes for controlling waste streams that could contain nanomaterials.

- Although nanomaterials are not specifically addressed in Federal waste disposal regulations and thus are not required by regulation to be disposed of as hazardous materials, TJNAF has established processes for conservatively marking, classifying, and dispositioning waste streams generated in a nanomaterial work area.
- At BNL, nanomaterial-bearing waste streams (solid and liquid wastes) that contain nanoscale materials are conservatively marked, classified, and dispositioned as hazardous waste. (It is recognized that regulations at some sites do not allow the designation of non-hazardous wastes as being hazardous.)

Transportation. TJNAF has established specific procedures for transportation of nanoscale materials, both onsite and offsite. Onsite transportation of nanoscale materials between facilities is prohibited, except for industrial hygiene samples and transportation of nanomaterial waste. Those movements are restricted to a specifically designated vehicle. For offsite transportation, the operational safety procedure follows current Department of Transportation (DOT) regulations for packaging hazardous materials in DOT Group I containers, although such regulations do not address the transportation of nanomaterials.

Requirements Management. BNL has developed effective mechanisms for ensuring that DOE expectations for nanomaterial safety are incorporated into the site requirements management system. To ensure that requirements are institutionalized and communicated, BNL has established procedures in its standards based management system (SBMS) for implementation of DOE policy and the NSRC Approach Document related to nanoscale material ES&H. Also, the BNL Director has established an Institutional Nanoscale Science Advisory Committee to provide information and guidance, ensure effective SBMS implementation and approach strategies, and ensure that nanomaterials are used properly and safely at BNL. Further, BNL management has placed emphasis on adherence to controls in order to mitigate any dispersion of free nanoparticles to work areas, the environment, or waste streams. ORNL has used a similar approach to incorporating the NSRC Approach Document into their SBMS and is working to further define site-specific expectations in supplemental institutional requirements.

Research Center at Lawrence Berkeley National Laboratory

Senior Management Initiatives. Senior management at BNL, NREL, and ORNL have taken proactive actions to promote research activities that can enhance nanomaterial safety in the long term.

- BNL senior management is supporting a directed research grant that addresses nanoscale material toxicology on human epithelial cells and has demonstrated that relevant safety and health information can be derived from this research.

- NREL has initiated discussions with NIOSH about possible participation in their Nanotechnology Field Research Effort. NIOSH has agreed, and a site review is tentatively scheduled for September 2008. As part of this program, NIOSH funds and dispatches a field research team to assess workplace processes, materials, and control technologies associated with nanotechnology and to conduct onsite assessments of potential occupational exposure to nanomaterials. Through this program, NREL will benefit from an unbiased, scientific baseline assessment of the potential sources of workplace exposure to nanomaterials and assistance in prioritizing areas of improvement. NIOSH will use information obtained from this and other assessments to determine potential occupational safety and health implications of exposure to engineered nanomaterials and to develop guidance to ensure safe working conditions. It is also recognized that the four other Research Centers have been engaged in a dialog with NIOSH since 2003 on various aspects of nanomaterial safety.

- ORNL senior management has supported a number of ORNL efforts to develop industrial hygiene exposure monitoring protocols, as well as efforts to support the development and maintenance of the NSRC Approach Document.

3 Successes in Implementing the NSRC Approach Document

In addition to the Notable Practices in Section 2, the Independent Oversight team identified a number of areas where DOE sites, for the most part, are effectively implementing elements of the NSRC Approach Document. While there may be some exceptions at the site level or within sites, for the areas below, most DOE sites have demonstrated successful performance relative to the expectations established in the NSRC Approach Document in the following areas.

Nanoscale material activity training has been developed and presented to nanomaterial researchers at most sites. Nanomaterial training material has been developed and is well designed and sufficiently comprehensive. Because of such training and support from ES&H staff, most laboratory principal investigators and researchers were found to be knowledgeable of the latest information on nanoscale activity recommendations/ site requirements.

Most sites have appropriate controls for limiting access to nanomaterial work areas. Some sites use automated access control systems at laboratory areas to limit access to authorized nanomaterial workers and to facilitate implementation of other hazard controls. For example, at SNL, access to individual laboratories in the CINT Core Facility is card-controlled, and the ES&H Coordinator verifies that researchers have the required training prior to activating card access.

Most observed work practices were performed in a manner that minimizes the likelihood of skin contact with, or release of, engineered nanoparticles. Consistent with the NSRC Approach Document suggestions, most observed experimenters used reasonable care to minimize their exposure to dispersible nanomaterials, and most work with dispersible materials was performed inside engineered containments. When these materials were transferred between workstations, most were contained in closed, labeled containers as specified by the NSRC Approach Document. With a few exceptions, gloves, laboratory coats, and safety glasses were worn when there was a potential for skin contact with dispersible nanomaterials.

In most cases, work areas that were observed in this review were established with appropriate engineered controls. Consistent with the NSRC Approach Document, engineered enclosures, such as fume hoods, glove boxes, and vacuum chambers were used in most workplaces to reduce the potential for exposure to dispersible nanoscale materials. Laboratories were separated from adjacent areas with walls and doors, and ventilation systems were typically balanced to provide a direction of air flow from adjacent areas into the laboratories to further control the spread of dispersible nanomaterials. Sinks, showers, and eye wash stations were provided for emergency decontamination. Such controls were used for most work with nanoscale materials, although some exceptions were identified (e.g., dispersible materials were handled on bench tops outside of engineered enclosures in a few cases).

4 Challenges in Implementing the NSRC Approach Document

Although there are several notable practices and some areas of positive performance, overall, most DOE sites are still in the early stages of implementing the NSRC Approach Document. There are numerous weaknesses in current programs at most sites, and there are a number of challenges to address to achieve consistently effective performance across DOE sites.

Some DOE line management and contractors have not ensured that nanomaterial safety programs were effectively defined and implemented at the site and activity levels. Although the DOE policy on nanoscale safety and the initial version of the NSRC Approach Document were issued over two years ago, only a few sites were proactive in translating the policy and guidance into site safety programs to address the unique and uncertain nanomaterial hazards. In some cases, efforts to specifically address nanomaterial safety in the site ES&H programs were not initiated until recently and were prompted by the recent IG report or the subsequent DOE/contractor direction to implement the NSRC Approach Document. Even after DOE indicated its expectations and the sites agreed to implement the NSRC Approach Document, the expectations were not consistently communicated, understood, and verified at the site level or at the activity level within sites. In three cases, nanomaterial activities were ongoing, but some of the appropriate site ES&H and line managers were unaware of the activities and thus sis not exercise appropriate control and review. As noted in this report, many of the recommendations were not effectively implemented, and some were not addressed without a documented technical basis.

In many cases, site nanomaterial safety programs have not been adequately incorporated into site ISM processes. Most DOE sites have not incorporated nanomaterial safety requirements into their site requirements management system. Within some sites, there were wide disparities in the methods and effectiveness of nanomaterial safety practices, indicating insufficient institutional control and review of work practices. At most sites, unique aspects of nanomaterial safety have not been incorporated into work planning and control processes, hazard analysis and control processes, and/or work documents. In a number of cases, sites do not have documented policies or instructions for such areas as packaging, shipping, transport, cleanup, and managing waste streams. In many cases, site assessments and reviews to date have not identified such process and implementation weaknesses.

In some cases, nanomaterial safety controls have not been applied to support organizations and personnel. At many sites, nanomaterial controls were developed and applied primarily with the researchers in mind. However, personnel from various other site organizational elements, such as maintenance, janitorial, waste management, shipping/receiving, and procurement, may encounter potential nanomaterial hazards in the course of their work activities. In a number of cases, site nanomaterial programs have not given sufficient attention to support organization personnel. Some sites have developed effective training and provided it to researchers but not to personnel in support organizations that may encounter nanomaterials. Similarly, in a number of cases, potential nanomaterial hazards were appropriately defined in research work control processes (e.g., experimental safety plans) but not in work control processes for conducting facility work (e.g., maintenance on equipment that could be contaminated with nanomaterials).

Chemical inventories and chemical management systems have not been consistently effective in identifying the presence and tracking the location of nanomaterials. When engineered nanomaterials are purchased, the purchase requisition often identifies nanomaterials. However, when the material arrives on site and is inventoried, the chemical management inventory often does not identify chemicals as nanomaterials. The NSRC Approach Document does not suggest an inventory of all naomaterials; however, the ASTM Standard calls for an inventory of processes/locations where nanomaterials can be found. In one example, palladium nanomaterial is listed only as palladium on the chemical inventory. Also, chemical inventories of nanomaterials on site are not maintained or not complete at most sites and typically do not identify the presence of nanomaterials in individual laboratories. Further, most chemical management systems are not searchable for nanomaterials. In addition, in many cases, nanomaterials are produced on site and are not captured in a chemical inventory. While this situation is also true for other materials produced in small quantities on site, some sites use the inventory to identify where nanomaterial research is being conducted; the usefulness of chemical inventories for this purpose is limited if the nanomaterials that are produced on site are not included.

Medical surveillance expectations are not consistently understood and implemented. The implementation of baseline medical evaluation requirements and the identification of workers classified as needing baseline evaluations vary widely across the sites reviewed and often has not been consistent with the recommendations in the NSRC Approach Document. Some sites have not determined who should be classified as a "nanomaterial worker," or what information should be collected and utilized to determine the absence of any unusual health effects. Some sites conduct baseline medical evaluations for all identified nanomaterial workers, while others restrict medical evaluations to one type of nanomaterial workers (i.e., those working with carbon nanotubes). Some sites consider the baseline evaluations to be voluntary. One site has chosen to defer any decisions specific to medical surveillance for nanomaterial workers until DOE provides further direction. As discussed elsewhere, support organization workers are not always considered for inclusion as nanomaterial workers and thus may not be evaluated for medical surveillance. Several site medical programs have not addressed the periodic monitoring clause as written in the NSRC Approach Document.

Research Center at Argonne National Laboratory

Nanomaterial contamination control work practices at a number of sites have not been fully effective. Rigorous controls are needed to minimize the spread of nanomaterials from work areas because the ability to monitor nanomaterials is limited, and the health effects from exposure are uncertain for many of these materials. However, in some cases, controls may not be adequate to prevent the inadvertent spread of contamination from work areas because the boundaries of potentially contaminated areas are not clearly defined, procedures are not established for removing protective clothing or for cleaning items before removing them from contaminated areas, and step-off pads are not used. In several work observations, the use of disposable gloves as controls for handling of potentially contaminated waste and objects being moved from potentially contaminated areas (e.g., fume hoods and glove boxes) was not well controlled. For example, some new PPE (i.e., gloves) was observed being stored within potentially contaminated fume hoods. Furthermore, current limits in instrumentation and protocols, in most cases, preclude effective monitoring of surfaces for nanomaterial contamination. Several laboratories that were visited have requirements that materials be wiped down before being removed from the glove boxes and/or designated nanomaterial work areas, but few sites incorporate nanomaterial contamination control practices in procedures or work documents, and the requirements are not well understood by workers or are not routinely implemented. Although glove boxes, glove bags, and chemical hoods are used for most research activities involving the handling of nanoscale particulate materials, several exceptions were noted (e.g., scales for weighing, and equipment for sonication or other mixing devices used on open bench tops without benefit of local exhaust ventilation). At several sites, potentially contaminated laboratory coats are sent off site to a commercial laundry for cleaning, and acceptable practices for re-use of laboratory coats are not defined.

Ventilation practices do not always conform to the recommendations of the NSRC Approach Document or have not been adequately evaluated. The NSRC Approach Document recommends using filters or other methods to reduce the release of nanomaterials. However, with some exceptions (primarily those laboratories with newly updated hoods), chemical fume hoods are not HEPA filtered. Most of the laboratories that do not currently filter the effluent streams stated that they were evaluating the need for installing HEPA filtration. Also, some nanomaterial activities are difficult to successfully perform in a standard fume hood because of the potential loss of material through the ventilation system. In a few cases, low-flow-rate hoods have been put into use by laboratories to minimize particle loss through the exhaust. In some cases, these laboratories do not have a documented basis to demonstrate that the reduced face velocity provides adequate worker protection from exposure to nanomaterials; however, in some other cases, the effectiveness of the hoods with respect to gases and particulates was adequately established before procuring the equipment.

Communication of potential nanomaterial hazards and controls to workers is not always effective. The signage guidance in the NSRC Approach Document has not been adequately implemented at some sites. Most laboratories have not established specific requirements for posting nanomaterial areas, equipment, and ventilation systems, and some areas processing nanomaterials, including benchtops, were not posted. Signage and postings often do not specify PPE or other administrative control requirements, and this information is often not clearly specified by other activity-level work control documentation. Labels and markings are not always applied to smaller containers or in-process vials of nanoscale materials. Although MSDSs were available for nanoscale materials purchased from suppliers, they are of limited value because the hazards and controls specified on these sheets are normally based upon the properties of bulk materials and do not account for the potential nanomaterial hazards.

Most DOE sites have not sufficiently defined PPE requirements and have not ensured consistent implementation at the activity level. Guidance for establishing minimum PPE requirements when working with nanomaterials has not been established at some sites. Although each of the sites conducts hazard evaluations as a basis for determining PPE requirements, some sites have not provided guidance concerning expected PPE considerations when working within nanomaterials in various forms (e.g., powders, liquids, and embedded particles). As a result, there is considerable inconsistency among sites and within a specific site as to the PPE requirements for the same nanomaterial hazard. In addition, both line management and safety professionals who lack experience in working with nanomaterials have no guidance in selecting PPE for certain nanomaterials, especially since the traditional sources of guidance (i.e., MSDSs or professional references) are lacking. For example, laboratory coat requirements at one site were ambiguous, resulting in differing interpretations of the requirement among researchers and ES&H professionals (e.g., whether it is permissible to wear laboratory coats outside a laboratory after they were worn during work with nanoscale materials in a laboratory). Practices for handling used PPE vary between sites and are not consistent between laboratories at some sites. Some used gloves were bagged and disposed of as contaminated wastes; at other locations, they were handled as ordinary trash unless visibly contaminated. Offsite laundries are routinely used for cleaning laboratory coats; some of these laundries have not been notified that the laboratory coats may be contaminated with nanoscale materials. One site has established requirements for the use of respiratory protection whenever work is performed outside of engineering controls, but these requirements were not being followed. Well-defined and consistently implemented PPE requirements are particularly important for nanomaterials because the ability to perform specific hazard evaluations and exposure assessments is limited by the lack of hazard and toxicological data for many nanoscale materials.

Implementing workplace characterization and exposure assessment programs for nanomaterials represents technical challenges for all sites, and some sites have not made significant progress. Workplace characterization and exposure assessment programs are to be performed for site workplaces to identify hazards and include an initial baseline characterization and updates as conditions change. The workplace characterizations may identify a need for continued monitoring and sampling. The NSRC Approach Document recognizes that "there is no validated or consensus approach for characterizing worker exposures" but "recommends a good faith effort to characterize the exposure of personnel exposed to engineered nanoparticles and to associate the resulting data to those nanoparticle-exposed personnel." Several sites indicated that quantitative exposure assessments are of limited value because occupational exposure limits for nanoparticles are not established for use in evaluating the results. Baseline assessments are recommended, but there are limitations in performing a baseline assessment based on particle counting because the variables, such as ventilation flow, room design, temperature and humidity, and high background particle counts from undefined sources, impact the usefulness of baseline monitoring. While these technical challenges are considerable, the efforts by the various sites to develop and implement workplace characterization and exposure programs has varied considerably. Most sites have identified the presence of potential nanomaterial hazards, but only three sites have attempted to apply their existing worker exposure assessment programs (developed to meet the requirements of 10 CFR 851) to assess worker exposures to nanomaterials. At one site, only three of the ongoing 75 nanomaterial projects have had a documented qualitative exposure assessment performed, although a number of these projects had been reviewed by industrial hygiene and, based on the professional judgment of the industrial hygienist, did not require sampling or monitoring. Only one site has attempted to conduct baseline monitoring prior to startup of new nanomaterial R&D projects, and only two have attempted to monitor for nanoparticles during nanomaterial research projects.

Implementing workplace monitoring and sampling programs for nanomaterials represents technical challenges for all sites, and some sites have not made significant efforts or progress. Workplace monitoring and sampling is to be performed where it is determined to be needed and at appropriate frequencies, based on workplace characterization and exposure assessments. The NSRC Approach Document provides a number of recommendations concerning workplace monitoring and sampling for nanomaterials and an example industrial hygiene sampling protocol. A few sites have attempted to develop sampling and monitoring protocols for nanomaterials, procure particle counters, and conduct monitoring for nanoparticles in the workplace. However, results of monitoring, when performed, have generally been inconclusive due to the difficulties in attempting to detect small quantities of nanoparticles in the midst of larger uncertain and fluctuating particle backgrounds. To date, monitoring of nanoparticle work activities has been limited to particle counting for ongoing work and comparing the measured particle counts against a baseline particle count. Due to the limitations of instruments and the lack of monitoring protocols, none of the sites conduct worker breathing zone monitoring or monitor work surfaces for potential nanomaterial contamination. One site relies on the example industrial hygiene sampling protocol provided in Attachment 1 to the NSRC Approach Document, and two other sites have incorporated elements of Attachment 1 in their sampling protocols. At these two sites, the full complement of sampling protocols and instrumentation, as recommended in the NSRC Approach document, was not deemed to be feasible and/or useful at this time. On the positive side, one site was able to collect more statistically significant data for nanomaterial work evolutions by using a mobile "clean room" to reduce contamination, which dramatically lowered background counts during sampling efforts.

Packaging, labeling, and transport provisions are not always effectively defined and implemented. The NSRC Approach Document provides recommendations for packaging, labeling, and transporting nanomaterials that are more conservative than DOT requirements. Some sites have not issued requirements for shipping, labeling, and transporting packages in accordance with the NSRC Approach Document recommendations; therefore, there is limited assurance that the recommendations are being implemented consistently. Some sites do not use DOT Group 1 packaging, as recommended by the NSRC Approach Document, for nanomaterial-bearing wastes that are not otherwise hazardous. At least one site does not apply labeling as recommended, and at least two sites have transported nanomaterials off site in personal automobiles without the recommended application of DOT Group 1 packaging and use of qualified transportation carriers. Transporting nanomaterials within the laboratories has not always been sufficiently addressed.

Waste management provisions for nanomaterial-bearing waste streams are not always implemented effectively. Most sites have adopted (or are in the process of adopting) policies for management of nanomaterial-bearing waste materials that are generally consistent with the recommendations of the approach document, but implementation is not rigorous and current practices, in most cases, do not meet the objectives. Only one of the reviewed sites manages these wastes consistent with all NSRC suggested practices. Wastes were labeled as hazardous but did not always indicate the presence of nanomaterial on the container labels and/or hazardous waste log sheets, as recommended by the NSRC Approach Document. Most sites have not established protocols for ensuring that otherwise non-hazardous materials (such as gloves being worn while working in a designated nanomaterial hood or enclosure) are treated as potentially contaminated, segregated, and placed in a hazardous waste receptacle for disposition. Most sites have not yet updated waste handling procedures, used by waste management service groups, to incorporate applicable guidance from the NSRC Approach Document. Some nanomaterial wastes (e.g., dry PPE, carbon nanotubes) that do not contain Resource Conservation and Recovery Act (RCRA)-listed constituents are re-characterized by local waste management services as non-hazardous and sent to disposal facilities for non-hazardous wastes, including sanitary landfills and solid waste incinerators. The intent of the NSRC Approach Document is not clear in this area; the document states "Send otherwise non-hazardous nanomaterial-bearing waste to a RCRA-permitted treatment storage and disposal facility." However, hazardous and non-hazardous wastes are disposed of at permitted facilities.

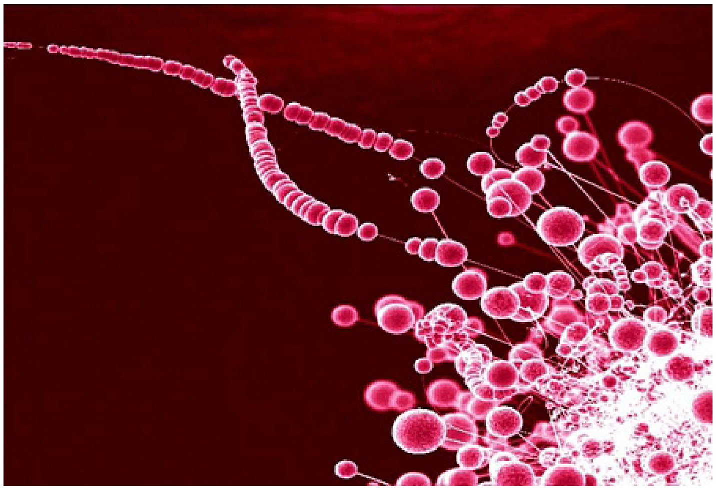
5 Assessment

As discussed in Sections 2, 3, and 4, the Independent Oversight Special Review identified a number of positive aspects and challenges and weaknesses in the implementation of DOE requirements and the NSRC Approach Document. Independent Oversight's assessment of status is organized according to three areas:

- DOE policy, requirements, guidance, and expectations
- Site implementation of the NSRC Approach Document and applicable requirements
- DOE oversight and contractor assurance.

Policy, Requirements, Guidance, and Expectations

At this time, there are no DOE requirements that apply to contractors and that specifically address the unique aspects of potential nanomaterial hazards. DOE policies are intended to reflect the philosophies and fundamental values of DOE and are not intended to provide specific operational requirements. Like other DOE policies and in accordance with the provisions of the DOE directives program, DOE Policy 456.1, *Secretarial Policy Statement on Nanoscale Safety*, provides general and high-level objectives for nanomaterial safety programs, does not include operational requirements, and does not directly apply to contractors. In accordance with DOE Order 251.1B, *Department Directives Program*, DOE orders that include contractor requirement documents are the mechanism for establishing requirements that apply to contractors. At this time, DOE has not issued any DOE directives that specifically address nanomaterials. Title 10 CFR 851 and the ISM requirements (which are invoked for contractors through a contractual clause) apply to contractors and establish processes and requirements that are intended to encompass all site hazards. At this time, however, 10 CFR 851 and ISM requirements do not include specific information that addresses the unique aspects of nanomaterial safety (e.g., unknown and uncertain health and toxicological impacts, lack of exposure standards, limited sampling and monitoring technological capability).



A Nanomaterial Bead Chain

DOE intends to establish requirements for nanomaterial safety through development of requirements for Paragraph 11 of 10 CFR 851 when adequate information (e.g., consensus standards) is available. DOE has also considered developing requirements, such as a DOE notice, to establish specific requirements for nanomaterial safety while Paragraph 11 of Appendix A of 10 CFR 851 is developed. However, DOE deferred issuance of specific requirements and currently relies on the broad requirements of 10 CFR 851 and ISM, which are complemented by the nanomaterial-specific information in the NSRC Approach Document.

The NSRC Approach Document appropriately addresses the elements of a nanomaterial safety program and provides approaches that reflect best practices in the industry. From a technical content standpoint, the NSRC Approach Document is consistent with guidance documents that have been issued by other organizations with nanomaterial expertise, such as the American National Standards Institute (ANSI), ASTM International, CDC, and NIOSH. The NSRC Approach Document explicitly states that it provides "non-mandatory guidance" and was originally intended to be used only by the five DOE Nanoscale Science Research Centers.

As discussed in Section 1, the IG report identified some implementation weaknesses and recommended adopting the NSRC Approach Document as a DOE requirement. DOE did not agree with the specific IG recommendation but acknowledges the need to develop specific requirements that apply to contractors and that address the unique aspects of potential nanomaterial hazards (as exemplified by the reserved Paragraph 11 in 10 CFR 851).

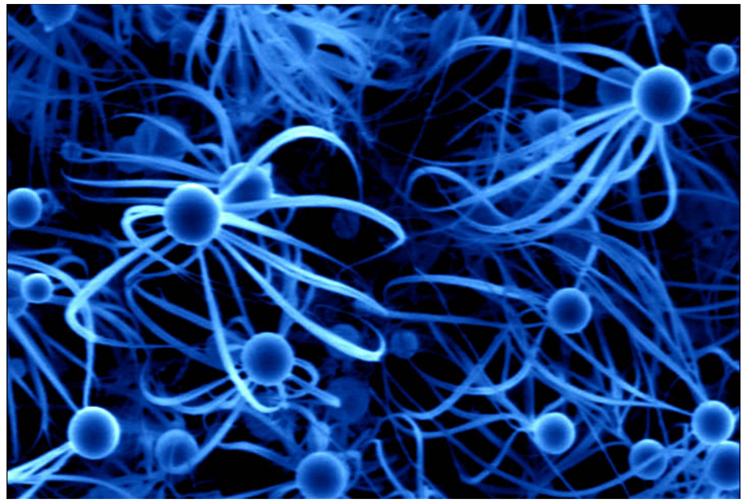
Partially in response to the IG report, the Under Secretary for Science endorsed the implementation of the NSRC Approach Document as a measure to ensure adequate worker safety pending the eventual development of DOE requirements that specifically address nanomaterials. The Under Secretary's expectations were communicated to all DOE Laboratories through the National Laboratory Directors' Council and applied to all DOE Laboratories that perform nanoscale material activities, including sites and facilities that are not part of one of the five Research Centers. Most of the Laboratories are under the cognizance of the Under Secretary for Science, but others are not.

All DOE Laboratories committed to implement the NSRC Approach Document in principle, as indicated in their letters provided to the Under Secretary for Science through the National Laboratory Directors' Council. Some of the DOE Laboratories indicated some caveats in their commitment to implementation. In addition, in the May 30, 2008, letter to the Secretary of Energy, several DOE Laboratories proposed conformance to the NSRC Approach Document in lieu of DOE issuing additional requirements.

This "voluntary compliance" approach was part of the DOE decision to disagree with the IG's recommendation for DOE to issue definitive requirements that apply to nanomaterials (i.e., to issue the NSRC Approach Document as a DOE requirements document). In its response to the IG report, DOE indicated that issuing additional policy or guidance was not necessary, in part because sites had committed to implement the NSRC Approach Document recommendations. In support of this decision, DOE line management and sites indicated that mandatory requirements would be overly restrictive and that DOE requirements would lag behind rapidly evolving nanoscale science/research, technology developments, and new/modified exposure standards for nanomaterials.

While Independent Oversight did not evaluate the technical adequacy of the NSRC Approach Document (the document was developed by recognized experts in the nanomaterial safety field and has been adopted by other organizations as an effective source of nanomaterial safety guidance), Independent Oversight examined the adequacy of the DOE approach to communicating its expectations and ensuring that the voluntary compliance approach meets its intended purpose. The review identified some positive aspects and some areas of concern, as discussed below.

The results of this Special Review indicate that the Under Secretary of Energy's expectations and the DOE Laboratories' commitment to the implementation of the NSRC Approach Document have led to a number of significant improvements and are continuing to have a positive impact. As noted throughout this report, there are many instances of actions that DOE sites have taken to meet the NSRC Approach Document, and other actions are planned as a result of gap analysis.



Nanowires

In addition, in coordination with DOE line management, several DOE sites have taken significant actions to institutionalize nanomaterial safety requirements. All of the reviewed DOE sites endorsed DOE Policy 456.1, and several have incorporated it into their contracts to reinforce management's expectations for compliance with the policy. Some other sites endorsed the policy in principle but correctly indicated that DOE policies are intended to apply to DOE organizations and are not the correct mechanism for including requirements in the contractor's site operating contract; some of these other sites took measures to include the essence of the policy in their site requirements (e.g., issuing a corresponding site policy). Also, several sites, with degrees of progress and rigor, have taken actions to incorporate the NSRC Approach Document into their site-specific requirements management system. In one case, cited as a notable practice in Section 2, BNL management effectively used their requirements management process to ensure that the DOE policy and NSRC Approach Document were evaluated and appropriately translated into site protocols for managing potential nanomaterial hazards (i.e., BNL incorporated the provisions of the NSRC Approach Document into its site-specific SBMS). This approach ensured that the NSRC Approach Document provisions were effectively communicated to site personnel as requirements that must be implemented or evaluated for an exception based on a documented basis. A few other sites have implemented less rigorous and comprehensive approaches to incorporating elements of the NSRC Approach Document into site-specific requirements. ORNL used a similar approach to incorporating the NSRC Approach Document recommendations into their site requirements management system, and TJNAF effectively addressed the NSRC Approach Document recommendations in a site procedure that covered their one ongoing nanomaterial project. The sites that took actions to incorporate the NSRC Approach Document into their site requirements demonstrated strong management commitment to the NSRC Approach Document recommendations and, for the most part, were effective in ensuring that most of the provisions were implemented at the activity level (e.g., the experiments at individual laboratories or specific work activities of support organizations).

DOE sites are also taking actions to ensure that they are aware of new information and developments in ES&H aspects of nanoscience. Site managers typically have established nanomaterials working groups, added nanomaterial subject matter experts to existing safety committees, and assigned subject matter experts to follow current trends and developments in the nanoscale research field. In addition, the five Centers have established their own working group to help develop ES&H guidance, follow current trends, and network with each other to expand the knowledge base for nanomaterial safety.

However, Independent Oversight identified concerns in three general areas: (1) implementation of the voluntary compliance approach, (2) the adequacy of the NSRC Approach Document to set DOE expectations

– a use for which it was not intended, and (3) despite the active engagement of senior DOE management in deciding to use the NSRC Approach Document as an interim requirements document, this approach essentially established a directive that is outside the DOE directives process. These three areas are discussed below.

Implementation of the "voluntary compliance" approach. Even after DOE's Under Secretary for Science indicated his expectations and sites agreed to implement the NSRC Approach Document, the expectations were not consistently understood and communicated at the site level or at the activity level within most sites. The "agreement" by some sites to implement the NSRC Approach Document, as documented in their letters to the National Laboratory Directors' Council, often only agreed to accept part of the recommendations or included language (e.g., "where feasible") that provided the sites the option of not implementing the recommendations without gaining DOE concurrence. At the activity level, some managers and principal investigators indicated that the NSRC Approach Document provided only guidance and were not aware of DOE or site senior management expectations for implementation of the recommendation. This situation was also evident during the recent nanomaterial safety workshop in July 2008, where several DOE participants from different sites were not aware of the expectations from senior DOE management to fully implement the recommendations of the NSRC Approach Document at each DOE Laboratory. As noted in this report, many of the recommendations were not effectively implemented, and some were not addressed without a documented technical basis. DOE and contractor assessments and operational awareness efforts were not sufficient to identify and correct these misperceptions and implementation weaknesses at the activity level.

In some cases, commitment letters to the Under Secretary from DOE sites included statements indicating that the implementation plan was in progress or identifying a commitment to implement the recommendations in the future. During the field reviews, Independent Oversight determined that some sites had a gap analysis and some of those had implementation plans, and that some sites were in the process of developing a gap analysis. Some other sites had no formal implementation plan. In many cases, the type of implementation weaknesses identified in this Special Review were not addressed by site implementation plans.

Near the end of this Special Review, the Under Secretary for Science issued a memorandum, dated July 21, 2008, that reinforced DOE's expectations for effective and rigorous implementation of the NSRC Approach Document. The memorandum also appropriately stressed the importance of ensuring safety in light of the uncertain risks associated with nanomaterials.

Adequacy of the NSRC Approach Document as a mechanism for delineating DOE expectations. Notwithstanding the positive aspects at some sites, two concerns were identified with the adequacy of the NSRC Approach Document as a mechanism for establishing DOE expectations. First, the NSRC Approach Document was not developed with the intention of serving as a requirements document. It contains a number of recommendations that are ambiguous and/or subject to interpretation, or that rely on individual sites to make decisions that should be made by DOE at the policy level. For example, the NSRC Approach Document indicates that ventilation exhaust emissions should be cleaned using filters (e.g., HEPA filters) or scrubbing before release to the environment, with the qualifier "whenever practical." Additional information is needed to determine the conditions that should trigger the use of filters and the steps to take (e.g., compensatory measures or development of a technical basis) when the use of filters or scrubbing is deemed to be impractical. In addition, the NSRC Approach Document does not include provisions that would normally be included in a requirements document, such as processes to follow if a requirement cannot be met (e.g., a documented technical basis for deviations from recommended practices).

Second, two aspects of the NSRC Approach Document are particularly challenging because consensus standards and approaches are not defined and/or the technology to accomplish the objective is not sufficiently developed: (1) workplace characterization and exposure assessment programs, and (2) workplace monitoring and sampling programs. In the area of workplace characterization and exposure, the NSRC Approach Document recognizes the challenges in these areas and recommends a "good faith" effort to characterize exposure. For workplace monitoring and sampling, the NSRC Approach Document recommends sampling, although sampling technologies and methods are not sufficiently developed to effectively implement this recommendation at this time. While these recommendations may be suitable for non-mandatory guidance, they are not suitable for a requirements document, as they cannot be effectively implemented. Independent Oversight's review indicates that some of the reviewed sites are devoting attention to, and attempting to, develop an implementation approach in these areas, recognizing the current limitations in technology and exposure standards, while other sites have taken little action and do not plan to until further DOE direction or guidance is received and/or consensus standards/methods are developed.

Use of an unofficial document instead of a DOE requirement. Although well intentioned and an interim measure, the expectation for DOE sites to implement the NSRC Approach Document does not have a basis in the DOE directives system. The NSRC Approach Document has been used as a guidance document for some time but has not been issued as a DOE guide. More recently, DOE line management has established the expectation for full compliance with the NSRC Approach Document, but such expectations have not been promulgated through the directives system and are not contractually binding. The use of an informal document is inconsistent with the Secretary's principles and the DOE directives program requirements, as delineated in DOE Policy 251.1A and DOE Order 251.1B. Establishing expectations through a non-standard process creates numerous problems (e.g., uncertainty in applicability, inability to ensure contractual accountability, no processes for change control). In the past few years, DOE has made a concerted effort to eliminate unofficial directives and ensure that requirements are established through a formal and systematic process.

The Special Review team recognizes the unique challenges associated with developing a formal DOE directive or guide. Because of the evolving science, nanomaterial safety guidance needs to be updated frequently; experience with DOE directives and guidance shows that the process of updating and revising directives and guidance is slow and can be cumbersome. Similarly, the process of incorporating revisions into contracts is also slower than would be necessary to keep up with evolving nanomaterial policy.

Nevertheless, the current situation amounts to unofficial expectations to implement an informal document and is not a sustainable solution. The results of this review show that the informal direction has not been consistently understood at the activity level, and personnel at the site and activity levels have widely varying interpretations of the intent of the DOE line management expectation to implement the NSRC Approach Document. As discussed previously, some sites and individual management/researchers interpreted the DOE expectation as requiring full compliance with every provision of the NSRC Approach Document (or an approved variance/exception), while other sites indicated that the NSRC Approach Document provided broad guidance but viewed the specific provisions as optional and subject to site determination about their applicability and implementation.

Based on the above considerations, the Special Review team believes that the optimal approach is to institutionalize DOE expectations (e.g., through a DOE notice issued through the DOE directives system) for using the NSRC Approach Document (and expected future revisions) as the technical guidance for nanomaterial safety. The Notice would not duplicate the information in the NSRC Approach Document but would provide formal direction for its use and address the gaps discussed in the above subsection. The DOE notice would need to ensure the ability to address the expected frequent revisions to the NSRC Approach Document and the development of other standards; this ability can be addressed by various means, such as requiring a site-specific nanomaterial safety plan that is updated frequently. The use of a time-limited DOE notice could be an effective interim step until DOE issues permanent direction (e.g., an additional section of the regulations or a DOE order or manual).

DOE Site Implementation of NSRC Approach Document and Applicable Requirements

For the sites that were reviewed, the effectiveness of site programs in implementing the recommendations of the NSRC Approach Document and other applicable policies (e.g., 10 CFR 851) varied considerably. As discussed below, there are a number of positive aspects of DOE site efforts to implement the NSRC Approach Document and DOE requirements, but there are a number of weaknesses in site processes and implementation of nanomaterial safety controls.

On the positive side, a few of the DOE sites have effectively implemented most aspects of the NSRC Approach Document; these sites have devoted significant attention to implementing a comprehensive and systematic nanomaterial safety program and have the benefit of sustained senior management support. In addition, there are areas of effective performance at all sites. In a number of cases, specific organizational elements or individual laboratory managers within a site organization have effectively implemented most aspects of the NSRC Approach Document. Although there are some exceptions, as noted in Section 3, most sites have been effective in implementing certain aspects of the NSRC Approach Document in the areas of training for researchers, access controls to laboratories, and certain elements of engineering controls (e.g., glove boxes and chemical hoods were used extensively). Further, all of the sites that were reviewed had one, or more, notable practice (i.e., instances of particularly effective or innovative means to meet the NSRC recommendations or to address technical challenges). As presented in Section 2, notable practices were identified at one or more sites in selected aspects of ventilation, engineering containment, nanomaterial worker identification and tracking, workplace hazard controls, chemical inventory management, managing nanomaterial waste streams, transportation, and requirements management.

There are also a number of areas where DOE sites are improving their nanomaterial safety programs. Many recent improvements were made or initiated as a result of the recent DOE expectations (i.e., the Under Secretary's expectations for assurance of implementation of the NSRC Approach Document). For example, several sites have performed assessments and/or developed a gap analysis to identify needed actions. Other sites have initiated efforts to better address the unique aspects of potential nanomaterial hazards in their hazards analysis and control process. In addition, most of the sites have indicated that they have addressed or plan to address the specific weaknesses identified during the Independent Oversight Special Review.

Notwithstanding the progress, successes, and initiatives, at most sites there were a number of weaknesses in implementing the NSRC Approach Document recommendations at the activity level. At three sites, the Independent Oversight team identified instances where nanomaterial activities were being performed, but the responsible site managers were not aware of the use of nanomaterials. For these activities, the sites had not systematically applied the NSRC Approach Document recommendations, and the observed practices were not adequate. In addition, site management at one site decided to suspend nanomaterial operations to address weaknesses identified during the Independent Oversight review. As discussed in Section 4, implementation weaknesses were prevalent in a number of important aspects of a nanomaterial safety program, including chemical management, medical surveillance, contamination control practices, ventilation controls (i.e., use of HEPA filters), communication of hazards to workers, use and control of PPE, shipment packaging and labeling, transport of shipments, and management of waste streams.

The cause of the implementation deficiencies varied from site to site and across organizations within the various sites. Some of the more prevalent causes include:

- Most sites are still in the early stages of implementing the NSRC Approach Document and/or specific safety measures for nanomaterials.

- In many cases, nanomaterial safety programs have not been sufficiently defined, or have not been effectively communicated or implemented at the activity level. As a result, work planning and control processes often did not result in potential nanomaterial hazards and associated controls (e.g., PPE requirements) being identified in work packages or other manuals/procedures used by workers.

- In many cases, expectations for nanomaterial safety controls are not explicitly documented in site requirements, but principal investigators were expected to consider nanomaterials as one of the many chemical hazards in the site hazard analysis and control process. While this approach is fine in theory, it does not work well in practice because there are typically no standards for evaluating potential nanomaterial hazards and acceptable exposure limits. At such sites, the effectiveness of nanomaterial safety controls depends on the principal investigator or industrial hygienist, varies widely, and is sometimes not adequate.

- Although sites have committed to implement the NSRC Approach Document provisions, the provisions are often either omitted from the site requirements management system or included as non-mandatory guidance that researchers and support personnel could choose to not implement without providing a technical basis or gaining management approval.

- Site processes often focus only on the research activity and do not consider the potential nanomaterial hazards to support personnel, such as maintenance and waste management workers, who may encounter nanomaterial hazards. Further, in some cases, sites have not developed site-specific directions/requirements for such areas as posting work areas, labeling shipments, and responding to spills.

- For the five DOE sites with designated Nanoscale Science Research Centers, implementation weaknesses are more pronounced at the locations that were not a part of the Research Center but that perform significant nanomaterial research. This situation occurs, in part, because the projects within Research Centers are funded differently, receive substantial ES&H support, and devote substantial attention to nanomaterial safety programs, while the facilities and laboratories outside the Centers receive less support and management attention.

Overall, significant work remains to address current technical challenges, to assess performance of all active nanoscience projects, and to ensure that effective practices are institutionalized in site requirements and work control systems. Continued management attention will be needed to meet the intent of the DOE policy with regard to keeping up with new information (e.g., research on health effects), technology, and guidance.

DOE Oversight and Contractor Assurance

In their letters provided as part of the National Laboratory Directors' Council submittal to DOE, all sites have committed to conduct independent assessments to confirm effective implementation of the NSRC Approach Document recommendations, in accordance with the SC expectations. Some of these assessments have been initiated or are scheduled for completion by the end of calendar year 2008. Others will be conducted in calendar year 2009.

DOE line management and contractors have performed oversight and reviews of various aspects of nanomaterial safety at most sites. For most of the sites reviewed, DOE line management, primarily through site offices, has performed some oversight activities that focus on nanomaterial activities, such as joint assessments, with the contractor, of nanomaterial safety programs and/or NSRC Approach Document implementation. Most site offices have also maintained operational awareness through various means, such as participation with site committees and working groups. At most sites, contractors have conducted some reviews that targeted nanoscale material activities. Based on their reviews, several sites have developed gap analyses to document the areas that need additional development to meet the NSRC Approach Document recommendations. Further, most sites have individuals participating with the NSRC ES&H working group and/or the Energy Facilities Contractors Group's working groups, and thus receive information about current safety-related information on nanotechnology.

In addition to the reviews that focus specifically on nanomaterials, all of the reviewed sites have established contractor assurance systems. These typically include programs for conducting self-assessments, independent reviews, safety walkthroughs, and other such feedback and improvement processes. These programs are intended to routinely evaluate compliance with institutional requirements, such as PPE usage, chemical hygiene, and waste handling, and may include reviews of relevant processes, such as work planning and control processes and the associated work packages. These programs are intended to encompass all site hazards and thus may examine potential nanomaterial hazards. However, the contractor assurance systems and associated processes typically do not include specific provisions and criteria related to nanoscale material activities. Other than the targeted reviews, the Independent Oversight review identified only a few instances where the established contractor assurance activities examined implementation of nanomaterial safety practices.

Although a number of nanomaterial reviews have been performed or are planned, the Independent Oversight Special Review identified some concerns that warrant additional attention. Many of the targeted reviews performed to date have focused on programmatic issues (e.g., the existence of a policy or procedure) and have not included work observations and performance reviews (e.g., evaluating the effectiveness of implementation of a site process). In addition, most of the assessments to date have not identified and documented deficient conditions/processes for corrective action. Further, the effectiveness of many of the site feedback and improvement processes is limited because they examine compliance with site requirements (e.g., ES&H manuals), and the site requirements often have limited information/requirements relative to nanomaterials.

6 Conclusions and Recommendations

Conclusions

The results of this Independent Oversight Special Review indicate that nanomaterial safety programs are in their early stages of implementation and that there are positive aspects and weaknesses in field implementation, DOE oversight and contractor assurance, and DOE policy and guidance. The NSRC Approach Document provides the basis for a comprehensive nanomaterial safety program, and some sites have taken action to institutionalize the recommendations into site-specific requirements. However, although the NSRC Approach Document fills some voids in DOE requirements, it is not within the directives system and has some shortcomings if it is used as a requirements document, which is beyond its intended purpose. In addition, the DOE expectation for implementing the NSRC Approach Document has not been adequately understood, communicated, and implemented at the site and activity levels. A few sites have effectively implemented most aspects of the NSRC Approach Document, and several sites have developed notable practices. However, most sites have a number of process and implementation weaknesses. DOE oversight programs and contractor assurance systems have performed one or more reviews of nanomaterial safety programs at most sites, but to date they have not been sufficiently effective in identifying and correcting many process and performance weaknesses.

Some actions are under way to address process and implementation weaknesses. In some cases, the individual sites that were reviewed have initiated corrective actions for site-specific weaknesses identified by this Special Review. Other appropriate actions, such as independent assessments of each site, have already been directed by DOE and scheduled by site contractors for 2008 or 2009. Further, the DOE Under Secretary for Science has recently taken action (including a July 21, 2008, memorandum to the National Laboratory Directors' Council emphasizing the importance of effective implementation of the NSRC Approach Document) to reinforce DOE expectations and prompt DOE sites to increase their efforts to ensure worker safety, recognizing the uncertain nature of nanomaterial hazards.

The National Laboratory Directors' Council, representing the DOE Laboratories, responded to the Under Secretary for Science memorandum and the draft results of the Special Review in an August 8, 2008, letter to the Secretary. This letter confirmed the commitment to effective nanosafety practices and acknowledged the unevenness in implementation of nanomaterial safety controls. The letter also expressed the perspective that DOE requirements for nanomaterial safety need to be flexible and called for a continuation of the approach established in the set of letters provided to DOE in May 2008 (one from each DOE Laboratory), indicating the approach to "implementing" the NSRC Approach Document. However, a review of these letters demonstrates that the site-specific approaches do not provide sufficient assurance that all sites will fully and effectively implement the provisions of the NSRC Approach Document or provide a documented rationale for an alternative approach that provides comparable levels of effectiveness. Further, the August letter indicates that the "implementation" of the NSRC Approach Document was intended to mean accepting the broad guidance but not necessarily implementing the specific provisions (or developing a suitable, documented alternative and an associated technical basis). In addition, the August letter does not address the other gaps in the current approach, including the concerns identified in Section 5 of this report (e.g., inability to implement an ISM standards-based approach given the lack of exposure standards, lack of direction for documenting alternative approaches, direction on actions to take in areas where current technology is not sufficient).

Recommendations

The ongoing actions are appropriate steps but do not fully address the current implementation weaknesses or resolve the issues associated with the current lack of DOE requirements. The following recommendations are provided for DOE line management and contractor site management consideration.

1. **HSS, in coordination with DOE line management at Headquarters, should develop and issue timely interim requirements that apply to DOE contractors and specifically address the unique aspects of potential nanomaterial hazards, in accordance with the DOE directives program requirements as delineated in DOE Policy 251.1A and DOE Order 251.1B.** Specific actions to consider include:

   - As an interim measure, issue a timely DOE notice that institutionalizes the current approach (which consists of unofficial direction to implement the NSRC Approach Document) in a manner that complies with DOE directive system requirements and is contractually binding.

   - Continue the current approach by adopting the NSRC Approach Document as the baseline for technical information, best practices, and implementation guidance. The NSRC Approach Document should be referenced in the new directive, including specific expectations for its application.

   - Maintain and update the interim direction above until permanent direction is developed (e.g., development of an order or manual, or issuance of regulations under Paragraph 11 of 10 CFR 851).

   - Ensure that the requirements provide a mechanism (e.g., a site-specific nanomaterial safety plan that is frequently updated and subject to DOE site office review and approval) to adapt generic guidance (e.g., the NSRC Approach Document provisions) to site-specific conditions in a manner that allows sites the flexibility to adapt and innovate while still providing the controls of mandatory requirements that DOE has accepted and approved as adequate to control the site hazards.

   - Ensure that the interim direction requires sites to specifically address (in a site-specific nanomaterial safety plan) each of the sections of the NSRC Approach Document and to define methods for implementation, site interpretations and site implementing requirements, any exceptions or alternative approaches, and plans for achieving compliance when a site requirement is established but cannot yet be fully implemented.

   - Include provisions that enable site contractors and DOE sites to regularly update their approved nanotechnology program when circumstances change, or as technology or the understanding of nanomaterial hazards evolves.

   - Consider giving HSS and other existing organizations, such as the National Laboratory Directors' Council, an advisory role to provide technical expertise, promote common understanding, and share lessons learned.

- Provide direction that covers areas not covered by the NSRC Approach Document, such as expectations for processes to follow when a recommendation cannot be implemented as written (e.g., develop a documented technical basis for deviations from recommended practices).

- Identify aspects of the NSRC Approach Document recommendations that may be overly prescriptive or restrictive (e.g., transportation packaging), and ensure that the DOE direction provides more flexibility.

- Provide direction for areas where current technology and/or methods are not sufficiently mature to enable full and effective implementation of the NSRC Approach Document, such as workplace characterization and exposure assessments and workplace monitoring and sampling.

- Establish clear criteria/guidance, or reference established consensus standards, for the identification of all nanomaterial workers and the collection and retention of all information necessary to verify the absence of any unusual health effects within that specific worker population. Medical and industrial hygiene subject matter experts should develop a minimum set of protocols to monitor workers for their general health status through a baseline medical evaluation and periodic general surveillance physicals, through the analysis of workplace characterization and exposure information, and by the utilization of the laboratories' data management system to link environmental data to potential nanoparticle worker exposures. (Some sites and organizations have developed such guidance, but it has not been implemented in most cases, in part because of uncertainty in the direction for implementation.)

2. **DOE contractors, in coordination with DOE site offices, should use the results of this Special Review to refine and improve current site nanosafety programs.** Specific actions to consider include:

- Systematically evaluating weaknesses and challenges identified in Section 4 at all sites to determine applicability and extent of condition. Corrective actions should be developed and implemented as needed.

- Review and revise site processes, such as work planning and control processes, hazard analysis and control processes, and environmental management systems, as necessary to incorporate the unique aspects of potential nanomaterial hazards and the provisions of the NSRC Approach Document.

- Review and revise site requirements documents, such as ES&H Manuals and other procedures/requirements (e.g., posting, PPE use, shipping and packaging procedures), as necessary to incorporate the unique aspects of potential nanomaterial hazards and the provisions of the NSRC Approach Document and other DOE direction (e.g., the above-mentioned DOE notice). This effort should be performed initially and repeated whenever DOE direction is revised; the NSRC Approach Document is revised; additional standards, including national consensus standards, are adopted by the site; or standards adopted by the site are revised.

- Evaluate the benefits of incorporating NSRC Approach Document provisions into site-specific requirements (e.g., similar to the SBMS approach at BNL, as described in Section 2) and/or contractor-specific health and safety program plans and associated procedures.

- Clarify and reinforce expectations for conformance to the NSRC Approach Document recommendations and site-specific requirements, including clear expectations for processes to follow to gain approval, based on a documented technical basis, for situations where NSRC Approach Document recommendations cannot be met as written.

- Provide supplemental information to clarify site-specific expectations for aspects of the NSRC Approach Document where current technology and/or methods are not sufficiently mature to enable full and effective implementation of NSRC Approach Document recommendations, such as workplace characterization and exposure assessments and workplace monitoring and sampling.

- Review and revise the processes for applying nanomaterial safety controls to support organizations.

- Improve methods used to identify nanomaterial work being performed at each site and all workers who may be exposed to nanomaterials, including researchers and maintenance, custodial, and waste management personnel.

- In light of the challenges in detecting contamination, increase emphasis on preventive contamination control efforts to ensure that nanoscale contamination is not spread from work areas.

- Consider strengthening the role of the NSRC working group or establishing a new complex-wide nanomaterial safety committee that includes within its charter a task to collect, track, and develop resolutions to DOE-wide nanomaterial safety issues, questions, and concerns.

- Ensure that the site office medical directors have a well defined and documented role in evaluating and controlling potential nanomaterial hazards, as part of the site's ISM processes.

3. **DOE and contractors should increase and/or accelerate assessment activities that focus on nanomaterial safety.** Specific actions to consider include:

- DOE sites that were reviewed during this Special Review should develop and implement corrective action plans that address the site-specific weaknesses identified by Independent Oversight. DOE site offices should review the corrective action plans and verify effective implementation of the corrective actions.

- Sites that perform work with nanomaterials that were not reviewed during this Independent Oversight Special Review should perform a timely self-assessment of their nanomaterial safety implementation against the recommendations of the NSRC Approach Document.

- DOE site office oversight processes and contractor assurance systems should include nanomaterial safety as a specific focus area and should perform targeted reviews of nanomaterial safety practices as a part of scheduled assessments of facilities and work activities. At least some of these reviews should be performance based and should evaluate implementation at the activity level, work packages, and application of work control processes.

- The weaknesses and challenges identified in Section 4 should be systematically evaluated to identify lines of inquiry and criteria that can be incorporated into DOE site office and contractor assurance feedback and improvement processes.

- DOE line management should work with contractors to determine whether scheduled independent assessments, some of which are currently scheduled as late as the end of 2009, can or should be performed sooner.

- DOE Independent Oversight should include nanomaterial safety as a focus area on upcoming inspections.

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APPENDIX A
Supplemental Information

A.1 Dates of Review

Argonne National Laboratory* (ANL)	June 16-20, 2008
Brookhaven National Laboratory* (BNL)	May 19-23, 2008
Lawrence Berkeley National Laboratory* (LBNL)	June 16-20, 2008
National Renewable Energy Laboratory (NREL)	June 2-6, 2008
Oak Ridge National Laboratory* (ORNL)	July 7-11, 2008
Sandia National Laboratories* (SNL)	May 19-23, 2008
Savannah River National Laboratory (SRNL)	June 2-6, 2008
Thomas Jefferson National Accelerator Facility (TJNAF)	June 2-13, 2008 (concurrent with scheduled ES&H inspection)

"*" indicates site has a Research Center

A.2 Review Team Composition

A.2.1 Management

Glenn S. Podonsky, Chief Health, Safety and Security Officer
Michael A. Kilpatrick, Deputy Chief for Operations, Office of Health, Safety and Security
William A. Eckroade, Director, Office of Independent Oversight
Thomas Staker, Director, Office of Environment, Safety and Health Evaluations
William Miller, Deputy Director, Office of Environment, Safety and Health Evaluations

A.2.2 Quality Review Board

Michael Kilpatrick
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Bill McArthur
Thomas Staker
Dean Hickman
Robert Nelson
William Sanders

A.2.3 Independent Oversight Review Team

Bill Miller, Team Leader
Al Gibson
Jim Lockridge
Larry Denicola
Mario Vigliani
Ed Stafford
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A.2.4 Program Office, Policy Office, and National Laboratory Participants

Don Harvey, NNSA
Robert Sabatini, BNL
Julie Henderson, Berkeley Site Office
Kensley Rivera, SC
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Jay Larson, SC
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A.2.5 Administrative Support

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APPENDIX B
Summary of Field Implementation of the NSRC Approach

The Special Review included onsite field reviews of work practices at selected U.S. Department of Energy (DOE) laboratories. The primary focus of the field reviews was to compare selected DOE laboratories operations against the approach outlined in Department of Energy *Nanoscale Science Research Centers Approach to Nanoscale ES&H [Environment, Safety, and Health] Revision 2 – June 2007* (NSRC Approach Document). The field reviews also considered applicable DOE policies, including DOE Policy 456.1, *DOE Secretarial Policy Statement on Nanoscale Safety*; DOE Policy 450.4, *DOE Safety Management System Policy*, which applies to all site hazards, including nanoscale materials, and requires a systematic process for identifying, analyzing, and controlling hazards; and 10 CFR 851, *Worker Safety and Health Program*, which requires a comprehensive program for protecting worker health and safety. Volume II of this Special Review provides the field reports for the eight reviewed sites.

For all eight sites, the Independent Oversight team addressed the following topical areas, which are derived from the topics and recommendations of the NSRC Approach Document:

- Site Approach to Nanoscale Material ES&H Activities
- Feedback and Improvement
- Work Processes and Implementation
- Engineering Controls
- Administrative Controls
- Personal Protective Equipment (PPE)
- Workplace Characterization and Exposure Assessments
- Worker Health Monitoring/Surveillance
- Worker Identification
- Transportation of Nanomaterials
- Management of Nanomaterial-Bearing Waste Streams
- Management of Nanomaterial Spills.

This appendix provides the Independent Oversight team's summary and analysis of the collective results for each of these areas, based on the results of the field reviews.

B.1 Site Approaches to Nanoscale Material ES&H Activities

Implementation of the NSRC Approach Document was in the early stages at many sites. At many of the sites and also at different facilities within a site, there were pockets of acceptable implementation of the NSRC Approach Document recommendations for nanomaterial safety practices. However, extensive work remains for most of the reviewed sites/facilities to fully implement the safety measures recommended in the NSRC Approach Document. Even those few sites that had implemented most of the NSRC Approach Document recommendations were found to have some significant tasks that remained to be completed. For some of the sites, nanomaterial safety implementation was in the early stages of development and consisted of adding the NSRC Approach Document recommendations to their ES&H procedures, performing a gap analysis, and developing an implementation plan. Most of the significant action items in the implementation plan remained to be completed. For two sites, the NSRC Approach Document recommendations had not been included in their suite of ES&H procedures and/or policies. In response to the weaknesses identified by the

Special Review teams, many of the sites have taken immediate measures to address some of the deficiencies; at one site, nanomaterial work was paused until the appropriate nanomaterial safety controls could be put in place. Immature integrated safety management (ISM) processes at a few sites proved to be a barrier to the implementation of the nanoactivity safety recommendations.

Several sites have included DOE Policy 456.1, *Secretarial Policy Statement on Nanoscale Safety*, in their site management and operating contract and have established specific procedures that closely follow the NSRC Approach Document. Site management has also established working groups, safety committees, and subject matter experts (SMEs) specific to nanomaterials research to help follow current trends and developments in the nanomaterial research field. The five Nanoscale Science Research Centers have established their own working group to similarly help develop guidance, follow current trends, and network with each other to expand the knowledge base for nanotechnology. Several other sites have not included the Secretarial policy in their contract (on advice from their general counsel) but have developed other procedures and/or documents that state their intentions concerning the Secretarial policy. Several of the sites have completed a gap analysis comparing their current program against the NSRC Approach Document and have developed an implementation plan that will develop site-specific procedures to address specific gaps in the program. Full implementation of the NSRC Approach Document was in the early stages of development, especially in the areas of processes and procedures concerning PPE, transportation, waste issues, labeling, medical surveillance, exposure monitoring, and worker identification parameters.

B.2 Feedback and Improvement

DOE ISM requirements were applicable to the sites reviewed. The DOE site and contractor feedback and improvement processes and implementation were reviewed as they related to nanomaterial safety activities.

DOE Oversight. The responsible DOE site and field offices have performed some level of oversight of nanomaterial activities at most of the sites visited as part of this Special Review. Half of the offices that were visited have participated in joint program status assessments of nanoscale material activities. A few offices have included nanoscale research activity locations as part of the routine oversight conducted by the Facility Representatives or other designated staff. Most offices have been involved in review of the design and readiness of Research Centers, participation with site committees and working groups, or periodic discussions with site nanomaterial SMEs. However, few formal DOE site office assessments have focused on nanomaterial work activities or resulted in the identification of potential areas of concern, indicating that to date, the effectiveness of DOE field office oversight in promoting continuous improvement has been limited. A few DOE offices have scheduled formal assessments of nanoscale activities for fiscal year (FY) 2009, following the sites' scheduled dates for full implementation of their respective nanomaterial safety programs.

Contractor Assurance System. Most contractors at the eight reviewed sites have conducted some level of operational and procedural reviews specific to nanoscale material activities. Depending on the site, these reviews included such activities as preparing a gap analysis of institutional procedures against DOE Policy 456.1 and the NSRC Approach Document, conducting walkthroughs and work observations, and review of hazard analysis and work control documents. As requested by the National Laboratory Directors' Council, these same sites have committed to conducting a formal assessment of their nanoscale material programs; half the sites that were reviewed have their assessments scheduled for FY 2009. Following the

Independent Oversight field review, one site temporarily stood down nanoscale material activities until interim nanoscale material safety measures could be put in place and the Laboratory Director approves resumption of activities.

All of the sites visited as part of this Special Review have established programs for conducting general safety walkthrough inspections and management reviews that ensure some level of periodic review of compliance with such institutional requirements as PPE usage, chemical hygiene, and waste handling. However, these processes typically do not have provisions specific to nanoscale material activities, and there were only a few instances in which the processes identified and documented implementation deficiencies for corrective action.

In addition to the reviews and assessments previously discussed, some sites have conducted gap analyses against other guidance, such as the ASTM International *Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings* (ASTM E2535-07, October 2007), the National Institute of Occupational Safety and Health (NIOSH) *Approach Toward Safe Nanotechnology* (July 2006), and the NIOSH *Interim Guidance for the Medical Screening of Workers Potentially Exposed to Engineered Nanoparticles* (November 2007). As a result, some aspects of these documents have been incorporated into institutional requirements at these sites.

Most sites have individuals participating with the NSRC ES&H working group and the Energy Facility Contractors' Group, maintaining contact with outside resources such as NIOSH and the American Industrial Hygiene Association, and monitoring technical publications and websites for current safety-related information on nanotechnology. Information and lessons learned are disseminated through a variety of means: directly to managers and researchers, through dedicated nanomaterial safety committees, or through pre-existing ES&H/chemical safety committees. There was anecdotal evidence that these communications resulted in action in a few situations.

B.3 Work Processes and Implementation

DOE Policy 450.4, *Safety Management System Policy*, outlines the five ISM core functions that provide the necessary structure for any work activity, such as working with nanomaterials, that could potentially affect the public, workers and the environment. At the selected sites, the Special Review team reviewed the implementation of the ISM core functions with respect to work processes and work implementation practices when working with nanomaterials.

Work Processes. Each of the reviewed sites has established formal work control processes for implementation of DOE Policy 450.4, as well as expectations that these processes will be applied when working with nanomaterials. However, at most sites, the use of nanomaterials has not been fully integrated into all aspects of the work control processes and ISM core functions.

In most cases, research work control processes have generally been effective in defining nanomaterial work through standard operating procedures (SOPs), experimental research packages, research proposals, and/or experimental safety plans. However, a number of the work control processes for conducting facility work (i.e., maintenance on potentially contaminated nanomaterial equipment) have not integrated nanomaterial hazard analysis and controls into work packages. The DOE sites with less mature ISM systems and processes in place are struggling with the implementation of the NSRC Approach Document more than those who have stronger processes for work planning and/or conduct of research for activity-level implementation of the core functions of ISM. At several of the sites with active nanomaterial research projects, there has been limited facility maintenance work to date involving potentially nanomaterial-contaminated equipment. However, in a least one instance, potentially contaminated ductwork was breached without any consideration that ongoing nanomaterials research used the ventilation system.

Some of the sites have attempted to address potential nanomaterial hazards in research work documents, but since the health hazards of working with various forms of nanomaterials are not well understood, the description of such hazards in work documents has been a challenge. The range of hazard classification for nanomaterials across the reviewed sites has ranged from an "irritant," to a "highly toxic chemical," to "unknown." One site has effectively included a section on "Novel Materials or Synthesis" in their Conduct of Research and Development Manual to address nanomaterials (as well as other materials) for which the health effects are not well known. Another site includes a conservative statement in their research safety summaries that "the hazards of nanomaterials have not been fully investigated, therefore all synthesized materials shall be treated as toxic and carcinogenic."

With respect to hazard controls when working with nanomaterials, several of the sites are revising sections of their ES&H manuals (training, PPE, conducting hazard assessments, environmental management, etc.) to reflect expected hazard controls when working with nanomaterials. A few sites are establishing nanomaterials as a specific ES&H manual chapter or Standards Based Management System Subject Area so that work control practices that involve training, safety and health, medical, and environmental control can be addressed in a comprehensive and integrated manner. Two sites have developed procedures for reviewing work activities against all the elements of the NSRC Approach Document.

A few of the sites have not attempted to modify site-level work control processes or ES&H manuals to reflect greater specificity when working with nanomaterials because the sites prefer establishing such direction at the division or department level (rather than at the institution level), or because the site has not perceived a need to pursue a fuller definition of nanomaterial hazard controls, or because the site has minimal ongoing nanomaterial work. At these sites, there is a wide disparity among departments or centers in the development and application of hazard controls for nanomaterial work. For sites that have not yet developed a formal system of hazard controls for nanomaterials, appropriate hazard controls are typically identified at the professional discretion of the industrial hygienist or ES&H coordinator. Each of the sites refers to a "graded approach" when identifying and applying work controls for nanomaterials, but in most cases the concept of a "graded approach" is not defined. One site has developed a "control banding" graded approach to nanomaterials and has developed detailed controls (PPE, labeling, waste management, etc.) depending on whether the nanomaterial is in the form of powder, liquid, or embedded particle. At the other extreme, another site allows the SMEs to define the "graded approach" based on professional judgment. When sites elect to not implement the hazard controls in the NSRC Approach Document, they rarely document the deviation or the justification for the deviation.

Work Implementation. The majority of nanomaterial work conducted at the reviewed sites is performed as research and development (R&D), though some is facility support work, such as maintenance and waste management. The current level of nanomaterial work at each of the reviewed sites ranges from one ongoing R&D project to over 75 projects. In most cases, the relevant work was conducted with nanomaterials either in solution or embedded in a matrix. In some cases, researchers worked with particulate or dry powder forms of nanomaterials, some of which was in a dispersible form. In nearly all cases, milligram or microgram quantities were used.

The scope of nanomaterial work at some sites was well documented, with each step of the R&D project described in detail. At other sites, the scope of work was not defined in sufficient detail to permit effective hazard analysis and/or development of controls. Most work documents that were reviewed did not have descriptions of the potential nanomaterial hazards, and at a number of sites the hazard controls in the work documents were not linked to the potential nanomaterial hazard. At one site, the hazard controls in the work documents were intended to bound aggregate hazards, such as solvents, nanomaterials, and carcinogens, without linking the hazard control to any specific hazard.

In general, most of the sites conducted nanomaterial work within the hazard controls specified within their work documents (e.g., SOPs or experimental research packages). However, in a number of cases, hazard controls for nanomaterials were not well defined in work documents because of the lack of well established site nanomaterial work control standards, processes, and/or procedures. When nanomaterial hazard controls are not well defined in work documents, the industrial hygienist, laboratory space manager, or principal investigator is pivotal to ensuring that the appropriate hazard controls are identified and appropriately implemented. Few of the work evolutions that were observed had defined contamination controls for working with nanomaterials.

B.4 Engineering Controls

Work Area Design. The NSRC Approach Document states the need to consider implementation of additional engineered or procedural controls to ensure that workers are protected in areas where engineered nanoparticles will be handled. Such controls were provided and used for most work observed during this review. Engineered enclosures, such as fume hoods, glove boxes, and vacuum chambers, were provided to reduce the potential for exposure to dispersible nanoscale materials. Laboratories were separated from adjacent areas by means of walls and doors, and ventilation systems were typically balanced to provide a direction of air flow from adjacent areas into the laboratories to further control the spread of dispersible nanomaterials. Sinks, showers, and eyewash stations were provided for emergency decontamination. While these controls were appropriate and were used for most work with nanoscale materials, dispersible materials were handled on bench tops outside of engineered enclosures in a few cases when conditions, such as air currents and vibration, inside the enclosures precluded performing the work inside. Administrative controls were applied in these cases but were not always adequate to control the spread of dispersible materials (discussed in Section B.5, Administrative Controls).

Ventilation Preferences. The NSRC Approach Document states the need to conduct any work that could generate dispersible nanoparticles in an enclosure that operates at a negative pressure differential compared to the workerís breathing zone. Examples of such enclosures include glove boxes, glove bags, and laboratory bench-top or floor-mounted chemical hoods. If a process (or subset of a process) cannot be enclosed, then other engineered systems (e.g., a local exhaust system, such as a "snorkel hood") are to be used to control fugitive emissions of nanomaterials or hazardous precursors. At most sites that were visited, glove boxes, glove bags, and chemical hoods were available and were used for research activities involving the handling of dispersible nanoscale particulate materials. Several exceptions were noted where scales for weighing and equipment for sonication or other mixing devices were used on open bench tops for work with dispersible nanomaterials without the benefit of containment enclosures or local exhaust ventilation. Some nanomaterial activities are difficult to perform successfully in a standard fume hood because of the potential loss of material through the ventilation system. For example, standard chemical fume hoods operating at 100 fpm face velocity can cause loss of dry nanoparticles through the ventilation system. To minimize particle loss, a few laboratories use low flow rate hoods, but they do not have a documented basis for demonstrating whether the reduced face velocity provides adequate protection.

The NSRC Approach Document states "do not exhaust effluent (air) reasonably suspected to contain engineered nanoparticles whose hazards are not well understood. Whenever practical, filter it or otherwise clean (scrub) it before release." However, with the exception of a few sites, and some individual laboratory hood installations at other sites (primarily those with newly updated hoods), many chemical fume hoods were not high efficiency particulate air (HEPA) filtered. Some laboratories made use of HEPA pre-filters or biosafety cabinets with HEPA filtration, and some of the newer laboratories incorporated designs in the fume hoods for adding HEPA filters at a later date, if needed. A few laboratories provided HEPA filtering in the building exhaust rather than providing a HEPA filter on each fume hood. Most of the laboratories that did not filter the effluent streams indicated that they were evaluating the need for installing HEPA filtration.

The NSRC Approach Document also recommends ducting the exhaust stream outside the building whenever feasible. Alternatively, filters, scrubbers, or bubblers may be appropriate to treat unreacted precursors and may also be effective in reducing nanomaterial emissions. The NSRC Approach Document also recommends that, if using portable bench-top HEPA filtered units, they should be exhausted through ventilation systems that will carry the effluent outside the building whenever possible. With some exceptions, emissions at all laboratories reviewed were ducted to the outside; however, in at least one case, HEPA-filtered air from a modified laminar flow hood used for nanomaterials was discharged back into the laboratory. In some glove boxes, HEPA-filtered exhaust air is also returned to the laboratory.

The NSRC Approach Document also recommends the maintenance and testing of the effectiveness of exhaust systems and components as specified by the manufacturer, and the evaluation of equipment previously used to synthesize, handle, or capture nanoparticles for contamination and incompatibility before reusing or disposing of it. The NSRC Approach Document also recommends that laboratory equipment and exhaust systems be evaluated for contamination before being removed, remodeled, or repaired. Most laboratories that were visited use laboratory chemical fume hoods as their designated areas for work with dispersible amounts of solid and liquid nanoscale materials. All observed hoods were inspected on either an annual or biennial basis, depending on local procedures, and all were within their required inspection interval. With some exceptions, the hoods had alarm features, and researchers were aware of appropriate use and settings. Hoods that were observed without alarm features were typically modified or locally constructed for a low flow application and may not meet all American National Standards Institute (ANSI) Z-9.5 specifications for laboratory ventilation or the NSRC Approach Document.

Glove boxes used at most sites typically are positive pressure in design to ensure material purity (moisture, oxygen content, etc.) or limit reactivity, and a variety of cover gases were used throughout the various institutions reviewed. The glove boxes, although not intended for worker protection, provide a clearly established, designated nanomaterial work area; however, care must be taken to ensure that any loss of gas through leaks is detected, because even small pinhole leaks in gloves can potentially spread nanomaterial contamination.

B.5 Administrative Controls

Chemical Hygiene Plan. Chemical hygiene plans were in place at each laboratory as required by 10 CFR 851, which incorporates 29 CFR 1910.1450 by reference. The NSRC Approach Document states that these plans "should be specific to the Center's scope of operation." Although some sites had recently revised their plans to specifically address nanoscale materials, most plans contained only general requirements for handling chemicals. Most sites supplemented their chemical hygiene plans with alternate policies or procedures, providing additional specificity for handling nanoscale materials.

While chemical inventories were maintained in accordance with chemical hygiene plans and other site procedures as specified by 10 CFR 851 (referencing 29 CFR 1910.1450), inventories of nanoscale materials present onsite were typically incomplete. Inventory system entries are based primarily on procurement records, which often do not specifically call out nanoscale constituents in procured material. Further, at some sites, much of the nanomaterial that is present is not procured from outside vendors but is synthesized on site, and thus would not be accounted for by the chemical inventory system (nor would most chemicals that are synthesized on site). In addition, some sites intend to use the chemical inventory as one tool to help identify where nanomaterial research is conducted; however, for the reasons outlined above, the inventory has only limited usefulness for this purpose because it does not identify all such activities.

Material safety data sheets are available for nanoscale materials purchased from suppliers. However, the hazards and controls specified on these sheets are often based upon the properties of bulk materials, do not adequately account for the potential nanomaterial hazards, and may be non-conservative with respect to the identification of health hazards and controls. In accordance with requirements, most laboratories create material safety data sheets for nanomaterials shipped off site but not for nanomaterials that they synthesize for use on site.

Housekeeping. Since nanomaterials cannot be easily detected, the NSRC Approach Document recommends routine housekeeping in laboratories where nanoscale materials are handled in order to control the potential for spread of contamination. HEPA vacuum cleaners were available at most sites, and one laboratory uses an ultraviolet light to monitor for gross quantum nanodot nanomaterial contamination.

Although housekeeping may be adequate for removing visible nanoscale materials (spills, etc.) in most cases, it is not consistently performed with enough rigor to ensure removal of particulate contamination that is not visible. Section 3.4.2 of the NSRC Approach Document states, in part, that "In areas where engineered nanoparticles might settle, perform precautionary cleaning, --- no less frequently than the end of each shift." While cleaning methods such as daily wet wipedowns are being used at some sites, the requirement for this cleaning has not been consistently incorporated into work controls, the need for it is not well understood by some workers, and it is not routinely performed in most laboratories.

Work Practices. Most observed experimenters used care to minimize their exposure to dispersible nanomaterials. Most work with dispersible materials was performed inside engineered containments, and when these materials were transferred between workstations, most were contained in closed, labeled containers as specified by Section 3.4.3 of the NSRC Approach Document. In general, appropriate PPE as described in the NSRC Approach Document was worn when there was a potential for inhalation or skin contact with dispersible nanomaterials. Some exceptions were noted in each of the above areas, but in general, experimenters were aware of potential hazards associated with nanomaterials and applied controls to minimize exposures.

The NSRC Approach Document suggests that workers take "reasonable precautions" to minimize the likelihood of skin contact with, or release of, engineered particles. Although care is used in handling nanomaterials, and engineered and administrative controls are applied to control exposures while performing experiments, controls may not be adequate to prevent the inadvertent spread of contamination from work areas. For example, at some sites the boundaries of potentially contaminated areas were not clearly defined, procedures were not established for removing protective clothing or for cleaning items before removing them from contaminated areas, and step-off pads were not used. At many sites, potentially contaminated laboratory coats were stored in common areas of the laboratory hallway and are sent off site to a commercial laundry for cleaning. Additionally, the frequency for re-use is not defined. More rigorous controls may be needed to minimize the spread of nanomaterials from work areas, in light of the limited ability to monitor these materials and the uncertainties about their health effects.

Nanomaterial contamination control work practices at a number of laboratories were not well developed. In several work observations, disposable gloves were used as a control for handling potentially contaminated waste, and objects that were moved from potentially contaminated areas (e.g., fume hoods and glove boxes) were not well controlled. Examples include some new PPE (gloves) that were stored in potentially contaminated fume hoods. Furthermore, current limitations of instrumentation and protocols preclude the development and implementation of monitoring of surfaces for nanomaterial contamination in most cases. Several laboratories that were visited had requirements that materials be wiped down before being removed from the glove boxes and/or designated nanomaterial work areas. However, few sites have incorporated nanomaterial contamination control practices in their procedures or work documents.

Labeling and Signage. The signage guidance in Section 3.4.4 of the NSRC Approach Document has not been adequately implemented at some sites. The NSRC Approach Document specifies the posting of "signs indicating hazards, PPE requirements and administrative control requirements at entry points into designated areas where dispersible engineered nanoparticles are handled." Although some sites post entry points and/or hoods as designated areas for nanomaterial use, most laboratories have not established specific requirements for these postings, and some areas processing nanomaterials, including bench tops, are not always marked as specified in the NSRC Approach Document. Signage and postings often do not specify PPE or other administrative control requirements, and this information is often not clearly specified by other activity-level work control documentation. Several sites are considering the development of standardized signs and labels, and one site has incorporated the "buckyball" symbol in nanomaterial labels and postings.

In several laboratories, nanomaterial storage containers, such as bottles of commercially procured nanomaterials and nanomaterial waste containers, were properly labeled with nanomaterial identifiers, consistent with the guidance in Section 3.4.3 of the NSRC Approach Document. However, labels and markings were not always applied to smaller containers or in-process vials of nanoscale materials. For example, small containers were often marked to indicate chemical contents but without indication of nanoscale constituents; in other cases, sample racks were labeled but the containers in the racks were not. This inconsistency was most evident at sites that have not developed institutional requirements for the marking and labeling of nanomaterials.

Training and Competency. Training on the safe handling of nanoscale materials is provided, or is being developed, at each of the laboratories visited during this review. The training to date has typically been at the orientation level, covering current knowledge (and uncertainty) about the potential hazards associated with nanoscale materials and emphasizing the importance of minimizing exposures. Priority has been placed on training researchers who routinely handle nanoscale materials, and most of these individuals have been trained. Training of support personnel, such as those providing maintenance, custodial, and waste management services, has not been considered or is still under development at some locations. The requirement for nanomaterial safety training has not been fully integrated into work control processes at some sites to ensure that individuals receive the training before performing work involving the potential for exposure to nanomaterials. In most cases, researchers interviewed during this review were knowledgeable of the potential hazards associated with the nanomaterials that they were handling.

B.6 Personal Protective Equipment

The NSRC Approach Document references the regulatory requirement (i.e., 10 CFR 851, which invokes 29 CFR 1910) to conduct a hazard evaluation of the planned work activity to appropriately determine the selection and use of PPE. Appropriate PPE for working with nanoscale materials would include that which would typically be required for wet chemistry laboratories, such as laboratory coats, polymer gloves resistant to both the nanomaterial and other chemicals being used, and adequate eye protection. The need for respiratory protection should be based on an evaluation of airborne exposure and, if warranted, should be a P-100 half-face cartridge-style respirator at a minimum. In addition, the wearing of closed-toe shoes, long pants without cuffs, and long-sleeve shirts would generally be appropriate.

A few sites have not established minimum PPE requirements specifically for work with nanoscale materials, relying instead on the results of a standard hazard evaluation. The remaining sites require a minimum of safety glasses and nitrile gloves; other glove materials may be substituted if necessary. With some exceptions, most laboratories require the use of nitrile gloves over hands prior to work within glove box gloves; however, a number of laboratories do not have or follow these requirements. In addition, many sites require the use of laboratory coats or other type of arm covering when working with nanoscale materials. However, the laboratory coat requirement at a few sites was ambiguous, resulting in differing interpretations of the requirement among researchers and ES&H professionals alike, and at two sites laboratory coats are not required because the industrial hygiene evaluation indicated that standard laboratory coats provided no protection against exposure to nanomaterials.

Practices for handling used PPE varied between sites and was not consistent between laboratories at some sites. Some used gloves were bagged and disposed of as contaminated wastes; at other locations, they were handled as ordinary trash unless visibly contaminated. Laboratory coats that were worn during work with nanoscale materials were sometimes worn outside of the laboratory. Offsite laundries are routinely used for cleaning laboratory coats; some of these laundries have not been notified that the laboratory coats may be contaminated with nanoscale materials. One site has begun using disposable laboratory coats for work with dry nanomaterials where the potential for contamination is high, and also disposes of standard laboratory coats contaminated with spilled materials.

Respiratory protection is available at most sites, and requirements for its use are usually linked to the results of exposure assessments (see Section B.7). Only a few sites were found to actively use it for work with dry nanomaterials outside of engineering controls. One site had established requirements for using respiratory protection whenever work was performed outside of engineering controls, but this requirement was not followed for work observed during this Special Review. Although respiratory protection is generally available, it was not observed being used and is not typically required by sites for work with nanoscale materials. At two sites, dust masks were in use, for comfort/personal preference reasons.

Since many of the nanomaterials being used and synthesized have not been extensively studied and characterized, there is a lack of specific hazard and toxicological data in many cases. In addition, most of these materials lack regulatory or consensus standard occupational exposure limits.

B.7 Workplace Characterization and Exposure Assessments

Workplace characterization and exposure assessments are addressed in Section 3.6 *Monitoring and Characterization* and Section 4.2 *Workplace Characterization and Exposure Assessments* of the NSRC Approach Document. The Special Review addressed workplace characterization and exposure assessment programs at the sites reviewed, and the instrumentation in use or envisioned at these sites collectively for monitoring and sampling of nanomaterials in the workplace.

The NSRC Approach Document recognizes that "there is no validated or consensus approach for characterizing worker exposures," but "recommends a good faith effort to characterize the exposure of personnel exposed to engineered nanoparticles and to associate the resulting data to those nanoparticle-exposed personnel." The NSRC Approach Document also recommends "conducting 'baseline' monitoring by measuring conditions prior to startup and measuring again at the conclusion of system commissioning and periodically thereafter." 10 CFR 851, which is applicable to each of the DOE sites reviewed, also requires initial or baseline surveys of all work areas or operations to identify and evaluate potential worker health risks, and periodic resurveys and/or exposure monitoring as appropriate. To meet this requirement, worker exposure assessments consisting of both qualitative exposure assessments of all work areas and quantitative assessments through sampling and/or monitoring, as appropriate, are recommended in 10 CFR 851 guidance documents.

For each of the reviewed sites, there have been efforts to identify the extent of nanomaterial work being conducted in the workplace. Several sites have used existing hazard assessment processes and/or checklists to identify nanomaterial work. In some cases, chemical inventory systems have provided additional insight concerning the location and use of nanomaterials in research projects.

Most sites that were reviewed have identified the presence of potential nanomaterial hazards, but only a few sites have attempted to apply their existing worker exposure assessment programs, developed to meet the requirements of 10 CFR 851, to assess worker exposures to nanomaterials, primarily due to a lack of established occupational exposure limits for nanoparticles. At one site, most of the nanomaterial projects had been reviewed by industrial hygiene, but only 3 of 75 ongoing nanomaterial projects had a qualitative exposure assessment performed to document the results of those reviews. At another site, at which there are fewer nanomaterial projects, each nanomaterial project has had a documented qualitative exposure assessment performed. However, even when performed, the evaluations/assessments have limited meaning or usefulness because no criteria (e.g., no nanoparticle occupational exposure limits) have been developed to evaluate the results.

Concerning baseline monitoring of nanomaterial projects, only two sites have attempted to conduct baseline monitoring prior to startup of new nanomaterial R&D projects. However, the sites acknowledge the limitations in performing a baseline assessment based on particle counting since a number of variables, such as ventilation flow, room design, temperature and humidity, and high background particle counts from undefined sources, impact the usefulness of baseline monitoring. In addition to "baseline" monitoring, a few sites have attempted to monitor for nanoparticles during nanomaterial research projects.

Monitoring and Sampling Instrumentation. The NSRC Approach Document provides a number of recommendations concerning workplace monitoring and sampling for nanomaterials, including (1) using a direct-reading particle-measuring device to screen for suspect emissions and more sophisticated techniques if necessary to characterize emissions and determine whether a control is needed or must be upgraded or serviced; (2) using the home laboratory's data management system, as appropriate, to link environmental data representative of exposure to workers; and (3) using available instrumentation and methods to characterize workplace conditions and estimate worker exposures by conducting "baseline" monitoring prior to startup and at the conclusion of system commissioning. In this regard, Attachment 1 of the NSRC Approach Document provides an example hygiene sampling protocol.

A few of the reviewed sites have attempted to develop sampling and monitoring protocols for nanomaterials, procure particle counters, and conduct monitoring for nanoparticles in the workplace. A few sites have attempted to establish protocols for baseline monitoring and have conducted baseline monitoring for newly commissioned nanomaterial research laboratories using a condensate particle counter. These same sites have also used the condensate particle counter for monitoring ongoing nanomaterial research activities when dry dispersible powders are used outside a fume hood or glove box. To date, monitoring of nanoparticle work activities has been limited to particle counting for ongoing work and comparing the measured particle counts against a baseline particle count. Due to the limitations of instruments and the lack of monitoring protocols, none of the sites conduct worker breathing zone monitoring or monitor work surfaces for potential nanomaterial contamination. One site has conducted particle counting for six research projects involving nanomaterials or ultrafine particles. At these sites, however, the results of monitoring have generally been inconclusive due to the difficulties in attempting to detect small quantities of nanoparticles in the midst of larger uncertain and fluctuating particle backgrounds. One site has constructed a mobile "clean room"-like filtered enclosure for monitoring ongoing work in chemical fume hoods. For these measurements, the backgrounds have been reduced dramatically, allowing for more statistically significant data collection associated with actual nanomaterial work evolutions.

One site relies on the example industrial hygiene sampling protocol provided in Attachment 1 to the NSRC Approach Document, and two other sites have incorporated elements of Attachment 1 in their sampling protocols. At these two sites, the full complement of sampling protocols and instrumentation as recommended in the NSRC Approach Document is not deemed to be feasible and/or useful at this time.

With respect to research in developing nanoparticle detectors, the industrial hygiene department at one site has initiated an R&D project to explore alternative methods for detecting nanoparticles, such as electrostatic precipitation sampling.

B.8 Worker Health Monitoring/Surveillance

Consistent with 10 CFR 851.24, site medical directors should define health monitoring and surveillance for workers engaged in nanoscale science research and support activities. Until a consensus emerges concerning what health monitoring and surveillance is effective, the NSRC Approach Document suggests that workers with jobs involving the potential for respiratory or skin exposure to engineered nanomaterials be offered a baseline medical evaluation and periodic monitoring; a post-incident evaluation as required by 10 CFR 851, which references Occupational Safety and Health Administration (OSHA) 1910.1450(g)(1)(i); and exemption of non-resident personnel from medical surveillance.

The medical programs that were reviewed offer workers who could be potentially exposed to nanomaterials the opportunity to receive a baseline medical evaluation, and a follow-up medical evaluation if a suspected incident should occur. Some sites consider the baseline evaluation mandatory, and some sites consider it voluntary. Several of the clinics are given detailed information associated with the actual experimental or job/task information specific to the individual worker in order to determine whether an evaluation and/or a targeted medical evaluation is needed. The most conservative site requires all site workers (including subcontractors) potentially exposed to dry particles or particles suspended in liquids to complete a medical evaluation. At this same site, "Nano-facility users" do not receive a medical evaluation; however, their primary institution is notified about the potential hazards of working with nanomaterials. Several site medical programs have not addressed the periodic monitoring clause as written in the NSRC Approach Document section, and one site that provides baseline medical evaluations for the general plant population has chosen to defer any decisions specific to nanomaterials until further direction is received from DOE. Several sites have not fully addressed the need for support workers such as maintenance, technical, and housekeeping employees, to be included in any specific medical program for nanomaterial workers. Most medical personnel did not feel that periodic screening of nanomaterial workers, beyond a baseline evaluation, would provide any useful information; however, each of the sites concurred that follow-up should be conducted after a suspected incident involving nanomaterials.

B.9 Worker Identification

The NSRC Approach Document recommends that any staff member meeting the criteria of a "engineered nanoparticle worker" (1) have their identity recorded, (2) have access to nanomaterial awareness training, (3) have their workplace conditions and potential exposures characterized, (4) be offered periodic medical evaluations, and (5) as information becomes available, have the site medical director regularly apprised of the current definition of the exposure risk. In addition, until more information concerning the potential toxicity of engineered nanomaterials is better understood and potential human health effects become known, the facilities performing nanomaterials work activities should consider a broad definition of an "engineered nanoparticle worker."

The sites that were reviewed were aware of the need to identify individuals that work with or around engineered nanomaterials. One site has developed an electronic job hazard questionnaire that all employees must complete as a new hire, annually, and following any significant job change. Several questions address working with nanomaterials from both the researcher and facilities/maintenance perspective. The questions and answers are linked to specific training requirements and a medical surveillance database that alerts medical personnel to the individual nanomaterial worker's status. Other sites have or are in the process of developing methods to better identify workers associated with nanomaterials research through the job hazard analysis or other similar methods; some have established listings from experimental reviews or SOPs. One site has chosen to alert visiting research "users" for the purpose of recommending follow-up from their parent institution. The inclusion of facilities, maintenance, technological, and custodial personnel is not mature at the sites that were reviewed (with the exception of one site). Several sites have not yet established a formal process to identify nanomaterial workers; some of these have committed to establish a process in their current implementation plan.

B.10 Transportation of Nanomaterials

Packaging. The transportation packaging guidance in the NSRC Approach Document is more conservative than Department of Transportation (DOT) regulations. Nanomaterials are not specifically designated by DOT as hazardous but may be classified as such based on known or suspected properties, such as toxicity, reactivity, or flammability. The NSRC Approach Document recommends that all nanomaterials shipped offsite be packaged in accordance with DOT hazardous material requirements in Package Group 1 (the packaging group for materials posing great danger), even if they do not meet DOT criteria for this level of packaging. Some of the sites that were reviewed had not issued institutional procedures requiring this level of control.

At two sites, where institutional procedures had not been developed, nanomaterials were most likely being transported off site in personal automobiles without DOT Group 1 packaging. Most of the sites were not using Group 1 packaging for nanomaterial bearing waste that was not otherwise hazardous.

Labeling. Labeling guidance in the NSRC Approach Document specifies that inner packages for offsite shipments be labeled with a caution statement identifying the material and a person to be contacted in case of breakage. Since the labeling is not required by DOT regulations, there is little assurance that it is being applied at sites where it is not required by procedure, and at least one site did not apply this labeling.

Mode of Transport. The transportation packaging guidance in the NSRC Approach Document is also more conservative than DOT regulations. This guidance specifies that all nanomaterials, whether classified as hazardous materials or not, should be transported by qualified carriers for which the DOE or the General Services Administration has a tender on file. This requirement has not been fully implemented. As previously stated, researchers had transported nanomaterials offsite from at least two DOE sites in personally owned automobiles, in briefcases, or through the post office mail.

B.11 Management of Nanomaterial-Bearing Waste Streams

Section 6 of the NSRC Approach Document suggests several practices related to the management of nanomaterial-bearing waste streams: conservative identification, packaging, and segregation of all potential nanomaterial-bearing wastes; clear labeling of waste containers to denote the presence of nanomaterial constituents; and disposition of nanomaterial-bearing wastes in a Resource Conservation and Recovery Act (RCRA)-permitted treatment, storage, and disposal site. Additional guidance applicable to marking, labeling, disposing, and transporting nanomaterial-bearing waste is provided in other sections of the guidance document.

Although most sites have adopted or are in the process of adopting policies for management of nanomaterial-bearing waste materials that are generally consistent with the recommendations of the NSRC Approach Document, implementation is not rigorous, and current practices generally do not meet the objectives. Most of the reviewed sites were not managing nanomaterial wastes consistent with all NSRC Approach Document recommendations.

At most sites, solid and liquid wastes resulting from operations involving nanomaterials are treated as hazardous waste at the point of generation, labeled accordingly, and stored in local satellite accumulation areas before being picked up by local waste management services. Although these wastes were labeled as hazardous, the labels and/or hazardous waste log sheets did not always indicate the presence of nanomaterials as recommended by the NSRC Approach Document. Most sites also did not have established protocols for ensuring that otherwise non-hazardous materials, such as gloves being worn while working in a designated nanomaterial hood or enclosure, are treated as potentially contaminated, segregated, and placed in a hazardous waste receptacle for disposition.

At most sites, an onsite waste management service group is responsible for collecting and determining the appropriate disposal path for nanomaterial-bearing waste streams. Waste management service groups typically collect waste from satellite accumulation areas, ensure that it is properly characterized, and repackage and label it for shipment and disposal. At some sites, sampling of waste materials is also performed on site. Despite hands-on work with these materials, most sites have not updated the waste handling procedures used by waste management service groups to incorporate applicable guidance from the NSRC Approach Document.

At the reviewed sites, nanomaterial-bearing wastes containing both nanomaterials and RCRA listed chemicals are classified as hazardous waste and are shipped off site for disposal at a RCRA-permitted facility for treatment, storage, or disposal of hazardous materials. Other nanomaterial wastes (e.g., dry PPE, carbon nanotubes) that do not contain RCRA listed constituents are sometimes recharacterized by local waste management services as non-hazardous and sent to non-RCRA disposal facilities, including landfills and solid waste incinerators. Section 6.3 of the NSRC Approach Document suggests sending this type of material to a RCRA permitted facility with direction as to the treatment method best suited to controlling hazards associated with the waste.

B.12 Management of Nanomaterial Spills

Recommendations of the NSRC Approach Document for managing nanomaterial spills include access controls, step-off pads, wet-wiping and HEPA vacuuming, and proper handling and waste disposition. Most sites have equipment, such as HEPA vacuums, available to support spill response, and some sites have dedicated trained spill response teams that respond to all types of hazardous materials spills. However, most sites rely on an appropriate response by experimenters and other experts and do not have formal policies, procedures, or technical work document provisions in place governing proper nanomaterial spill responses. One site (where external users perform research) directs that if nanomaterials are spilled outside an engineered enclosure, only the trained resident staff should conduct spill cleanup. The review team did not witness any spill response actions during the course of this Special Review and thus did not have an opportunity to evaluate actual performance.