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Number 8

PRELIMINARY ANALYSIS OF EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION IN
OCCUPATIONAL SETTINGS: MANUFACTURED NANOMATERIALS

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Series on the Safety of Manufactured Nanomaterials

No. 8

PRELIMINARY ANALYSIS OF EXPOSURE MEASUREMENT AND
EXPOSURE MITIGATION IN OCCUPATIONAL SETTINGS:
MANUFACTURED NANOMATERIALS

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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- No. 1, *Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication (2006)*
- No. 2, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials (2006)*
- No. 3, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials (2007)*
- No. 4, *Manufactured Nanomaterials: Programme of Work 2006-2008(2008)*
- No. 5, *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials*
- No. 6, *List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme*
- No. 7 *Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 4th Meeting of the Working Party on Manufactured Nanomaterials*

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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (<http://www.oecd.org/ehs>).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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or contact:

OECD Environment Directorate,
Environment, Health and Safety Division

2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

The OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology (the Joint Meeting) held a Special Session on the Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety (June 2005). This was the first opportunity for OECD member countries, together with observers and invited experts, to begin to identify human health and environmental safety related aspects of manufactured nanomaterials. The scope of this session was intended to address the chemicals sector.

As a follow-up, the Joint Meeting decided to hold a Workshop on the Safety of Manufactured Nanomaterials in December 2005, in Washington, D.C. The main objective was to determine the “state of the art” for the safety assessment of manufactured nanomaterials with a particular focus on identifying future needs for risk assessment within a regulatory context.

Based on the conclusions and recommendations of the Workshop [ENV/JM/MONO(2006)19] it was recognised as essential to ensure the efficient assessment of manufactured nanomaterials so as to avoid adverse effects from the use of these materials in the short, medium and longer term. With this in mind, the OECD Council established the OECD Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the OECD Chemicals Committee. This programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and aims to ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonised standard. This programme promotes international co-operation on the human health and environmental safety of manufactured nanomaterials, and involves the safety testing and risk assessment of manufactured nanomaterials.

This document was endorsed by the Working Party on Manufactured Nanomaterials at its 4th Meeting on June and declassified by the OECD’s Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology on March 2009. It is intended to provide information on the outcomes and developments of the WPMN related to the safety of manufactured nanomaterials.

This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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THE WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

The Working Party on Manufactured Nanomaterials¹ was established in 2006 to help member countries efficiently and effectively address the safety challenges of nanomaterials. OECD has a wealth of experience in developing methods for the safety testing and assessment of chemical products.

The Working Party brings together more than 100 experts from governments and other stakeholders from: a) OECD Countries; b) non-member economies such as Brazil, China, the Russian Federation, Singapore, and Thailand; and c) observers and invited experts from UNEP, WHO, ISO, BIAC², TUAC³, and environmental NGOs.

Although OECD member countries appreciate the many potential benefits from the use of nanomaterials, they wished to engage, at an early stage, in addressing the possible safety implications at the same time as research on new applications is being undertaken.

The Working Party is implementing its work through eight main areas of work to further develop appropriate methods and strategies to help ensure human health and environmental safety:

- Development of a Database on Human Health and Environmental Safety (EHS) Research;
- EHS Research Strategies on Manufactured Nanomaterials;
- Safety Testing of a Representative Set of Manufactured Nanomaterials;
- Manufactured Nanomaterials and Test Guidelines;
- Co-operation on Voluntary Schemes and Regulatory Programmes;
- Co-operation on Risk Assessment;
- The role of Alternative Methods in Nanotoxicology; and
- Exposure Measurement and Exposure Mitigation.

Each project is being managed by a steering group, which comprises members of the WPMN, with support from the Secretariat. Each steering group implements its respective “operational plans”, each with their specific objectives and timelines. The results of each project are then evaluated and endorsed by the entire WPMN.

This document combines two former texts produced by the steering group on Exposure Measurement and Exposure Mitigation: 1) Exposure Measurement in Occupational Settings and 2) Exposure Mitigation in Occupational Settings.

This document was endorsed by the Working Party on Manufactured Nanomaterials at its 4th Meeting on June 2008.

¹ Updated information on the OECD’s Programme on the Safety of Manufactured Nanomaterials is available at: www.oecd.org/env/nanosafety

² The Business and Industry Advisory Committee to the OECD

³ Trade Union Advisory Committee to OECD.

PROJECT ON EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION

The project on Exposure Measurement and Exposure Mitigation was established as a formal Steering Group of the OECD Working Party on Manufactured Nanomaterials at the 3rd meeting in November 2007.

The operational plan outlines three phases of work: 1) exposure in occupational settings; 2) exposure to humans resulting from contact with consumer products and environmental releases of manufactured nanomaterials; and 3) exposure to environmental species resulting from environmental releases of manufactured nanomaterials including releases from consumer products containing manufactured nanomaterials.

The objectives of phase 1 are described as:

- To identify and compile guidance information for exposure measurement and exposure mitigation for manufactured nanomaterials in occupational settings, including manufacture and use of products in industrial, institutional and commercial settings; and
- To analyse existing guidance information for their adequacy in addressing manufactured nanomaterials, identify issues that are unique to manufactured nanomaterials, and prepare recommendations for next steps to be undertaken by the WPMN.

This report provides preliminary analyses and recommendations as well as brief summaries of background documents listed in the operational plan relevant to phase 1 of the project on exposure measurement and exposure mitigation.

This report also incorporates information gathered in a draft annotated bibliography of exposure mitigation documents prepared by the project on Co-operation on Voluntary Schemes and Regulatory Programmes.

More information about the work of the WPMN, as well as publications and updates on efforts of governments and other stakeholders to address safety issues of nanomaterials is available at <http://www.oecd.org/env/nanosafety>.

EXPOSURE MEASUREMENT IN OCCUPATIONAL SETTINGS

A. Preliminary analysis

Exposure measurements in the workplace can be grouped into three broad categories: personal and area sampling (air and surfaces); biological monitoring; and worker health monitoring and medical surveillance. The following observations can be made upon review of the background documents for each of these categories.

1. Personal and area sampling

There are currently no national or international consensus standards on measurement techniques for nanoparticles in the workplace. However, a number of standards and reference nanomaterials are under development. Information and guidance for monitoring nanoparticle exposures in workplace atmospheres have recently been developed by the International Organization for Standardization (ISO TR27628:2007). Due to a lack of reference nanomaterials, quality control of measurements remains a challenge.

Currently, no commercially available personal samplers are designed to measure the particle number, surface area, or mass concentration of nanoaerosols.

There have been few developments reported on techniques to discriminate between engineered and incidental airborne nanomaterials and to analyse nanomaterials on surfaces.

Sampling and analytical methods developed for assessing dermal exposures to chemicals have not been evaluated for their applicability to characterize dermal exposures to nanomaterials in the workplace.

Currently, there is no agreement on the metrics of exposure to nanomaterials. Therefore, several organizations recommend using a multifaceted approach incorporating several sampling techniques to characterize workplace exposure to nanomaterials.

Even in the absence of specific exposure limits or guidelines for engineered nanoparticles, exposure measurements can still be used to determine the need for and effectiveness of engineering controls or work practices.

2. Biological monitoring

Currently, biomonitoring of exposures to nanomaterials is very limited because biomarkers of exposure to nanoparticles needed to conduct biomonitoring are in the early stages of the development. This is complicated by great variety of chemical and physical properties of nanoparticles resulting in a wide range of biological responses.

3. Worker health monitoring and medical surveillance

In the context of workplace exposures to low concentrations of nanomaterials, health surveillance in the form of measuring changes in biological indicators from baseline levels can be used as an indicator of whether exposure is occurring. A number of organizations recommend basic worker health monitoring consisting of identifying workers handling engineered nanomaterials; conducting workplace characterization and worker exposure assessments; providing nanomaterials workers with “baseline” medical evaluations and including them in a nonspecific routine health monitoring program.

B. Preliminary recommendations

The following potential specific projects are recommended by the Drafting Group on Exposure Measurements and Exposure Mitigation for pursuit by the OECD Working Party on Manufactured Nanomaterials with a goal of raising awareness and harmonizing approaches to exposure measurements globally:

- Provide guidance on appropriate metrics (e.g. nanoparticle number, surface area, mass) of exposure;
- Provide recommendations on measurement techniques and sampling protocols for inhalational and dermal exposures in the workplace;
- Identify reference nanomaterials for quality control of exposure measurements;
- Compare available Workplace Industrial Hygiene Survey and Sampling protocols;
- Identify biomarkers of exposure to nanomaterials; and
- Compare available Health Surveillance guidance and protocols.

C. Brief summaries

German Chemical Industry Association (VCI) and German Federal Institute for Occupational Safety and Health (BAuA). Guidance for handling and use of nanomaterials in the workplace⁴.

This document provides guidance regarding OSH measures in the production and use of intentionally produced nanomaterials in the workplace reflecting the current state of science and technology. Nano- and micro-scale particles can be measured in the workplace with only relatively coarse resolution of the particle size distribution. It is critical to measure background incidental particle concentrations. Commonly used methods are:

- a. Condensation Particle Counter is the most wide-spread method for particle counts in the nanometer range. It is commonly combined with an upstream connected fractionating unit. Scanning or Stepped Mobility Particle Sizer is the most frequently used instrument to measure particle size distribution in the size range from 3 to 800 nm.
- b. Aerosol mass spectrometry is a wide-spread method for the chemical on-line analysis of particles and aggregates in the size range of over 100 nm. Electron microscopy (TEM and SEM) is used as an off-line method to characterize size, morphology and particle structure. Energy Dispersive X-Ray Fluorescence Analysis in combination with electron microscopy enables resolution of spatial elemental distribution.
- c. Nano-Aerosol Sampler can be used to characterize and semi-quantitatively measure particle morphology and elemental composition for particles in the size range from 1 to 100 nm.

⁴The document was finalized on March 2007 and it is available on-line at: http://www.baua.de/nan_49456/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/guidance.pdf , an updated version will be available in 2009.

Exposure measuring methods for nanoparticles are not fully standardized as yet. Existing standardized particle exposure methods measure mass of dust respirable fraction. There is a need to develop complementary measuring methods for particle counts and sizes using for example SMPS. Assessment of health hazards based exclusively on particle mass is not sufficient in every case. At present, factors assumed to influence health hazards – such as particle surface area, surface structure and surface composition – still require highly sophisticated measuring methods in the nanometer range. So far, there is no uniform approach in the characterization of nanoparticles. In Germany the suitability of measuring and protection methods is assessed by the umbrella organization of employer's liability insurance associations (HVBG).

Health and Safety Laboratory, RR513, "The Assessment of Different Metrics of the Concentration of Nano (Ultrafine) Particles in Existing and New Industries", 2006.

This report describes results of a study investigating relationships between mass (using Tapered Element Oscillating Microbalance), number (using Scanning Mobility Particle Sizer) and active surface area (using Diffusion Charging) of nanoscale particles of different chemical composition and particle shape. Specifically, measurement were conducted on sodium fluorescein (amorphous shape with 120-257 nm mean diameter), sodium chloride (cubic with 35-175 nm mean diameter), latex (spheres with 88 – 773 nm mean diameter), caffeine (rods with aspect ratio of 6:1 and mean diameter of 34-247 nm), zinc oxide (rods with aspect ratio of 3:1 and mean diameter of 91-167 nm).

For each of the five aerosol types investigated the response of the TEOM and the DC at a particular size is consistent with increasing particle number concentration measured by SMPS but overall the response of the TEOM and the DC shows no consistent ranking with size. No simple relationship was found for predicting the active surface area as measured by DC, from SMPS measurements. But for aerosols smaller than 100 nm the DC results for most of the materials investigated were broadly similar to those calculated from the SMPS data. The degree of agglomeration was more likely to be responsible for the inconsistency of instrument response to size. The filter in the TEOM is mechanical in action and so is not totally efficient in capturing nanoscale particles.

The following recommendations were made:

- a. Because of the lack of consistent relationships between measurements of mass, number and surface area, measurements of all three parameters should be conducted in the workplace. None of these parameters taken in isolation can give sufficient information to predict toxicity.
- b. The performance of any device, currently available, that can discriminate between ultrafine/nano particle species should be investigated.
- c. For reasonable accuracy the SMPS must not be used to calculate surface area and mass without prior knowledge of aerosol composition and state of agglomeration.
- d. Improve efficiency of the TEOM filter.

US National Institute for Occupational Safety and Health, “Approaches to Safe Nanotechnology: Information Exchange with NIOSH,” 2006⁵.

This document provides an overview of techniques available to characterize exposures in the workplace and provides specific recommendations.

Until more information becomes available on the mechanisms underlying nanoparticle toxicity, it is uncertain as to what measurement technique should be used to monitor exposures in the workplace. Current research indicates that mass and bulk chemistry may be less important than particle size and shape, surface area, and surface chemistry (or activity) for nanostructured materials.

Many of the sampling techniques that are available for measuring airborne nanoaerosols vary in complexity but can provide useful information for evaluating occupational exposures with respect to particle size, mass, surface area, number concentration, composition, and surface. Unfortunately, relatively few of these techniques are readily applicable to routine exposure monitoring. Currently, no commercially available personal samplers are designed to measure the particle number, surface area, or mass concentration of nanometer aerosols. However, several methods are available that can be used to estimate surface area, number, or mass concentration for particles smaller than 100 nm. In the absence of specific exposure limits or guidelines for engineered nanoparticles, exposure data gathered from the use of respirable samplers can be used to determine the need for engineering controls or work practices and for routine exposure monitoring of processes and job tasks. When chemical components of the sample need to be identified, chemical analysis of the filter samples can permit smaller quantities of material to be quantified, with the limits of quantification depending on the technique selected. The use of conventional impactor samplers to assess nanoparticle exposure is limited to a lower efficiency of 200 to 300 nm. Low-pressure cascade impactors that can measure particles to ³ 50 nm may be used for static sampling, since their size and complexity preclude their use as personal samplers. A personal cascade impactor is available with a lower aerosol cut point of 250 nm, allowing an approximation of nanometer particle mass concentration in the worker’s breathing zone. For each method, the detection limits are of the order of a few micrograms of material on a filter or collection substrate. Cascade impactor exposure data gathered from worksites where nanomaterials are being processed or handled can be used to make assessments as to the efficacy of exposure control measures.

The real-time (direct-reading) measurement of nanometer aerosol concentrations is limited by the sensitivity of the instrument to detect small particles. Many real-time aerosol mass monitors used in the workplace rely on light scattering from groups of particles (photometers). This methodology is generally insensitive to particles smaller than 300 nm. Optical instruments that size individual particles and convert the measured distribution to a mass concentration are similarly limited to particles larger than 100 to 300 nm. The Scanning Mobility Particle Sizer (SMPS) is widely used as a research tool for characterizing nanometer aerosols, although its applicability for use in the workplace may be limited because of its size, cost, and the inclusion of a radioactive source. The Electrical Low Pressure Impactor (ELPI) is an alternative instrument that combines a cascade impactor with real-time aerosol charge measurements to measure size distributions.

Relatively few techniques exist to monitor exposures with respect to aerosol surface area. Isothermal adsorption is a standard off-line technique used to measure the specific surface area of powders that can be adapted to measure the specific surface area of collected aerosol samples. Portable aerosol diffusion chargers provide a good estimate of aerosol surface area when airborne particles are smaller than 100 nm in diameter.

⁵ Available on-line at: <http://www.cdc.gov/niosh/topics/nanotech/safenano/>

Aerosol particle number concentration can be measured relatively easily using Condensation Particle Counters (CPCs). These are available as hand-held static instruments, and they are generally sensitive to particles greater than 10 to 20 nm in diameter. CPCs designed for the workplace do not have discrete size-selective inputs, and so they are typically sensitive to particles up to micrometers in diameter. Commercial size-selective inlets are not available to restrict CPCs to the nanoparticle size range; however, the technology exists to construct size-selective inlets based on particle mobility, or possibly inertial pre-separation. An alternative approach to estimating nanoparticle concentrations using a CPC is to use the instrument in parallel with an optical particle counter. The difference in particle count between the instruments will provide an indication of particle number concentration between the lower CPC detectable particle diameter and the lower optical particle diameter (typically 300 to 500 nm). Although using nanoparticle number concentration as an exposure measurement may not be consistent with exposure metrics being used in animal toxicity studies, such measurements may be a useful indicator for identifying nanoparticle emissions and determining the efficacy of control measures. Portable CPCs are capable of measuring localized aerosol concentrations, allowing the assessment of particle releases occurring at various processes and job tasks.

Currently, there is not one sampling method that can be used to characterize exposure to nanosized aerosols. Therefore, any attempt to characterize workplace exposure to nanoparticles must involve a multifaceted approach incorporating many of the sampling techniques mentioned above. The first step would involve identifying the source of nanoparticle emissions. A CPC provides acceptable capability for this purpose. It is critical to determine ambient or background particle counts before measuring particle counts during the manufacture or processing of the nanoparticles involved. If a specific nanoparticle is of interest (e.g. TiO₂), then area sampling with a filter suitable for analysis by electron microscopy should also be employed. Transmission electron microscopy (TEM) can identify specific particles and can estimate the size distribution of the particles. Once the source of emissions is identified, aerosol surface area measurements should be conducted with a portable diffusion charger and aerosol size distributions should be determined with an SMPS or ELPI using static (area) monitoring. A small portable surface area instrument could be adapted to be worn by a worker, although depending on the nature of the work, this may be cumbersome. Further, losses of aerosol with the addition of a sampling tube would need to be calculated. The location of these instruments should be considered carefully. Ideally they should be placed close to the work areas of the workers, but other factors such as size of the instrumentation, power source, etc. will need to be considered. Lastly, personal sampling using filters or grids suitable for analysis by electron microscopy or chemical identification should be employed, particularly if measuring exposures to specific nanoparticles is of interest. Electron microscopy can be used to identify the particles, and can provide an estimate of the size distribution of the particle of interest. The use of a personal cascade impactor or a respirable cyclone sampler with a filter, though limited, will help to remove larger particles that may be of limited interest and allow a more definitive determination of particle size. Analysis of these filters for air contaminants of interest can help identify the source of the respirable particles. Standard analytical chemical methodologies should be employed.

By using a combination of these techniques, an assessment of worker exposure to nanoparticles can be conducted. This approach will allow a determination of the presence and identification of nanoparticles and the characterization of the important aerosol metrics. However, since this approach relies primarily on static or area sampling some uncertainty will exist in estimating worker exposures. When feasible, personal sampling is preferred to ensure an accurate representation of the worker's exposure, whereas area sampling (e.g., size-fractionated aerosol samples) and real-time (direct reading) exposure measurements may be more useful for evaluating the need for improvement of engineering controls and work practices.

Health surveillance.

The unique physical and chemical properties of nanomaterials, the increasing growth of nanotechnology in the workplace, and information suggesting that engineered nanoscale materials may pose a health and safety hazard to workers all underscore the need for medical and hazard surveillance for nanotechnology. Every workplace dealing with nanoparticles, engineered nanomaterials or other aspects of nanotechnology should consider the need for an occupational health surveillance program.

U.S. DOE Nanoscale Science Research Centers, Approach to Nanomaterials ES&H, 2007⁶.

The document offers “reasonable guidance for managing the uncertainty associated with nanomaterials whose hazards have not been determined and reducing to an acceptable level the risk of worker injury, worker ill-health and negative environmental impacts” in laboratories of Nanoscale Science Research Centers.

The document recommends basic worker health and environmental monitoring consisting of

- a) Identifying staff (nanoparticles workers) exposed to engineered nanoparticles of unknown health effects;
- b) Conducting workplace characterization and worker exposure assessments;
- c) Providing nanoparticles workers with “baseline” medical evaluations and; including them in a nonspecific routine health monitoring program;
- d) Checking wastes for evidence of uncontrolled release of engineered nanomaterials;
- e) Effluent monitoring.

Any worker meeting one or more of the following criteria is considered an “engineered nanoparticles worker”:

- a) Handles engineered nanoscale particulates that have the potential to become dispersed in the air
- b) Routinely spends significant amounts of time in an area in which engineered nanoparticles have the potential to become dispersed in the air
- c) Works on equipment that might be contaminated with materials that could foreseeably release engineered nanoparticles during servicing or maintenance.

It is recommended that each laboratory

- a) Record the identity of engineered nanoparticles workers
- b) Use available methods to characterize workplace conditions and exposures of engineered nanoparticles workers
- c) Ensure that engineered nanoparticle workers are offered periodic medical evaluations that may include routine test such as pulmonary, renal, liver, and hematopoietic function and pulmonary function testing
- d) Revisit and refine the definition of engineered nanoparticle workers and make recommendations to the Site Occupational Medical Director for changes to any applicable medical examination program.

⁶ Available online at: http://www.sc.doe.gov/bes/DOE_NSRC_Approach_to_Nanomaterial_ESH.pdf.

Workplace characterization and nanomaterial exposure assessment challenges include:

- a) Substantially different “parameters” may prove hygienically significant for different nanomaterials
- b) Materials of the same chemical composition can have markedly different forms at the nanoscale and the different forms can have markedly different properties
- c) No professional consensus on monitoring instrumentation and protocols exists and it may be decade before one emerges.

For monitoring and characterization the document recommends to

- a) Conduct “baseline” monitoring by measuring conditions prior to start up. Measure again at the conclusion of system commissioning and periodically thereafter. These efforts should be considered a vital part of an overall strategy of ensuring that controls are well conceived, well constructed, and remain effective.
- b) Use direct-reading particle-measuring devices to screen for suspect emissions and atypical conditions.
- c) Use more sophisticated techniques, to collect and analyze samples to characterize emissions and potential exposure and to determine if a control is needed or must be upgraded or serviced.
- d) Use Laboratory’s data management system to link environmental data indicative of exposure to engineered nanoparticle workers exposed to engineered nanoparticles of unknown health effects.

Appendix to the document contains description of an example Industrial Hygiene Sampling Protocol for Nanomaterials.

U.S. EPA Nanotech White Paper. EPA 100/B-07/001, 2007⁷.

The document describes challenges of environmental detection and analysis of nanomaterials and available techniques. Challenges:

- a) Unique and varying physical structure and physico-chemical characteristics
- b) Interactions of nanomaterials with and in the environment, including agglomeration, and chemical surface treatments complicate the detection and analysis
- c) Need to distinguish between the nanoparticles of interest and other ultra-fine particles.

The level of effort needed and costs to perform analysis for nanomaterials will depend on which environmental compartment samples are being taken from, as well as the type of desired analytical information. The analysis of nanomaterials from an air matrix requires significantly less “sample” preparation than samples taken from a soil matrix. Analyzing samples for number concentration requires significantly less effort than broadening such analyses to include characterization of particle types and elemental composition.

In the case of inseparable mixtures of engineered and other nanomaterials, the use of single particle analysis methodologies may be necessary to provide definitive analysis for the engineered nanomaterials.

⁷ Available online at: <http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf> .

Methods and technologies are available commercially that have demonstrated success. For aerosols, multi-stage impactor samplers based upon the aerodynamic mobility properties are available commercially that can separate and collect nanoparticles size fractions for subsequent analysis, for example, micro-orifice uniform deposit impactors and electrical low-pressure impactors. There are also aerosol fractionation and collection technologies based upon the electrodynamic mobility of particles such as differential mobility analyzers and scanning mobility particle sizers. Available technologies for the size fractionation and collection of nanoparticles fractions in liquid mediums include size-exclusion chromatography, ultrafiltration and field flow fractionation. On-line particle size analysis in liquid mediums can be done using various techniques including dynamic light scattering to obtain a particle size distribution. Inductively-coupled plasma mass spectrometry can provide chemical characterization information. Single-particle laser microprobe mass spectrometry can provide chemical composition data on single particles from a collected fraction. Electron microscopy techniques can provide particle size, morphological and chemical composition information on collected single nanoparticles in a vacuum environment. Atomic Force Microscopy can provide particle size and morphological information on single nanoparticles in liquid, gas, and vacuum environments.

Biological monitoring.

Biomonitoring data, when permitted and applied correctly, provides the best information on the dose and levels of a chemical in the human body. Biomonitoring can be the best tool for understanding the degree and spread of exposure information that cannot be captured through monitoring concentrations in ambient media. Biomonitoring, however, is potentially limited in its application to nanotechnology because it is a science that is much dependent on knowledge of biomarkers, and its benefits are highest when there is background knowledge on what nanomaterials should be monitored.

ISO TC 229 Technical Report “Health and safety practices in occupational settings relevant to nanotechnologies”.

Exposure measurement section of ISO TC 229 technical report contains information from the ISO Technical Report 27628:2007 on Workplace atmospheres – Ultrafine, nanoparticles and nano-structured aerosols – Inhalation exposure characterization and assessment.

Ideally the equipment for taking the occupational hygiene measurements should be:

- Portable;
- Capable of measuring multiple nanoparticle characteristics
- Capable of obtaining breathing zone samples;
- Capable of being used in industrial settings;
- Battery-powered;
- Real-time.

At this time there is not a single instrument for nanomaterials that meets all criteria.

While a strong case can be made for using aerosol surface-area as an exposure metric, it is also necessary to consider characterizing exposures against aerosol mass and number concentration until further information is available.

The actual cut size that particle selection should be made for assessing potential human health impact is still open to debate and depends upon particle behavior and subsequent biological interactions. The cut size for nanoparticles is 100 nm, although this is not derived from particle behavior in the respiratory tract following deposition and it excludes larger particles of nanomaterials, e.g. agglomerates and aggregates.

Mass concentration can be determined by a number of direct reading instruments utilizing collection of particles on filters (aerosol samplers, cascade impactors and oscillating microbalance) and resonator crystals (piezobalance). It is also possible to derive estimates of mass by calculation using a tandem of instruments such as Electrical Low Pressure Impactor and Scanning Mobility Particle Sizer.

The most widely used instrument for determining the number concentration of nanoparticles is the Condensation Particle Counter (CPC).

The diffusion charger measures the Fuchs or active surface area of the aerosols from the attachment rate of positive unipolar ions to particles, from which the aerosol active surface-area can be inferred.

Nanoparticle size distributions can be measured using particle mobility analysis and inertial impaction.

Determination of the physical and chemical properties of airborne nanomaterials relevant to their potential effect on human health is often required. The main analytical techniques routinely available for determining the particle size, shape and composition are high resolution electron microscopies such as scanning electron microscopy (SEM), field emission gun SEM, transmission electron microscopy, and scanning transmission electron microscopy, combined with x-ray microanalysis, Electron Energy Loss Spectroscopy and electron diffraction.

Sampling. Until it has been agreed which is (are) the most appropriate metric(s) for assessing exposure to nanoparticles in relation to potential adverse effects, it has been recommended that a range of instrumentation be used to provide full characterization of the aerosols in workplaces where nanoparticles are being produced, handled or used to make new materials.

To improve the comparability of exposure data, the accepted practice of giving personal exposure as an eight-hour-shift value should also be observed in the case of nanoaerosols.

Worker exposure to nanoparticles derived from a process are likely to be over-estimated due to the presence of incidental nanoparticles introduced from outside(e.g. vehicle exhausts, other industrial activities, power stations, etc.). One way to overcome this problem is to determine ambient or background particle counts prior to the commencement of manufacturing or processing of the nanoparticles.

Dermal exposures

Sampling of nanoparticles deposited on skin in the workplace can be accomplished by adapting well established sampling methods developed for chemicals.

Electron microscopy can be used to characterize size distribution, number concentration and shape of nanoparticles collected on samplers. Light scattering, laser diffraction, size exclusion chromatography, acoustic techniques and field flow fractionation could be used to characterize size distribution and number concentration, while spectroscopic techniques can be useful in obtaining information about chemical composition and structure of nanoparticles.

Biomarkers

Biomarkers can provide direct evidence for the exposure to a particular toxicant if there is a unique correlation between a particular biomarker and a toxicant. Biomarkers of exposure to nanoparticles are in the early development stage complicated by great variety of nanoparticles chemical and physical properties resulting in wide range of biological responses.

Health surveillance

Health surveillance should be considered for all workers where there is risk of exposure to nanoparticles, and where it has been demonstrated that there is a relationship between exposure to the substance and a measurable biological indicator.

Given that exposure to very low concentrations of nanoparticles might be widespread, measurable changes in biological indicators from baseline levels, rather than comparison of body burden with the Biological Exposure Index, might be the most appropriate parameter to examine.

ISO, Workplace atmospheres – Ultrafine, nanoparticles and nano-structured aerosols – Inhalation exposure characterization and assessment. PD ISO/TR 27628:2007.

In addition to the techniques described in the ISO TC 229 Technical Report “Health and safety practices in occupational settings relevant to nanotechnologies,” aerosol mass spectrometry is highlighted as the predominant commercial method for on-line size-resolved chemical analysis of nanoscale aerosols, while scanning probe microscopy such as Atomic Force Microscopy are described as methods to map topographic features of individual nanoparticles at sub-nanometer resolution. ORC Worldwide. Nanotechnology Consensus Workplace Safety Guidelines. Available at <http://www.orc-dc.com/Nano.Guidelines.Matrix.htm>.

The web site contains a selection of Health, Safety & Environment tools and reference materials that may be useful to practitioners involved in deployment of nanotechnology. Specifically, for the area of exposure measurements there are a number of detailed and practical documents on Assessment Strategy for Nanoparticle Aerosols, Qualitative Exposure Assessments, and State-of-the-art Monitoring Techniques.

Assessment Strategy for Nanoparticle Aerosols (http://www.orc-dc.com/oshmem/nanotech/Assess_Strategy_Nanoparticle_Aerosols.pdf) is a basic assessment strategy for evaluating nanoparticles aerosol concentrations in occupational settings, which follows common exposure assessment principles not unique to nanomaterials.

Qualitative Exposure Assessment Tool (http://www.orc-dc.com/oshmem/nanotech/QUAL_EXP_Assess_Tool.pdf) describes how to detect exposure sources, conduct systematic analysis and rank sources in terms of risk and provides a sample survey matrix. The tool was developed for detection of micron sized dusts derived from a potential respiratory allergen and has not been tested for nano sized dusts.

State-of-the-art Monitoring Techniques (<http://www.orc-dc.com/oshmem/nanotech/QEAI1.pdf>) provides description (including limitations, size and costs) of instrumentation available to assess nanoaerosol concentrations in the workplace in the form of mass, number and surface area. The recommendations largely apply to area rather than personal sampling. It recommends to use cascade impactor for measuring mass concentration due to the relatively low cost, ease of use and direct mass measurement; scanning mobility particle sizer for monitoring number concentration due to it providing a full size distribution in a short period of time; diffusion charger for measuring surface area since it provides a real time measurement over a wide detection range and less expensive than other methods. In addition, the document describes particle collection techniques (thermal precipitator, nanometer aerosol sampler, cascade impactor) and particle characterization using electron microscopy.

International Council on Nanotechnology (ICON), Review of Current Practices in Nanotechnology. Phase One Report: Current Knowledge and Practices Regarding Environmental Health and Safety **in the Nanotechnology Workplace**⁸ and Phase Two Report: Survey of Current Practices in the Nanotechnology Workplace⁹.

The first report compiles and summarizes global efforts to document current practices and to establish risk assessment frameworks. The reviewed efforts are critically evaluated for their approaches, completeness and foci. The second report presents the findings of an international survey of current environmental health and safety and product stewardship practices in the global nanotechnology industry. Specifically, the questionnaire inquired about the following areas: environmental health and safety training, use of engineered controls, personal protective equipment and clothing recommendations, exposure monitoring, waste disposal, product stewardship practices, and risk characterization.

Weis, B. K., et al. Personalized Exposure Assessment: Promising Approaches to Human Environmental Health Research. *Environmental Health Perspective*, 2005, July; 113(7): 840-848.

The report describes a “toolbox” of methods for measuring external (environmental) and internal (biologic) exposure and assessing human behaviors that influence the likelihood of exposure to a broad range of environmental agents. The methods are discussed in relation to current use in human health research; specific gaps in the development, validation, and application. Recent efforts have focused on automated “lab-on-a-chip” sensing devices for detecting environmental agents.

D. Other Sources of Information

European Commission funded several projects addressing exposure measurements, i.e. “Nanosafe2”, “Nanosh” and “Nanotransport”, which generated different outputs: (1) for “Nanosafe2”¹⁰ a compiled report informs on: (a) detection, monitoring and characterization techniques including aspects related to the monitoring of nanoparticles at industrial sites; (b) development and evaluation of on-line monitoring techniques including aspects of gas phase detection, liquid phase detection, tracing and marking techniques and off-line monitoring and sampling techniques; (c) monitoring chains; (d) environmental and societal aspects including information on the development of a societal risk assessment methodology at workplaces and training; (2) “Nanosh”¹¹ addresses chain/comparison of measurements to distinguish manufactured nanoparticles from other nanoparticles; use of precipitators for direct deposition of nanoparticles on Transmission Electron Microscope grids; direct deposition of nanoparticles on Transmission Electron Microscope grids in breathing zone tackling the characterisation of particles and personal exposure; and (3) “Nanotransport”¹² provided preliminary results on aerosol dynamics of nanoparticles addressed aspects related to the adherence and coagulation of nanoparticles after release. Moreover, there was a call for proposals which included measures to measure exposure of workers and that generated two additional new projects, “Nanodevice”¹³ and “Nanoimpactnet”¹⁴.

⁸Available on-line at:

http://cohesion.rice.edu/CentersAndInst/ICON/emplibary/Phase%20I%20Report_UCSB_ICON%20Final.pdf

⁹Available on-line at:

<http://cohesion.rice.edu/CentersAndInst/ICON/emplibary/ICONNanotechSurveyFullReduced.pdf>

¹⁰ See <http://www.nanosafe.org/>

¹¹ See <http://www.ttl.fi/Internet/partner/Nanosh/>

¹² See <http://research.dnv.com/nanotransport/>

¹³ See presentation at the EC Workshop held 17+18 April 2008 on <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>

¹⁴ See <http://www.nanoimpactnet.eu/> and presentation at the EC Workshop held 17+18 April 2008 on <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>

EXPOSURE MITIGATION IN OCCUPATIONAL SETTINGS

A. Preliminary analysis.

A number of organizations recommend prudent practices for the safe handling of nanomaterials based upon the best available knowledge.

General occupational safety and health guidelines based on established guidelines for controlling exposures to general aerosols are recommended. More specific guidelines for exposure mitigation have been reported for laboratory settings.

Given the limited knowledge about the hazardous properties of nanomaterials and exposure levels in the workplace, it is recommended to use performance-based approaches to exposure mitigation aimed at monitoring performance of mitigation measures and minimizing exposures and based on qualitative hazard and exposure assessments.

B. Preliminary recommendations.

The following potential specific projects are recommended by the Drafting Group on Exposure Measurement and Exposure Mitigation for pursuit by the OECD Working Party on Manufactured Nanomaterials with a goal of raising awareness and harmonizing approaches to exposure mitigation globally:

- Compare guidance on personal protective clothing, gloves and respirators.
- Compare guidance on engineering and work practice controls and worker training and education.
- Compare minimum exposure mitigation measures for nanomaterials required within government nanotechnology risk management programs (for example, as part of voluntary reporting programs for engineered nanomaterials).
- Compare exposure mitigation guidance for laboratories.
- Analyse Exposure Mitigation frameworks, such as Control Banding approach, for applicability to nanotechnology.

C. Brief summaries of Published Documents.

German Chemical Industry Association (VCI) and German Federal Institute for Occupational Safety and Health (BAuA). Guidance for handling and use of nanomaterials in the workplace¹⁵.

This document provides guidance regarding OSH measures in the production and use of intentionally produced nanomaterials in the workplace reflecting the current state of science and technology.

It states that the general dust limit value does not apply for ultra-fine dusts and therefore exposures should be minimized. The following course of action is recommended to provide protective measures:

¹⁵The document was finalized on March 2007 and it is available on-line at: http://www.baua.de/nan_49456/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/guidance.pdf , an updated version will be available in 2009.

1. Use dispersions, pastes or compounds instead of powder substances, wherever this is technically feasible and economically acceptable.
2. Perform activities in closed systems wherever possible. If this cannot be done, avoid formation of dusts or aerosols. Ensure regular function testing and maintenance. Extracted air must not be fed back without exhaust air purification.
3. Inform workers about the specific physical properties of nanoparticles, the need for special measures, and potential long-term effects of dusts. Include relevant information in the operating instructions. Limit the number of workers handling nanomaterials to the smallest group of persons possible. Deny unauthorized persons access to the relevant work areas. Ensure clean work area, which must be cleaned by the employer. Private clothing and work wear are to be stored separately. Ensure the regular cleaning of workplaces. Spilled substances must be vacuumed or wiped up with a moist cloth; do not remove spilled substances by blowing.
4. Where technical protection measures are not sufficient or cannot be put into place provide for personal protection measures – such as a respiratory protection. Protection gloves, standard protection goggles with side protection and protective clothing are to be worn. It is recommended to test the efficacy of deployed personal protective equipment where protection against other substances is concerned.
5. It is also necessary to observe further measures necessary due to special substance properties, e.g. anti-explosion measures in the handling of flammable nanoparticles, or specific protection measures in the handling of reactive or catalytic nanoparticles.

US National Institute for Occupational Safety and Health, “Approaches to Safe Nanotechnology: Information Exchange with NIOSH,” 2006¹⁶.

This document provides an overview of techniques available to mitigate exposures in the workplace and provides interim recommendations for exposure control procedures.

1. Given the limited amount of information about the health risks associated with occupational exposure to engineered nanoparticles, it is prudent to take measures to minimize worker exposures.
2. For most processes and job tasks, the control of airborne exposure to nanoaerosols can be accomplished using a wide variety of engineering control techniques similar to those used in reducing exposure to general aerosols.
3. The implementation of a risk management program in workplaces where exposure to nanomaterials exists can help minimize the risk to nanoaerosols. Elements of such a program should include:
 - a) Evaluating the hazard posed by the nanomaterial based on available physical and chemical property data and toxicity or health effects data;
 - b) Assessing potential worker exposure to determine the degree of risk;
 - c) The education and training of workers in the proper handling of nanomaterials (e.g. good work practices)
 - d) The establishment of criteria and procedures for installing and evaluating engineering controls (e.g. exhaust ventilation) at locations where exposure to nanoparticles might occur
 - e) The development of procedures for determining the need and selection of personal protective equipment (e.g. clothing, gloves, respirators)
 - f) The systematic evaluation of exposures to ensure that control measures are working properly and that workers are being provided the appropriate personal protective equipment.

¹⁶ Available on-line at: <http://www.cdc.gov/niosh/topics/nanotech/safenano>

4. Engineering control techniques such as source enclosure (i.e. isolating the generation source from the worker) and local exhaust ventilation systems should be effective for capturing airborne nanoparticles. Current knowledge indicates that a well-designed exhaust ventilation system with a high-efficiency particulate air (HEPA) filter should effectively remove nanoparticles.
5. The use of good work practices can help to minimize worker exposures to nanomaterials. Examples of good practices include: cleaning of work areas using HEPA vacuum pickup and wet wiping methods, preventing the consumption of food or beverages in workplaces where nanomaterials are handled, and providing hand-washing facilities and facilities for showering and changing clothes.
6. No guidelines are currently available on the selection of clothing or other apparel (e.g. gloves) for the prevention of dermal exposure to nanoaerosols. However, some clothing standards incorporate testing with nanoscale particles and therefore provide some indication of the effectiveness of protective clothing with regard to nanoparticles.
7. Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. Currently, there are no specific exposure limits for airborne exposures to engineered nanoparticles although occupational exposure limits exist for larger particles of similar chemical composition. The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and the frequency and likelihood of the worker's exposure. Preliminary evidence shows that for respirator filtration media there is no deviation from the classical single-fiber theory for particulates as small as 2.5 nm in diameter. While this evidence needs confirmation it is likely that NIOSH certified respirators will be useful for protecting workers from nanoparticles inhalation when properly selected and fit tested as part of a complete respiratory protection program.

U.S. DOE Nanoscale Science Research Centers, Approach to Nanomaterials ES&H, 2007¹⁷.

The document offers "reasonable guidance for managing the uncertainty associated with nanomaterials whose hazards have not been determined and reducing to an acceptable level the risk of worker injury, worker ill-health and negative environmental impacts" in laboratories of Nanoscale Science Research Centers.

The document recommends to follow a graded approach in specifying controls based on disposability of nanomaterials and provides specific advice on work area design, ventilation preferences, chemical hygiene plan, housekeeping, work practices, marking/labeling/signage, clothing and personal protective equipment.

U.S. EPA Nanotech White Paper. EPA 100/B-07/001, 2007¹⁸.

The document describes challenges for controlling exposures in the workplace. It states that approaches exist to mitigate exposure to fine and ultrafine particulates which can apply to the workplace. In the hierarchy of exposure reduction methods, engineering controls are preferred over PPE. Engineering controls and particularly those used for aerosol control, should generally be effective for controlling exposures to airborne nanoscale materials. No research has been identified evaluating the effectiveness of engineering controls for nanoparticles. Properly fitted respirators with a HEPA filter may be effective at removing nanomaterials. PPE may not be as effective at mitigating dermal exposure as macro-sized particles from both human causes and PPE penetration. No studies were identified that discuss the efficiency of PPE at preventing direct penetration of nanomaterials through PPE or from failure due to human causes.

¹⁷ Available online at: http://www.sc.doe.gov/bes/DOE_NSRC_Approach_to_Nanomaterial_ESH.pdf.

¹⁸ Available at: <http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>.

ISO TC 229 draft Technical Report “Health and safety practices in occupational settings relevant to nanotechnologies”.

Exposure control section of ISO TC 229 WG3 PG1 draft technical report covers control of both health hazards and safety (physico-chemical) hazards, and specific examples of controls used in companies and research laboratories are presented. The control of emissions containing nanoparticles in occupational settings is not a new subject. Controls are well established for preventing and controlling exposure to, for example, welding fumes and diesel emissions (which contain incidental nanoparticles). What is new and unique is the need to control exposure to engineered nanomaterials in an increasing number of research laboratories and commercial workplaces. Using existing knowledge for the control of fine and ultrafine particles (including incidental nanoparticles) as a starting point, informed guidance is presented for the control of engineered nanomaterials. Based on existing knowledge and information, advice is provided on the likely effectiveness of different control strategies in preventing exposure.

ORC Worldwide. Nanotechnology Consensus Workplace Safety Guidelines¹⁹.

The web site contains a selection of Health, Safety & Environment tools and reference materials that may be useful to practitioners involved in deployment of nanotechnology. Specifically, there are a number of detailed and practical documents on exposure mitigation: General Considerations for Engineering Controls for Nanomaterials (guidance on physical and chemical containment, ventilation and flow extraction, HEPA filtration), Workplace Operational Guidelines (qualitative description of housekeeping standards), Guidelines for Safe Handling of Nanoparticles in Laboratories (recommendations on exposure risk assessment, engineering controls, PPE and respirators, spill cleanup and disposal).

International Council on Nanotechnology (ICON), Review of Current Practices in Nanotechnology. Phase One Report: Current Knowledge and Practices Regarding Environmental Health and Safety **in the Nanotechnology Workplace**²⁰, and Phase Two Report: Survey of Current Practices in the Nanotechnology Workplace²¹.

The first report compiles and summarizes global efforts to document current practices and to establish risk assessment frameworks. The reviewed efforts are critically evaluated for their approaches, completeness and foci. The second report presents the findings of an international survey of current environmental health and safety and product stewardship practices in the global nanotechnology industry. Specifically, the questionnaire inquired about the following areas: environmental health and safety training, use of engineered controls, personal protective equipment and clothing recommendations, exposure monitoring, waste disposal, product stewardship practices, and risk characterization.

¹⁹ Available at: <http://www.orc-dc.com/Nano.Guidelines.Matrix.htm>

²⁰ Available on-line at:

http://cohesion.rice.edu/CentersAndInst/ICON/emplibary/Phase%20I%20Report_UCSB_ICON%20Final.pdf

²¹ Available on-line at:

<http://cohesion.rice.edu/CentersAndInst/ICON/emplibary/ICONNanotechSurveyFullReduced.pdf>

“Nanosciences and Nanotechnologies: An action for Europe 2005-2009. First Implementation Report 2005-2007”. Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee²².

This document provides a summary of the activities and progress on nanotechnology in Europe during 2005-2007. The European standards bodies CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization), and ETSI (European Telecommunications Standards Institute) are engaged in developing and/or revising standards in relation to health, safety and environmental protection. Under the European Technology Platform (ETP) on Sustainable Chemistry (SusChem), several documents have been produced on exposure mitigation including a code of conduct on nanotechnology; a guide on safer manufacturing and activities involving nanoparticles at workplaces; and detailed information on nanomaterial characterisation. The ETP on Industrial Safety (ETPIS) has also examined monitoring technologies as well as workplace and environmental safety for nanomaterials.

ASTM International — ASTM E56-03, “Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings”. Draft of 30 September 2005²³.

This document “describe actions that could be taken in occupational settings to minimize human exposures to unbound, intentionally produced nanometer-scale particles, fibers and other such materials in manufacturing, processing, laboratory and other occupational settings where such materials are expected to present. It is intended to provide guidance for controlling such exposures as a precautionary measure where relevant exposure standards and/or definitive risk and exposure information do not exist.”

National (U.S.) Council for Occupational Safety and Health — Hierarchy of Health and Safety Controls²⁴.

This document contains a simple chart outlining safety measures which can be implemented in an occupational setting.

Health and Safety Executive — United Kingdom Information Note: Nanotechnology²⁵.

This document “gives information on the health and safety issues surrounding some aspects of nanotechnology. It is aimed at researchers and developers creating and working with nanomaterials.” Information includes considerations for monitoring, control measures, personal protective equipment.

Health and Safety Executive — United Kingdom, COSHH (Control of Substances Hazardous to Health) — Achieving Control²⁶.

This document outlines the hierarchy of controls which should be used to mitigate exposure to hazardous substances. Although the recommendations are not specific to nanomaterials, the same principles can be applied.

²² Available electronically at http://ec.europa.eu/nanotechnology/pdf/comm_2007_0505_en.pdf

²³ Available electronically at: <http://www.astm.org/DATABASE.CART/WORKITEMS/WK8985.htm>

²⁴ Available electronically at: <http://www.coshnetwork.org/Hierarchy%20of%20Controls%20Chart.PDF>

²⁵ Available electronically at: <http://www.hse.gov.uk/pubns/hsin1.pdf>.

²⁶ Available electronically at: <http://www.hse.gov.uk/cossh/control.htm>

Environmental Defense and DuPont Corporation, Nano Risk Framework (July 2007)²⁷.

This document describes a process for the responsible development of nanomaterials throughout their lifecycle (from production to disposal). This includes recommended principles and measures to follow to mitigate exposure in occupational settings.

Council Directive 98/24/EC of the 7th April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. In this respect, there are also 'Practical Guidelines' available covering aspects linked to methods for the measurement and evaluation of workplace air concentrations, risk assessment, general principles for prevention, specific protection and prevention measures and the surveillance of the health of workers.

European Commission,

Protection of the Health and Safety of Workers. Information available electronically at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:131:0011:0023:EN:PDF>
<http://osha.europa.eu/en/legislation/directives> ,
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm#r14 at the bottom of the website under Occupational Exposure Estimation at the bottom of this web-site".

Guidance on information requirements and chemical safety assessment on "*Occupational Exposure Estimation - Chapter R.14*" explaining the REACH obligations and how to fulfill them were recently published by the European Chemicals Agency (ECHA) and provides support for estimating occupational exposures. Available at:
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm#r14 at the bottom of the website under Occupational Exposure Estimation.

D. Unpublished Documents

Thailand National Nanotechnology Center is funding development of nanosafety guidelines which are expected to be completed by the end of 2007.

Belgium Public Federal Service for Health, Safety of the Food Chain and Environment will be leading a group to assess and manage risks in connection with handling nanomaterials according to existing regulations [ENV/CHEM/NANO(2007)2/ADD1].

"Good practice guide for the workplace"; INRS in France was tasked to draw up a good practice guide for the protection of workers exposed to nanomaterials.

"Code of Good Practice" Germany Nanocommission is in the process of developing a good product document which should be available by the end of 2008²⁸.

"Guide to Safe Handling and Disposal of Free Engineered Nanomaterials"; British Standards Institute²⁹.

²⁷ Available electronically at: www.nanoriskframework.com

²⁸ You can download it at: http://www.bmu.de/gesundheits_und_umwelt/nanotechnologie/nanodialog/doc/42655.php (only in German, English version in preparation, short information at: <http://www.bmu.de/english/nanotechnology/nanodialog/doc/40549.php>)

E. Other Sources of Information

Report of the OECD workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination, and Communication”; Washington, USA, 7th-9th December, 2005³⁰.

A survey completed before the Joint meeting revealed the following:

1. France has launched a call for projects as part of a program “Health and Environment” “Health and Work”, part of which focuses on the impact of nanoparticles. This program will be crucial in risk assessment and developing good practices. French Agency for Environmental Health and Safety has been asked by the Ministries of Health, Labour and Environment to draw up a summary of the scientific knowledge on a variety of issues, including exposure data to the general public and workers.
2. European Commission funded several projects including “Nanosafe & Nanosafe2”, “Nanosh” and “Nanotransport”, which generated different outputs: (a) While Nanosafe³¹ addressed “the risk assessment in production and use of nanoparticles with the development of preventative measures and practice codes” and Nanosafe2 compiled a report on “conventional protective devices such as fibrous filter media, respirator cartridges, protective clothing and gloves and their efficiency against nanoaerosols”; (b) Nanosh³² addresses filter efficacy testing; and (c) Nanotransport³³ provided preliminary results on aerosol dynamics of nanoparticles addressed aspects related to the adherence and coagulation of nanoparticles after release. There was a call for proposals which included measures to minimize exposure of workers and generated two additional new projects, “Nanodevice”³⁴ and “Nanoimpactnet”³⁵.
3. BIAC mentioned a survey conducted in Germany which included measuring types and quantities of nanoparticles at the workplace and from products, which is a good indication towards future exposure mitigation protocols.

U. S. NIOSH released a report of the progress of the NIOSH Nanotechnology Research Center since its inception in 2004 though 2006 in February 2007. The Progress Toward Safe Nanotechnology in the Workplace (NIOSH Publication No 2007-123)³⁶.

²⁹ You can download it at:
<http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/>

³⁰ OECD Series on the Safety of Manufactured Nanomaterials No.1 - ENV/JM/MONO(2006)19 available at:
www.oecd.org/env/nanosafety

³¹ See report at: <http://www.nanosafe.org/> and see the last hyperlink at the bottom of this web-page.

³² See: <http://www.ttl.fi/Internet/partner/Nanosh/>

³³ See: <http://research.dnv.com/nanotransport/>

³⁴ See presentation at the EC Workshop held 17+18 April 2008 on:
<ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>

³⁵ See: <http://www.nanoimpactnet.eu/> and presentation at the EC Workshop held 17+18 April 2008 on:
<ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>.

³⁶ Available electronically at: <http://www.cdc.gov/niosh/docs/2007-123/>

U. S. NIOSH funded research:

1. Principal investigator, Doug Evans has proposed studying the toxicity of workplace-related aerosols. See: http://www.nanotechproject.org/index.php?id=18&action=view&project_id=2 .
2. Principal investigator, Keith Crouch has proposed to investigate ultrafine particle intervention in Automotive Production Plants. See: http://www.nanotechproject.org/index.php?id=18&action=view&project_id=30.
3. Principal investigator, Appavoo Rengasamy has proposed to study the filter efficiency of typical respirators for nanoscale particles. See: http://www.nanotechproject.org/index.php?id=18&action=view&project_id=788 .
4. Principal investigator, Mark Hoover has proposed to study exposure of nanoparticles in the workplace. See: http://www.nanotechproject.org/index.php?id=18&action=view&project_id=28

Extramural-NIOSH funded research:

1. Principal investigator, Patrick O'Shaughnessy has proposed to write a report on the assessment methods for nanoparticles in the workplace, who will be developing tools and instruments to accurately airborne levels of nanoparticles and to assess the efficacy of respirator use for controlling nanoparticle exposures. See: http://www.nanotechproject.org/index.php?id=18&action=view&project_id=697.

The Nanoparticle Occupational Safety and Health Consortium (NOSH) has undertaken a project that focuses on workplace exposure monitoring capabilities and strategies with the design and development of portable aerosol monitoring instrumentation for conducting assessments of worker exposure to airborne engineered nanoparticles and nanomaterials. Additionally the project will conduct studies to obtain knowledge of the barrier performance, characteristics of various protective clothing fabrics to aerosols of nanoparticles or nanomaterials and provide the measurement capabilities as a service. The project was completed in 2007.

European Agency for Safety and Health at Work. Risk Assessment Essentials³⁷.

European Agency for Safety and Health at Work. Priorities for occupational safety and health research in the EU-25, 2005³⁸.

European Agency for Safety and Health at Work. Documents and study information linked to dust and particles at workplaces that are considered useful when working on exposure measurements and exposure mitigation for nanomaterials can be downloaded from http://ec.europa.eu/employment_social/health_safety/docs_en.htm. Links to specific relevant documents are:

1. http://ec.europa.eu/employment_social/health_safety/docs/chemical_agent_en.pdf;
2. http://ec.europa.eu/employment_social/publications/2004/ke6404175_en.pdf;
3. http://ec.europa.eu/employment_social/health_safety/docs/5th14_en.pdf;
4. http://ec.europa.eu/employment_social/health_safety/docs/5th02_en.pdf;
5. http://ec.europa.eu/employment_social/health_safety/docs/occ_epidemiological_en.pdf.

³⁷ Available electronically at <http://hwi.osha.europa.eu/about/material/rat2007>

³⁸ Available electronically at <http://osha.europa.eu/publications/reports/6805648>.

Presentations at Nanosafety-HUB Meeting held on March 23 in Brussels, Belgium³⁹ include presentation relevant to exposure mitigation:

1. François TARDIF, CEA (FR) presentation available at http://euvri.risk-technologies.com/events/event_3/II%207%20Cambier.pdf
2. Christophe GOEPFERT, CILAS (FR) presentation available at http://euvri.risk-technologies.com/events/event_3/I%207%20goepfert.pdf

Presentations at the 8th Joint Symposium on “Food Safety and Applied Nutrition: Nanotechnology in Foods and Cosmetics”⁴⁰ jointly organized by the Central Science Laboratory (CSL), UK and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), University of Maryland, College Park, and held on June 26-28, 2007 in Greenbelt Maryland, US.

Information about the EU-Nanosafe2-Project is available from

1. <http://www.nanosafe.org/> <http://www.nanosafe.org/node/815>;
2. <http://enero.issep.eu/seminar>;
3. <http://enero.issep.eu/page.asp?id=68&langue=EN>.

³⁹ Available electronically at: http://euvri.risk-technologies.com/events/event_3/default.htm

⁴⁰ Are available electronically at <http://www.jifsan.umd.edu/csl2007proc.html>. The presentation on nanoparticle reference materials given by Dr. H. Emons (EC, DGJRC-IRMM, Geel, BE) is available electronically at http://www.jifsan.umd.edu/presentations/csl_2007/PDF/Wed/5.H.Emons_JIFSAN_CSL_Symp.pdf