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Number 12

COMPARISON OF GUIDANCE ON SELECTION OF SKIN PROTECTIVE EQUIPMENT AND RESPIRATORS FOR USE IN THE WORKPLACE: MANUFACTURED NANOMATERIALS

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No. 12

COMPARISON OF GUIDANCE ON SELECTION OF SKIN PROTECTIVE EQUIPMENT AND RESPIRATORS FOR USE IN THE WORKPLACE: MANUFACTURED NANOMATERIALS

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

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No.12, *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials (2009)*

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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.

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 is intended to provide information on activities of the WPMN related to the safety of manufactured nanomaterials. The Working Party endorsed this report at its 5th Meeting on March 2009. 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 Nanomaterials[1] 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, BIAC[2], TUAC[3], 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
Co-operation on Exposure Measurement and Exposure Mitigation.

Each area of work 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 was prepared by the WPMN steering group 8 leading the work on *Co-operation on Exposure Measurement and Exposure Mitigation*. The Working Party endorsed this report at its 5th Meeting on March 2009.

[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.

CO-OPERATION ON EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION

In November 2007 the OECD Working Party on Manufactured Nanomaterials decided to start work on **Co-operation on Exposure Measurement and Exposure Mitigation**. A steering group lead by the US, and comprising delegates from the WPMN was tasked with developing this work.

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 analyze 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.

As part of Phase 1, the WPMN decided to develop project on *Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Nanotechnology Workplaces*. This document compares guidance on personal protective clothing, gloves and respirators, including compilation of efficacy of personal protective equipment, especially respirator cartridges and gloves. Thus, it provides an overview for experienced health and safety professional such as industrial/occupational hygienists[4]. The document is to be seen as one element within the frame of limiting worker exposure.

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

[4] Please note that in this document “industrial hygienist” and “occupational hygienist” are used interchangeably.

COMPARISON OF GUIDANCE ON SELECTION OF SKIN PROTECTIVE EQUIPMENT AND RESPIRATORS FOR NANOTECHNOLOGY WORKPLACES

1. Introduction

The use of Personal Protective Equipment (PPE) such as Skin Protective Equipment (SPE), face masks or safety goggles, and respirators should be considered as the last line of defence in the hierarchy of exposure mitigation techniques in the workplace after all other available measures have been implemented. The selection of PPE should be based on an adequate risk assessment including hazard evaluation[5] that would result in a clear picture on the level of protection that is needed. However, presently for nanomaterials both a quantitative exposure assessment and Occupational Exposure Limits are lacking, so the decision to use PPE can only be based on qualitative risk assessment. This limits the possibilities to give guidance for the selection of appropriate PPE.

Nevertheless, a number of documents providing recommendations for the use of personal protective equipment including clothing, gloves and respirators have been developed. For example, in the U.S. National Institute for Occupational Safety and Health (NIOSH) is mandated by law to certify respirators and to provide recommendations on personal protective clothing and gloves for use in the workplace. U.S. NIOSH outlines considerations for PPE and respirator selection for nanotechnology workplaces in "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH" (U.S. NIOSH, 2008). German Chemical Industry Association (VCI) and German Federal Institute for Occupational Safety and Health (BAuA) published "Guidance for handling and use of nanomaterials in the workplace," which contains guidance on the selection and use of personal PPE including data on filter efficacy for nanoscale particles (VCI, 2007). U.S. DOE Nanoscale Science Research Centres "Approach to Nanomaterials ES&H" provides specific guidance for the selection of personal protective equipment in laboratory settings (U.S. DOE, 2007), while BSI Published Document (PD) "Guide to safe handling and disposal of manufactured nanomaterials" provides such guidance for R&D, manufacturing and processing of nanomaterials (BSI, 2008).

At European level a number of different activities are currently pursued including the assessment, consolidation and/or development of nanomaterials production processes to achieve solutions in relation to containment, efficient local exhaust system equipped with an effective filtering system as well as extended personal protection equipments such as gloves, masks, suits, safety shoes, etc. for the manufacturing of nanomaterials. More information and an information update of these activities can be found in the respective presentations of various EU research projects (i.e. NANOSAFE2[6] and SAPHIR[7]); and the respective presentations at the recently held NANOSAFE2008 Conference in Grenoble 3-5 November 2008[8]. Especially the EU-SAPHIR-project adapts the outputs from the safety aspects obtained in the EU-NANOSAFE2-Project on the production pilot lines and aims to generate concrete guidelines allowing solutions to secure installations adapted to the respective manufacturing process for nanomaterials. A large

[5] As described, for example, in U.S. 29 CFR 1910 Subpart I App B "Non-mandatory Compliance Guidelines for Hazard Assessment and Personal Protective Equipment Selection."

[6] www.nanosafe.org

[7] www.saphir-project.eu

[8] www.nanosafe2.org

portion of the EU-SAPHIR-Project will be devoted to sorting the real enhancement given by nanomaterials and developing the exposure elimination or reductions required and fine-tuned to the respective various production processes. This will be obtained by integrating nanomaterials properties, processes (here, also 3D and 2D processes), various process tools for secured integrated processes, safety issues of integrated production process monitoring, on-line characterization, on-line liquid monitoring, testing sampling and measurements, process control, risk assessments and cost evaluations. Furthermore, the European Agency for Safety and Health at Work established a Risk Observatory[9] that includes also nanomaterials and addresses exposure to these materials during manufacturing and use that may occur through inhalation; dermal contact and ingestion.

To facilitate development and global adoption of science-based guidance on the use of skin protective equipment and respirators in nanotechnology workplaces, OECD's Working Party on Manufactured Nanomaterials (WPMN) agreed to start a project to *compare guidance on personal protective clothing, gloves and respirators*. This project was implemented by the WPMN Steering Group 8 (SG8) leading the work on *Co-operation on Exposure Measurement and Exposure Mitigation*.

Accordingly, the project aimed at:

- compare guidance on personal protective clothing, gloves and respirators, including compilation of efficacy of personal protective equipment, especially respirator cartridges and gloves; and
- develop OECD WPMN guidance on personal protective clothing, gloves and respirators for nanotechnology workplaces.

This document is a compilation of various activities and provides an overview for experienced health and safety professional such as industrial/occupational hygienists[10]. This document was developed as a component of the overall work of the programme on the safety of manufactured nanomaterials, which is been developed by OECD's WPMN. It should be consider as one element within the frame of limiting worker exposure.

2. Scope

If worker exposure to nanomaterials remains a concern after instituting engineering, administrative and work practice controls to eliminate or mitigate exposure, the use of skin protective equipment and respirators can further reduce exposures. In addition, it is recommended that appropriate PPE are worn on a precautionary basis whenever the failure of a single control, including an engineering control, could entail a significant risk of exposure to workers (U.S. DOE, 2007).

Conventional selection of personal protective equipment relies on quantitative hazard and exposure assessments for a given workplace (e.g. see U.S. NIOSH, 2004 for respirator selection). Since there are currently no exposure limits for the majority of engineered nanomaterials, a qualitative assessment could be used to determine whether nanomaterial emissions occur (OECD, 2009) and whether personal protective equipment should be used. The need and selection of respiratory and skin protection could be linked to the results of tiered assessments of inhalation and skin exposure such as the adjusted DREAM method (Wendel-de-Joode et al, 2003).

[9] See http://osha.europa.eu/en/sub/riskobservatory/teaser/nanotechnologies

[10] Please note that in this document "industrial hygienist" and "occupational hygienist" are used interchangeably.

The effectiveness of applied protection measures must be periodically reviewed. Masks and respirators that are not certified (to a nationally recognized standard) should not be relied upon for protection against nanomaterials, since users cannot be assured that they provide a certain level of protection.

This guidance on the use of skin protective equipment and respirators utilizes prudent approach to exposure mitigation and relies on qualitative hazard and exposure assessments. It may be useful to health and safety professionals such as occupational hygienists who develop exposure mitigation programs in nanotechnology workplaces.

3. Skin protective equipment

3.1 Performance

There are many factors that contribute to the effectiveness of skin protective equipment such as clothing and gloves (Schneider *et al.*, 1999; Brouwer et al, 2005). The two primary routes of exposure to particulates for workers using protective clothing are direct penetration through the materials and leakage through gaps, seams, defects, and interface and closure areas. The relative contributions from these two inward leakage sources are not well-understood (U.S. NIOSH, 2008).

The lack of available data is further complicated by the limitations and difficulties of current test methods which fall into two basic categories: penetration tests on material swatches to determine barrier efficiency and system level aerosol testing to determine product ensemble integrity. The former are usually bench-scale testing methods, while the latter require an exposure chamber that is large enough for at least one human test subject or manikin. Chamber design requirements for system level aerosol testing have been reviewed by Gao, King, and Shaffer (2007). Little scientific data exists, but some systems level test methods are available. ISO standard method 13982 (ISO, 2004a) and EN standard method 943 (CEN, 2002) specify the use of sodium chloride with a mass median aerodynamic diameter (MMAD) of 0.6 μm to determine the barrier efficiency of protective clothing against aerosols of dry, fine dusts. The standard method issued by National Fire Protection Association (NFPA, 2007) is a method that is not dependent on filtration-based approaches. Penetration of fluorophore-impregnated silica particles with a MMAD of 2.5 μm and a geometric standard deviation of 2.6 are qualitatively visualized by black light that causes the fluorescent glow of the challenge aerosol particles. Note that the polydisperse particle challenges used in these methods include a large number of nanoparticles, when measured by count rather than mass (U.S. NIOSH, 2008).

Particle penetration test methods can be further categorized into those that are analogous to the process used in respirator filter testing and those that are not dependent on filtration-based approaches. Test methods that involve measuring aerosol concentrations using a sampling flow rate do not mimic in-situ situations because the skin does not “breathe”. Standardized methodology that is not dependent on filtration-based approaches for examining the overall barrier-effectiveness of the full protective clothing ensemble for different materials to particulate hazards is needed. In this respect, U.S. NIOSH has presented preliminary results (Wang and Gao, 2007) on development of a magnetic passive aerosol sampler for more accurate determination of particle penetration through protective clothing ensembles.

The bulk of the penetration data available on clothing has been done with filtration based testing. One study found that penetration levels of 30 nm to 2 μm sized potassium chloride particles through an unidentified military garment ranged from about 20% to 60%, with the maximum penetration occurring in the 100 nm to 400 nm range (Hofacre, 2006). Another group of researchers studied the barrier efficiency of 10 unidentified fabric samples (woven, non-woven, and laminated fabrics) using 477 nm sized latex spheres at a flow rate of 1.8 cm/second (Shavlev *et al*., 2000). Particle penetration measurements ranged from 0% to 54%, with the three fabrics exhibiting a measurable pressure drop all having penetration levels less than 1%. In general, these findings suggest that increased external air pressure (e.g., from wind)

results in increased particle penetrations. Thus, only impermeable barrier materials are likely to provide complete barrier protection against aerosol penetration. Body movement (i.e., bellows effect) can also impact penetration (Bergman *et al*., 1989).

Another widely used test method incorporates testing with nanoscale particles in solution, and therefore also provides some indication of the effectiveness of protective clothing to nanoparticles. ASTM standard F1671–03 (ASTM, 2003) and ISO standard 16604 (ISO, 2004b) specify the use of a 27 nm bacteriophage to evaluate the resistance of materials used in protective clothing from the penetration of blood-borne pathogens. One study (Edlich, et al., 1999) evaluated the integrity of powder-free examination gloves and found that no bacteriophage penetration was detected for powder-free nitrile, powder-free latex examination gloves, and polyvinyl chloride synthetic examination gloves tested.

Recently protective clothes were tested by two methods: "through diffusion method" based on NF EN ISO 6529 and NF EN 374 and "air flow through the media"; and the same trends were obtained. The tests were performed using an air flow ranging from 5.3 to 9.6 cm/s with graphite nanoparticles ranging from 10 to 150 nm in electrical mobility diameter and centered at 30 and 80 nm. The tests showed that nanoparticles can penetrate through certain glove material and that high density polyethylene textile (Tyvek type) seems to perform better than cotton and paper against nanoparticle penetration. The 80 nm particles were found to diffuse more than 30 nm particles. In addition, HEPA filters and respirator cartridges made with fibrous filters are even more efficient for nanoparticles than for larger particles. Non woven fabrics (air-tight materials) seem to be effective against nanoparticle penetration, whereas cotton fabrics are less effective (Golanski et al., 2008).

3.2 Selection

Currently, there are no generally acceptable guidelines available based on scientific data for the selection of protective clothing or other apparel against exposure to nanomaterials (U.S. NIOSH, 2008). This is due in part to minimal data being available on the efficacy of existing skin protective equipment including clothing and gloves. In any case, although nanoparticles may penetrate the epidermis, there has been little evidence to suggest that penetration leads to disease; and no dermal exposure standards have been proposed. However, based on a recent survey of nanotechnology workplaces (ICON, 2006), 84% of employers recommended SPE for employees working with nanomaterials. These recommendations were generally based on conventional occupational hygiene practices, but also varied with the size of the company, type of nanomaterials being handled, and commercial sector. While some guidelines on the use of protective clothing and gloves have been developed by organizations for use in their own laboratories (U.S. DOE, 2007), or country (BSI, 2008), or by consensus standards development organizations (ASTM, 2007); these are generally based upon good industrial hygiene practices rather than scientific data specific to nanomaterials.

A challenge to making appropriate recommendations for dermal protection against nanoparticles is the need to strike a balance between comfort and protection. Garments that provide the highest level of protection (e.g., an impermeable Level A suit) are also the least comfortable to wear for long periods of time, while garments that are probably the least protective (e.g., thin cotton lab coat) are the most breathable and comfortable for employees to wear (U.S. NIOSH, 2008).

Based upon the uncertainty of the health effects of dermal exposure to nanoparticles, it is prudent to consider using skin protective equipment (e.g., clothing, gloves) to minimize dermal exposure with particular attention given to preventing exposure of nanomaterials to abraded or lacerated skin. Until scientific data exists specific to the performance of protective clothing and gloves against nanomaterials, current industrial hygiene best practices should be followed by taking also actively the results of recent studies (Golanski et al 2008) and other relevant publications (e.g. NANOSAFE2-Dissemination Report DR-331 200810-6) into account, which show that, e.g. non-woven fabrics (air-tight materials) seem to be effective against nanoparticle penetration. Moreover, the conclusions of the German Chemical Industry

Association (VCI) and German Federal Institute for Occupational Safety and Health (BAuA) guidance document should also be actively applied. The VCI and BAuA guidance states that depending on substance properties, it might be necessary to wear protective gloves, protection goggles with side protection and protective clothing (VCI, 2007). Additionally to hand protection, it can be necessary to protect further parts of the skin with protective equipment. This includes in particular protective suits, aprons and boots. Specifically the guidance recommends using protective clothing, gloves and respirators when workplace manufacturing processes include open systems. The guidance states that in the selection of protective gloves, it must be ensured that the glove material is suitable. The glove material must fulfil requirements for maximum wearing time under practical conditions. In case liquid suspensions are used, the minimal requirement should be that the materials do not show neither degradation nor breakthrough times below task time for the major solvent(s) or substance in the liquid.

The BSI British Standards Published Document PD 6699-2:2007 (2008) states that simply selecting gloves solely on the basis of glove manufacturers' published data is insufficient in ensuring adequate protection. There are four basic criteria for the selection of protective gloves: they should be appropriate for the risk(s) and conditions where they are to be used; they should be suitable for the ergonomic requirements and state of health of the intended wearer; they should fit the intended wearer correctly; and they should prevent exposure without increasing the overall risk. This, of cause, assumes that the gloves are worn and maintained correctly. The development of a glove management system, which emphasizes and reinforces the factors that need to be considered and addressed, how these interlink with each other and when they should be reviewed, should help ensure adequate protection. Packman (2006) emphasizes several of the key elements to be considered in a glove management system, including an assessment of tasks/exposure scenario, glove material selection, ergonomics, training (both managers and workforce), monitoring the system and storage, maintenance and disposal. The guidance specifically recommends using skin protective equipment in maintenance and cleaning of any nanomaterials.

The U.S. DOE (2007) guidance recommends for laboratory settings to:

1) use protective clothing that would typically be required for a wet-chemistry laboratory would be appropriate and could include but not limited to:

- closed-toe shoes made of a low permeability material (disposable over-the-shoe booties may be necessary to prevent tracking nanomaterials from the laboratory);
- long pants without cuffs;
- a long-sleeved shirt;
- laboratory coats;

2) wear polymer (e.g. nitrile rubber) gauntlet-type gloves or nitrile gloves with extended sleeves when handling engineered nanomaterials and particulates in liquids. Choose gloves only after considering the resistance of the glove to the chemical attack by both the nanomaterial and, if suspended in liquids, the liquid;

- recognizing that exposure to nanomaterials is not known to have "good warning properties," change gloves routinely to minimize potential exposure hazards. Alternatively, double glove;
- keep contaminated gloves in a plastic bag or other sealed container in a hood until disposed;
- dispose of contaminated gloves in accordance with Section 6 of the document;
- wash hands and forearms after wearing gloves;

3) wear eye protection, e.g., (spectacle type) safety glasses, face shields, chemical hazard splash goggle, or other safety eyewear appropriate to the type and level of hazard. Do not consider face shields or safety glasses to provide sufficient protection against unbound, dry materials that could become airborne.

4. Respiratory protection

4.1 Performance

Performance of respirators is commonly described using protection factors. Table 1 lists protection factors used in the U.S. and Europe for various classes of respirators. The U.S. NIOSH assigned protection factor (APF) is defined as the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users (U.S. NIOSH, 2008). The APF values developed by U.S. NIOSH are based in part on laboratory studies and take into consideration a variety of factors including the inward leakage caused by penetration through the filter and leakage around the respirator face seal. The relative contributions of these two sources of inward leakage are critical, because for many applications the predominant source of exposure to the respirator wearer results from leakage around the face seal (due to a poor fit) and not penetration directly through the filter media. In 2006, U.S. OSHA published updated APF values that supersede the NIOSH APF values (see Table 1) (Federal Register, 2006). Since the UK approach to derive APF is based on so called 'as is' designed Workplace Protection Factor (WPF) studies, this resulted, amongst other factors, in different (slightly lower) APF values (BSI, 1997).

Presently there are not any data specific to respirator face seal leakage of nanoparticles. However, numerous studies have been conducted on larger particles and on gases/vapors with one total inward leakage (TIL) study that utilized nanoparticles. For example, work done by researchers at the U.S. Army RDECOM on a head-form showed that mask leakage (i.e., simulated respirator fit factor) measured using submicron aerosol challenges (0.72 μm polystyrene latex spheres) was representative of vapor challenges such as sulfur hexafluoride (SF_6) and isoamyl acetate (IAA) (Gardner et al, 2004). Other studies using particles > 100 nm have shown that face seal leakage can be affected by particle size, however the impact of this is still the subject of some debate. A recently completed laboratory study to measure protection factors (total inward leakage) of four NIOSH certified N95 filtering facepiece respirator models donned by human test subjects exposed to 40 nm – 1.3 μm particles found that the minimal protection factors were observed for particles between 80 and 200 nm. The geometric mean of the protection factors for all four models across all particle sizes tested was 21.5; but wide model to model variation was observed (Rengasamy et al, 2007, 2008b).

U.S. NIOSH certifies respirators in accordance with 42 Code of Federal Regulations Part 84. The NIOSH Respirator Selection Logic (RSL) contains a process for selecting respirators for protection against particular hazards. The two respirator classes (air purifying respirators and powered air purifying respirators) most commonly used for protection against particulates utilize filter media to collect/trap particles before they reach the users breathing zone. Among the various test methods and criteria U.S. NIOSH uses as part of the certification process, respirator filter performance testing is the one most affected by the particle size. Since respirator users are exposed to a variety of hazards in different scenarios, respirator certification filtration testing was designed to use "worst-case" test conditions (e.g., particle size, flow rates, etc), so that filter performance in the workplace would not be worse. The NIOSH certification test for N-designated respirators uses a polydisperse distribution of NaCl particles with a count median diameter (CMD) of 0.075 +/- 0.020 μm and a geometric standard deviation (GSD) of less than 1.86 (NIOSH, 2005a). For R- and P- designated respirators, U.S. NIOSH tests using a polydisperse distribution of dioctyl phthalate (DOP) particles with a CMD of 0.185 +/- 0.020 μm and a GSD of less than 1.60 (NIOSH, 2005b). For the lognormal distribution of NaCl aerosols used in the N series certification test, a broad range of particle sizes (e.g., 95% of the particles lie in the range of 22 nm – 259 nm) with a mass median diameter (MMD) of about 0.24 μm (or 240 nm) is used to determine whether the respirator filter performance is at least 95%, 99%, or 99.97% efficient. Most of the particles penetrating through the filter are measured simultaneously using a forward light scattering photometer. However, as noted in a recent review, the instrumentation used in the NIOSH certification test is not capable of measuring the light scattering of all particles less than 100 nm (Eninger, 2008).

Particles larger than 0.3 μm are collected most efficiently by impaction, interception, and gravitational settling, while particles smaller than 0.3 μm are collected most efficiently by diffusion or electrostatic attraction (Hinds 1999). In the development of the test method used for respirator certification, penetration of approximately 0.3 μm particles was considered to be the worst case because these particles were considered to be in the range of the most penetrating particle size (Stevens and Moyer 1989; NIOSH 1996). However, in practice, the most penetrating particle size range (MPPS) for a given respirator can vary based on the type of filter media employed and the condition of the respirator. For example, the most penetrating particle size for N95 air purifying respirators containing electrostatically charged filter media can range from 50-100 nm (Martin and Moyer, 2000; Richardson et al, 2005) to 30-70 nm (Balazy et al, 2006). These test results were recently confirmed by NIOSH (Rengasamy et al. 2007) in which 5 different models of respirators with N95 filters were challenged with 11 different monodisperse NaCl particles ranging in size from 20 to 400nm. The monodisperse aerosol penetrations showed that the MPPS was in the 40 nm range for all respirator models tested. Under the aggressive laboratory test conditions employed in the study, mean penetration levels for 40 nm particles ranged from 1.4% to 5.2%, which suggested that the respirators would be effective at capturing nanoparticles in the workplace. The NIOSH study also investigated whether there was a correlation between filtration performance using the existing NIOSH certification protocol for N series air purifying respirators and the filtration performance against monodisperse particles at the MPPS. A good correlation ($r = 0.95$) was found (e.g., respirators that performed better using the NIOSH certification test also had higher filter efficiencies against monodisperse 40 nm nanoparticles), which is not surprising given that changes in filtration performance follow a consistent trend as a function of particle size.

According to single fiber filtration theory, below the most penetrating particle size, filtration efficiency will increase as particle size decreases. This trend will continue until the particles are so small that they behave like vapor molecules. As particles approach molecular size, they may be subject to thermal rebound effects, in which particles literally bounce through a filter. As a result, particle penetration will increase. The exact size at which thermal rebound will occur is unclear. However, a study by Heim et al (2005) found that there was no discernable deviation from classical single-fiber theory for particles as small as 2.5 nm diameter. Subsequently, a NIOSH-funded contract with the University of Minnesota (Kim et al, 2007) and another study (Kim et al, 2006) showed that the penetration of nanoparticles through fibrous filter media decreased down to 2.5 nm as expected by the single fiber

filtration theory. Thermal rebound phenomena were observed for nanoparticles below 2 nm diameter (Kim et al, 2006). Recent studies provide additional data on nanoparticle penetration for NIOSH certified N95 and P100 filtering face-piece respirators (Rengasamy et al, 2008a), NIOSH certified N95 and European Certified FFP1 respirators (Huang et al, 2007), and FFP3 filter media (Golanski et al, 2008) using particles greater than 4 nm. Measuring data from the Berufsgenossenschaftliches Institut für Arbeitsschutz (BGIA) substantiate a "total number penetration efficiency" for three P3 filters – used for sodium chloride particles from 15 and 100 nm – of between 0.011 and 0.026%, referred to the particle count. Data for P2 filters show a penetration of 0.2%, referred to the particle count (VCI, 2007).

It is to be noted that the results from the Golanski et al 2008 study based on graphite nanoparticles are consistent with other results described in the literature obtained with Ag, NaCl and dioctyl phthalate DOP particles. Moreover, no thermal bounce is observed down to 10 nm. Consequently, these filters are even more efficient for nanoparticles smaller than 100 nm. Nevertheless for certain types of HEPA filters represented by HEPA 2 filter the penetration does not decrease monotonously. It reaches a plateau from 80 nm to 20 nm. The efficiency of HEPA filters to graphite nanoparticle penetration depends strongly on the filter class; i.e. the HEPA H14 and the ULPA U15 show the best efficiency for nanoparticles below 100 nm. In comparison, Electrostatic FPP3 filters are less efficient against nanoparticles penetrations by comparison to HEPA filters. For this kind of electrostatic filters the MPPS was observed to be around 30 nm. This result is in accordance with a recent study performed on N95 filters with NaCl monodispersed aerosol for respirators masks (Rengasamy et al, 2007). The penetration of nanoparticles through the FPP3 electrostatic filter increases when used, probably due to the moisture brought by human respiration. For the tested masks, after 2 hours of utilization the penetration of nanoparticles through an FPP3 electrostatic filter is found just below the maximum allowed penetration certified by NF EN 149 (defined for NaCl particles centred at 0.6 μm). It appears necessary to perform the integrity test on this kind of masks with challenge particles centred around 30 nm. The influence of face velocity on penetration was investigated by the Golanski at al 2008 study and results are obtained for HEPA filters and for an FPP3 electret filter. This study also shows that higher face velocities result in a higher penetration and these results are consistent with others described in the literature for silver nanoparticles in the size range of 3 to 20 nm. It is important to note that the efficiency of commercial fibrous HEPA filters and electrostatic filters need to be evaluated under harsh conditions, e.g. for a high velocity of 9.6 cm/s.

4.2 Selection

The use of respirators is often required when engineering and administrative controls do not adequately keep worker exposures to an airborne contaminant below a regulatory limit or an internal control target. Currently, there are no specific exposure limits in the United States for airborne exposures to engineered nanomaterials although occupational exposure limits and guidelines (e.g., OSHA, NIOSH, ACGIH) exist for airborne particles of similar chemical composition regardless of particle size. Current scientific evidence indicates that nanoparticles may be more biologically reactive than larger particles of similar chemical composition and thus may pose a greater health risk when inhaled. In determining the need for respirators, it would therefore be prudent to consider current exposure limits or guidelines (e.g., PELs, RELs, TLVs) for larger particles of similar composition, existing toxicological data on the specific nanoparticle, and the likelihood of worker exposure (e.g., airborne concentration, time exposed, job task).

The decision to institute respiratory protection should be based on a combination of professional judgment and the results of the hazard assessment and the selection of risk management practices. The effectiveness of administrative, work-practice, and engineering controls can be evaluated using the measurement techniques described in the OECD' document on *Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace – Compilation of Existing Guidance* (2009). If worker exposure to airborne nanomaterials remains a concern after instituting control measures, the use of respirators can provide further worker protection.

Based on the preliminary findings, NIOSH certified respirators should provide the expected levels of protection if properly selected and fit tested as part of a complete respiratory protection program. However, as noted elsewhere (Rengsamy et al, 2007), in the unlikely event that the workplace exposure consists of a large percentage of particles in the most penetrating particle size range, the employer should take this information into account during the respirator selection process, perhaps by choosing a respirator with higher levels of filtration performance (e.g., changing from an N95 to a P100, even though the APF will remain the same) as suggested by OSHA (Federal Register, 2006) or by selecting a respirator with a higher APF (e.g., full face-piece respirator or powered air purifying respirator).

Several classes of respirators exist that can provide different levels of protection when properly fit tested on the worker. Table 1 lists various types of particulate respirators that can be used along with information on the level of exposure reduction that can be expected. Table 2 describes the advantages and disadvantages of each respirator type. To assist respirator users, U.S. NIOSH has published the document *NIOSH Respirator Selection Logic (RSL)* that provides a process that respirator program administrators can use to select appropriate respirators (U.S. NIOSH, 2004).

In the U.S., when respirators are required for use in the workplace, the U.S. Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134) requires that a respiratory program be established that includes the following program elements: (1) a medical evaluation of the worker's ability to perform the work while wearing a respirator, (2) regular training of personnel, (3) identify and evaluate respiratory hazards in the workplace, (4) respirator fit testing, and (5) respirator maintenance, inspection, cleaning, and storage. The standard also requires that the selection of respirators be made by a person knowledgeable about the workplace and the limitations associated with each type of respirator.

The VCI and BAuA guidance states that filters of protection levels P2, FFP2, P3 or FFP3 according to EN 143 or EN 149 should be selected in the hazard assessment (VCI, 2007). Where respiratory protection equipment is used, limited wearing times and preventive occupational medical checks must be observed. The effectiveness of applied protection measures must be reviewed. In this respect, the results of the Golanski et al. 2008 study and the other published documents such as the NANOSAFE2-Dissemination Report DR-331 200810-6 should be used. Moreover and based on the actual manufacturing processes performed, the effectiveness of the actual applied guidance from various guidance document should be confirmed for these actual process especially as far as filtering systems and penetration of PPEs are concerned.

In the UK information on the selection and use of respirators is given in the Health and Safety Executive's (HSE) HSG53 (HSE, 2003a). Depending on the outcome of the risk assessment process, appropriate types of respiratory protective equipment (RPE) include disposable filtering facepieces, half and full facemasks and a range of powered (air supplied) hoods, helmets, blouses and suits. High efficiency filters (P3 and FFP3 type) should always be used. All wearers of RPE should undergo face-piece fit testing to ensure correct fitting and proper wearing (HSE, 2003b). PPE, especially respiratory protection, needs a significant investment in training, supervision and maintenance if it is to provide the intended level of protection. Incorrect selection or fitting or insufficient use can render it ineffective. The BSI guidance specifically recommends to use respirators in 1) transferring, mixing, filling, scooping of dry insoluble/soluble nanomaterials if only small (e.g. mg) quantities are involved; 2) transferring, mixing, filling of suspensions of any nanomaterials if only small (e.g. mg) quantities are involved (BSI, 2008). It also recommends using respirators in maintenance and cleaning of any nanomaterials.

U.S. DOE (2007) guidance recommends using industrial hygiene professionals or paraprofessionals working under the direction of an industrial hygiene professional to evaluate airborne exposures to engineered nanomaterials in laboratory settings. If respirators are to be used for protections against engineered nanoparticles, select and use half-mask, P-100 cartridge-type respirators or respirators that provide a higher level of protection.

Table 1. Assigned protection factors for respirators.[11]

Type of Respirator	OSHA 29 CFR 1910.134 (2006)	NIOSH Decision Logic (2004)	ANSI Z88.2 (1992)[b]	EN 529 (2005)	BS 4275 (1997)
APR - quarter mask	5	5	10	4-30	4-20
APR - filtering facepiece	10	10	10	4-30	4-20
APR - tight fitting half mask	10	10	10		
APR-tight fitting full face (if part. filter ≠ N-P-R 100)	50	10	100		
APR-tight fitting full face (if part. filter = N-P-R 100)	50	50	100		
PAPR - tight fitting half mask	50	50	50	10-500	10-500
PAPR - tight fitting full facepiece	1000	50	1000[c]	10-500	10-40
PAPR - helmet/hood	25/1000[a]	25	1000[c]	5-100	10-40
PAPR - loose fitting	25	25	25		
SAR - demand mode - half mask	10	10	10		
SAR - demand mode - full facepiece	50	50	100	1000	
SAR - continuous flow - half mask	50	50	50	100	
SAR - continuous flow - full facepiece	1000	50	1000	1000	
SAR - continuous flow - helmet/hood	25/1000[a]	25	1000	100	
SAR - continuous flow - loose fitting	25	25	25	30	
SAR - pressure demand - half mask	50	1000	50	30	
SAR - pressure demand - full facepiece	1000	2000	1000		
Combo SAR/SCBA - pressure demand - full facepiece	----	10000	----	∞	
SCBA - demand mode - half mask	10	----	10		
SCBA - demand mode - full facepiece	50	50	100	∞	
SCBA - demand mode - helmet/hood	50	----	----		
SCBA - pressure demand - full facepiece	10000	10000	10000[d]	∞	
SCBA - pressure demand - helmet/hood	10000	----	----		
[a]Employer must have evidence provided by manufacturer that testing these devices demonstrates performance at a level of protection of 1000 or greater.					
[b]Rescinded in 2003.					
[c]For HEPA filter if used for particulate protection; if less than HEPA, APF=100.					
[d]For emergency planning purposes only.					

[11] The U. S. NIOSH assigned protection factor (APF) is defined as the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users. The APF values developed by U. S. NIOSH are based in part on laboratory studies and take into consideration a variety of factors including the inward leakage caused by penetration through the filter and leakage around the face seal of the respirator. Numerically, an APF of 10 for a respirator means that a user could expect to inhale no more than 10% of the airborne contaminant present, whilst an APF of 100 means user could expect to inhale no more than 1% of the airborne contaminant. APR – Air Purifying Respirator; PAPR – powered APR; SAR – Supplied Air Respirator; SCBA – Self-Contained Breathing Apparatus. The UK approach to derive APF is based on so called 'as is' designed WPF studies.

Table 2. Advantages and disadvantages of different types of Air-Purifying Particulate Respirators based on the U. S. NIOSH Respirator Selection Logic (NIOSH, 2004).

Respirator type	Advantages	Disadvantages
Filtering facepiece (disposable)	–Lightweight –No maintenance or cleaning needed – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Some do not have adjustable head straps – Difficult for a user to do a seal check – Level of protection varies greatly among models – Communication might be difficult – Fit testing required to select proper facepiece size – Some eyewear might interfere with the fit – Respirator must be replaced whenever it is soiled, damaged or has noticeably increased breathing resistance.
Elastomeric half-facepiece	– Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Communication might be difficult – Fit testing required to select proper facepiece size – Some eyewear might interfere with the fit
Powered with loose-fitting facepiece	– Provides eye protection – Protection for people with beards, missing dentures or facial scars – Low breathing resistance – Flowing air creates cooling effect – Face seal leakage is generally outward – Fit testing is not required – Prescription glasses can be worn – Communication less difficult than with elastomeric half-facepiece or full-facepiece respirators – Reusable components and replaceable filters	– Added weight of battery and blower – Awkward for some tasks – Battery requires charging – Air flow must be tested with flow device before use
Elastomeric full-facepiece with N-100, R-100, or P-100 filters	– Provides eye protection – Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility – More effective face seal than that of filtering facepiece or elastomeric half-facepiece respirators	– Can add to heat burden – Diminished field-of-vision compared to half-facepiece – Inward leakage at gaps in face seal – Fit testing required to select proper facepiece size – Facepiece lens can fog without nose cup or lens treatment – Spectacle kit needed for people who wear corrective glasses
Powered with tight-fitting half-facepiece or full-facepiece	– Provides eye protection with full-facepiece – Low breathing resistance – Face seal leakage is generally outward – Flowing air creates cooling effect – Reusable components and replaceable filters	– Added weight of battery and blower – Awkward for some tasks – No eye protection with half-facepiece – Fit testing required to select proper facepiece size – Battery requires charging – Communication might be difficult – Spectacle kit needed for people who wear corrective glasses with full face-piece respirators – Air flow must be tested with flow device before use

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