Engineered Nanomaterials

Guideline

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Applies To: All research use of "Engineered" nanomaterial, i.e., materials consisting of or containing structures of between 1 and 100 nanometers (nm) that make use of properties unique to nanoscale forms of materials.

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Summary

Basic and applied research involving nanotechnology is rapidly expanding at the University of Michigan. Nanomaterials present seemingly limitless possibilities but bring with them new challenges in anticipating, recognizing, evaluating, and controlling potential safety and health risks to workers. *Environment, Health & Safety (EHS)* is charged with overseeing the safe use, storage, transportation, and disposal of these materials when they are produced or brought onto campus for research or development enterprises. This guideline is designed to provide reasonable and consistent guidance for managing the potential risks associated with nanomaterials whose hazards have not been fully characterized. To achieve the goal of protecting employees and the environment, the University will adopt precautionary principles and *control banding* tools in conjunction with sound risk assessment.

The University "Precautionary Principle" for engineered nanomaterials is:

> *In the absence of complete scientific evidence, the potential threat of research materials on human health and the environment are assumed to be such that precautionary measures must be taken until the material is known to be safe. Lack of scientific certainty or cause and effect relationships will not be used as a reason for postponing reasonable measures that could prevent human exposure and environmental release. The burden of proof is upon the researcher obtaining or creating these materials. When new scientific evidence of safety becomes available, EHS will revisit containment determinations and support changes where appropriate.*

The rapid advance of nanotechnology has exceeded the capabilities of regulatory agencies. There are currently no specific governmental regulations. However, the MIOSHA Part 431 Hazardous Work in Labs standard is applicable and requires protective measures, written procedures, and training. EHS will use modern methods of Control Banding (CB) as a qualitative risk characterization and management strategy to guide the assessment of workplace risks and set standard control measures for engineered nanomaterials. This strategy groups workplace risks into control bands based on evaluations of hazard and exposure information. CB is used as a part of our comprehensive safety and health program to assess and control occupational hazards. Specifically, EHS will utilize the assessment tool provided in "Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures" David M. Zalk, Samuel Y. Paik, Paul Swuste, / Published online: 27 June 2009_ Springer Science+Business Media B.V. 2009.

The completed risk assessment will dictate control measures and the extent to which Standard Operating Procedures (SOP) are developed to train students and staff on the hazards and precautions that must be used to prevent exposure and possible adverse effects. Such SOP's are expected to address process containment and personnel precautions in the manufacture, transport, storage, use, and disposal of these potentially hazardous materials.

Additionally, uncontrolled release preparedness, clean-up & decontamination response, and personnel exposure assessments are also an integral part of these required standard procedures.

Scope

This Guideline applies to all research use of "Engineered" nanomaterial, i.e., materials consisting of or containing structures of between 1 and 100 nanometers (nm) that make use of properties unique to nanoscale forms of materials.

Additional EHS guidelines will apply to engineered nanomaterials that contain or are augmented with compounds/agents that present characteristic chemical, biological, or radioactive risks that are covered under state and federal regulations or those requiring registration and review by campus research oversight bodies including the Institutional Biosafety Committee (IBC), Radiation Policy Committee (RPC), and University Committee on Use and Care of Animals (UCUCA).

Reference Document

- MIOSHA Part 431. Hazardous Work in Laboratories
- Application of a Pilot Control Banding Tool for Risk Level Assessment and Control of Nanoparticle Exposures. Samuel Y. Paik, David, M. Zalk and Paul Swuste, Annals of Occupational Hygiene 52(6), 2008, 419-428.
- "Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures" David M. Zalk, Samuel Y. Paik, Paul Swuste, / Published online: 27 June 2009_ Springer Science+Business Media B.V. 2009
- Approaches to Safe Nanotechnology - Managing the Health and Safety Concerns Associated with Engineered Nanomaterials. DHHS/CDC/NIOSH publication, March 2009
- Nanotechnology White Paper. EPA/OSA Science Policy Council, Nanotechnology Workgroup, February 2007
- Approach to Nanomaterials ES&H (Environmental Safety & Health). DOE Office of Science publication, May 2008
- Nanotechnologies – Guide to Safe Handling and Disposal of Manufactured Nanomaterials. BSI British Standard - PD 6699-2:2007 ISBN 978 0 580 60832 2
- Potential Risks of Nanomaterials and how to Safely Handle Materials of Uncertain Toxicity. J M HALLOCK, et.al. Journal of Chemical Health and Safety (2009), Volume: 16 Issue: 1 Pages: 16-23
- Safe Handling of Nanotechnology (Commentary), A D MAYNARD, et.al. Nature (2006) 444, 267-269

Glossary of Terms

TERM	DEFINITION
Biological Safety Cabinet (BSC)	Is a special safety enclosure used to handle pathogenic microorganisms in a laboratory. It can be exhausted outside or inside the facility.
Building/Departmental Contact	Is the person empowered by a dean, director, or department head to arrange for and coordinate maintenance and operational activities for a designated facility.
Control Banding	Is a technique to guide the assessment of workplace risks. It is a generic technique that determines a control measure (for example dilution ventilation, engineering controls, containment, etc.) based on a range or "band" of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc) and exposures (small, medium, large exposure). It is an approach that is based on two pillars; the fact that there are a limited number of control approaches, and that many problems have been met and solved before.
Fume Hood (Chemical Fume Hood)	Is a ventilated enclosed work space intended to capture, contain and exhaust fumes, vapors, and particulate matter generated inside the enclosure to the outside of a facility.
Environment, Health & Safety (EHS)	Is the University of Michigan department that works to maintain a safe and healthy environment. The Department will survey matters of environmental sanitation, occupational safety, occupational health, and radiation safety; coordinate and assist in educating faculty, staff and students on standards applicable to University-associated activities and safety efforts throughout the University; advise faculty and staff on procedures relating to biosafety and biological safety cabinets; develop accident prevention programs; provide advice; render service; investigate accidents; and maintain statistics related to occupational safety and health. Refer to the EHS website for guidance and educational materials.
Radioisotopes/Radioactive Materials	Are elements with unstable nuclei that give off energy in the form of ionizing radiation through a process called nuclear decay.

Responsibility

Everyone working at the University of Michigan has the right to expect a safe and healthy work environment. They also have a responsibility to help assure a safe and healthy environment for themselves and others. These responsibilities are detailed in the University of Michigan Academic Laboratory and Research Safety Policy, issued jointly by the Department of Environment, Health & Safety (EHS) and the Office of Research Ethics & Compliance (UMOR). Please click on the Policy link to view role specific responsibilities including but not limited to the following categories:

- All faculty, staff, other employees and students
- Graduate Student Research Assistants/Trainees
- Post-Doctoral Trainee/Fellow

- Laboratory Director (Faculty/Lab Manager/Supervisor
- Department Chair
- Facility Managers/Department Managers/Key Administrators/Chief Department Administrators
- Unit (School/College/Department) Safety Coordinators

Additional responsibilities specific to the implementation of this guideline follow.

Laboratory Director

- Implement and document appropriate safety policies and procedures in accordance with the U-M Chemical Hygiene Plan.
- Ensure that adequate facilities, ventilation, and equipment are provided for the safe use of engineered nanomaterials.
- Ensure employees are instructed on and follow proper procedures and utilize protective equipment provided during their work as detailed in written SOPs.
- Include all engineered nanomaterials in the lab chemical inventory
- Submit an engineered nanomaterial survey to EHS for review

Identification

The University has modified the Proposal Approval Form (PAF) and Material Transfer Agreement (MTA) to request information regarding engineered nanomaterials. The PAF is a summary of information about the project that is used for internal review and approval and data management. MTAs are used for incoming and outgoing research-related materials at the University. In addition, Animal protocols involving the use of nanoparticles must include completion of the Hazardous Chemical Information Page and obtain approval through the University Committee on the Use and Care of Animals (UCUCA) and EHS. EHS is provided all of this information to assist in our health, safety, and environmental goals regarding engineered nanomaterials.

Evaluation

EHS will send Laboratory Directors an initial web-based nanomaterial questionnaire to gather information on the specific project identified. EHS will then work with the Laboratory Director to evaluate the materials, planned uses, support facilities, and proposed hazard controls. An important part of the evaluation is the CB Nanotool to determine the level of risk and propose control measures.

The nanotool rates the severity of potential exposures by collecting information on the following factors: surface chemistry, particle shape, particle diameter, solubility, carcinogenicity, reproductive toxicity, mutagenicity, dermal toxicity, toxicity. The probability factor attempts to rate the potential for an adverse outcome by determining: the amount of nanomaterial used, dustiness/mistiness, number of employees with similar exposure, frequency of operation, and duration of operation. Based on this information EHS will determine the Risk Level and will work with the laboratory management to select and implement appropriate hazard controls.

Hazard Controls

Based on the CB Nanotool evaluation each project will be placed into one of four Risk Levels (RL): RL1 (Low) requires standard lab with general ventilation, RL2 (Medium) requires local exhaust hoods or *fume hoods*, RL3 (High) requires containment and enclosures, RL4 (Very High) requires specialist advice and control measures.

In all cases EHS will stress the importance of designing good engineering controls as the primary means to manage the exposure risks. Administrative controls and personal protective equipment will also be required but the emphasis must be to separate the hazard from the employee with properly engineered controls.

Good engineering controls most often will involve local exhaust ventilation. Any work that could generate airborne engineered nanomaterials should be conducted in an enclosure that operates at a negative pressure differential. Examples include gloveboxes, chemical hoods, or local exhaust systems like a snorkel hood or slot hood.

Minimization of risk associated with exhaust effluent (air) or potentially contaminated water discharges is to be practiced wherever it is reasonably suspected these will contain engineered nanoparticles whose hazards are not well understood. Whenever practical, filtration or otherwise scrubbing the exhaust effluents prior to release must be designed into containment systems. HEPA filtration appears to effectively remove nanoparticles from the air.

Standard Operating Procedures (SOP)

The Laboratory Director is required to prepare a SOP that meets the requirements of MIOSHA Part 431 (Hazardous Work in Laboratories) and includes detailed information on how the procedure is performed safely; who is authorized to do the work; what hazard controls are utilized; environmental considerations; training; personal protective equipment (PPE); and waste management procedures.

Work Practices

Good work practices will help minimize exposure to nanomaterials. The following practices, which are consistent with standard good laboratory practice, should be used:

General Workplace Control Practices

- Prohibit the storage or consumption of food or drink in areas where nanomaterials are handled.
- Prohibit the application of cosmetics in areas where nanomaterials are handled.
- Require personnel to wash hands before leaving the work area and after removing protective gloves.
- Require lab coats to remain in the lab where the work is performed.
- Avoid touching the face or other exposed skin when working with nanomaterials.
- Change gloves regularly (at least every two hours) and wash hands at the time of the glove change.

Workspace

- Set up a designated area for work with nanomaterials and suspensions away from entrances and high traffic areas.
- Post signs indicating hazards, personal protective equipment requirements, and administrative control requirements at entry points into designated areas where engineered nanomaterials are handled.
- A designated area may be an entire laboratory, a section of a laboratory, or a containment device such as a laboratory hood or glove box.
- Handle dry nanomaterials in a fume hood, *biological safety cabinet*, glove box or a vented filtered enclosure. Do not work on the open bench with dry nanomaterials.
- Aerosol producing activities (such as sonication, vortexing and centrifuging) may not be conducted on the open bench. Perform these activities in a fume hood, biological safety cabinet, glove box, or a vented filtered enclosure.

Labeling

Label all containers used to store nanomaterials with particle size to indicate that the contents are in nanoscale form. If the nanomaterial is in the form of dry dispersible particles, add the following line of text: "Nanoparticulates can exhibit unusual reactivity and toxicity. Avoid breathing dust, ingestion, and skin contact."

Transferring

- Transport dry nanomaterials in closed containers. Handle solutions containing nanomaterials over disposable bench covers.
- Transfer engineered nanomaterial samples between workstations (such as exhaust hoods, glove boxes, furnaces) in closed, labeled containers.
- If weighing dry powders and the balance cannot be located in a fume hood or BSC, tare a container then add the material to the container in a hood, then seal the container before returning to the balance to weigh the powder.

Cleaning

NOTE: Dry sweeping or using compressed air are prohibited for cleaning areas and equipment contaminated with nanomaterials.

- Clean areas where nanomaterials are prepared and/or administered immediately following each task and each day after work with the nanomaterials is complete.
- Use wet wiping or HEPA vacuuming to clean large surfaces (ie. floors, benches).

  NOTE: HEPA vacuuming is not recommended for reactive materials, as they may react with other materials collected in the vacuum, or with components of the vacuum itself.
- Daily vacuuming of benches and floors with a HEPA vacuum should be performed in labs that handle dry nanomaterials.
- Using wet methods, routinely clean containment device interiors, equipment, and laboratory surfaces where there is potential for nanomaterial contamination. Consider the potential for

complications due to the physical and chemical properties of the material to avoid reactions with cleaning agents.

Shipping Engineered Nanomaterials

- Complete dangerous goods declaration or shipping papers for offsite shipments of nanomaterials in accordance with the IATA and DOT regulations. Contact EHS for instruction on shipping potentially hazardous materials.
- Materials sent offsite must also include a prepared document that describes known and suspected properties likely to be exhibited and notification of potential hazards. The institution may be required to create a Safety Data Sheet (SDS) for the material.

Maintenance

- If using a HEPA vacuum, change the filter inside a chemical fume hood or biological safety cabinet. If the HEPA vacuum may be used for incompatible materials, maintain a log of vacuum use so that collection of incompatible materials can be avoided. Keep containers closed as much as possible.
- Notify applicable personnel of potential hazards before removing, remodeling, servicing, maintaining, or repairing laboratory equipment and exhaust systems used for nanomaterial research. The EHS laboratory equipment decontamination form must be completed.
- Wet cleaning or HEPA vacuuming of lab equipment and exhaust systems is required prior to repair, disposal or reuse.

Disposing of Nanomaterial Waste

- All solutions and solid materials must be disposed of as hazardous waste following established University guidelines
- Disposal of contaminated cleaning materials must comply with hazardous waste disposal policies

Validation of Hazard Controls

EHS will examine, test and validate that hazard controls are effective at reducing or eliminating exposures to potentially airborne nanomaterials. EHS validation will consist of the following: certification that engineering controls are working as designed, periodic inspections of facilities, and monitoring to confirm containment of nanoparticles.

EHS will use a direct-reading nanoparticle-detection device to screen for suspect emissions. Detection of airborne nanomaterials above background and outside the containment device will determine if additional controls are needed or upgrades necessary.

EHS will use direct reading air velocity devices to determine if point-source (aerosol emission) collection devices are working at acceptable capture velocities and according to manufacturers' recommendations.

Identification of Contaminated Equipment

Equipment that filters or contains nanomaterials must be identified. An example is Biological Safety Cabinets (BSC), which contain HEPA filters that effectively capture airborne nanoparticles. These units are identified to EHS on the BSC Clearance Form and in the BSC Database. Once these units are identified, EHS will follow standard procedures for hazardous materials when servicing them. Likewise, personnel from other departments or outside vendors who service, handle, or maintain this equipment must be notified of potential exposures and precautions. The University of Michigan Occupational Safety and Environmental Health (EHS) Laboratory Equipment Decontamination form must be completed and attached to each piece of equipment to be sent offsite for maintenance or disposal and for onsite repairs. See EHS Guideline on Laboratory Decommissioning:

Environment and Disposal

The University will attempt to prevent the release of nanomaterials to the environment to the greatest extent feasible and comply with all regulatory standards. Waste materials will be collected for disposal by EHS Hazardous Materials Management (HMM). EHS will continually update and develop environmental and disposal guidelines as needed.

There are no specific guidelines from the EPA for disposal of waste nanomaterials. However, many nanomaterials may contain toxic components that are strictly regulated. Therefore, call EHS-HMM before the first-time disposal of any nanomaterial waste including:

- Pure nanomaterials (e.g., carbon nanotubes)
- Items contaminated with nanomaterials (e.g., wipes/protective equipment)
- Liquid suspensions containing nanomaterials (e.g., hydrochloric acid containing carbon nanotubes)
- Material that has come into contact with dispersible engineered nanoparticles (that has not been decontaminated) as belonging to a nanomaterial-bearing waste stream. This includes PPE, wipes, blotters and other disposable laboratory materials used during research activities.
- Solid matrixes with nanomaterials that are friable or have a nanostructure loosely attached to the surface such that they can reasonably be expected to break free or leach
- out when in contact with air or water, or when subjected to reasonably foreseeable mechanical forces.
- Needles used for nanoparticle injection. **NOTE**: Needles must be disposed of in approved sharps containers immediately following use.

All rules for disposal of hazardous materials must be followed. In addition, each container and waste manifest must include the words “Contains Nanomaterials". Information characterizing known and suspected properties should also be noted.

This guidance does not apply to nanomaterials embedded in a solid matrix that cannot reasonably be expected to break free or leach out when they contact air or water.

Training

All persons working in laboratory facilities are required to take EHS’s online required general laboratory safety training. Login to MyLinc and select course BLS025w. In addition, the PI must ensure that all personnel working with engineered nanomaterials are provided information and focused training on the specific hazardous operations. Training procedures and written documentation must be maintained in the lab’s Chemical Hygiene Plan (CHP) Document Binder.

Emergency Procedures

Exposures involving nanomaterials or any other acutely hazardous material should be reported to your supervisor and Occupational Health Services as soon as possible. A completed Work Connections Injury and Illness form will also be required.

Small spills can be cleaned up by trained laboratory staff familiar with the hazards and precautions. Larger spills should be referred to EHS-HMM at (734) 763-4568.

General procedures for spills are to employ a normal hazardous materials response based on the spilled material's known hazards. All procedures should be performed in a manner that minimizes the creation of aerosols. Methods for cleaning dry materials include using wet wiping methods or a certified HEPA vacuum. Dry sweeping or the use of compressed air is not an acceptable method.

Personal Protective Equipment (PPE)

PPE should be selected and used to minimize potential exposures to nanomaterials. The PI or lab manager shall conduct a hazard evaluation to select the appropriate PPE. See the EHS PPE guideline .

One of the most critical PPE choices is the selection of gloves. The glove selection process must consider the resistance of the glove to the nanomaterial as well as the residual chemicals or liquid solutions. EHS can also provide guidance on glove compatibility.

Standard laboratory safety apparel should include safety glasses or safety goggles, lab coats or disposable clothing, closed-toe shoes, and pants. Lab coats should not be worn outside the laboratory to avoid transferring any contamination to other areas of the facility.

PPE used for nanomaterial processes should remain in the laboratory or change out area to prevent contamination from being transported into common areas. Contaminated PPE must be stored in sealed containers in the same manner as waste materials of the same type.

An air-purifying respirator will not be assigned unless there is no feasible engineering control for the work process or the respirator is being used as a precautionary measure. The work site must be evaluated by EHS and the complete respirator safety program must be followed including a physical evaluation and respirator fit test as required in the EHS Respiratory Protection guideline: http://www.EHS.umich.edu/guidelines/rp.shtml

Shipping and Receiving

Nanomaterials that are known or suspected to be hazardous (e.g., toxic, reactive, flammable) should be classified, labeled, marked, and manifested according to Department of Transportation rules. Nanomaterials that do not meet the DOT's criteria and may still pose health and safety issues to personnel handling the material, should be packaged in a DOT-certified Packing Group I (PG I) container. The innermost container should be tightly sealed to prevent leakage. It should have a secondary seal to prevent inadvertent opening during transport. The outer package should be filled with shock absorbing material that can protect the inner sample container from damage and absorb liquids that might leak.

The generation of a Safety Data Sheet (SDS) may be required for novel materials that are shared across academic units or collaborators at other institutions.

Technical Support

EHS is a resource and is available to provide consultative services for all of the process control and risk-reduction activities described in this Guideline.

All referenced guidelines, regulations, and other documents are available through EHS at 734 763-6973 or on the EHS Website.

Appendices

Appendix A: "Application of a Pilot Control Banding Tool for Risk Level Assessment and Control of Nanoparticle Exposures" Samuel Y. Paik, David, M. Zalk and Paul Swuste, Annals of Occupational Hygiene 52(6), 2008, 419-428.

Appendix B: "Evaluating the Control Banding Nanotool: a qualitative risk assessment method for controlling nanoparticle exposures" David M. Zalk, Samuel Y. Paik, Paul Swuste, / Published online: 27 June 2009_ Springer Science+Business Media B.V. 2009