#### **RESPIRATORY PROTECTION FOR NANOPARTICLES**

## I. <u>INTRODUCTION</u>

A. Nanoparticles are very small (nearly atomic scale) with diameters less than 100 nm (<0.1 micron) in at least one dimension. Because of their small size, air sampling results indicating low mass concentrations actually contain greater numbers and larger surface area/unit mass of nanoparticles than for the same mass concentration of larger particles. Also, nanoparticles may be more biologically reactive than larger particles of similar chemical composition because of their smaller, more lung penetrating size, and their increased surface area dose.

## II. NANOPARTICLE OCCUPATIONAL EXPOSURE LIMITS

A. There are few specific exposure limits for most nanoparticles although occupational exposure limits exist for larger particles with the same chemical composition.

1. In April 2011, NIOSH established recommended exposure limits (RELs) for fine<sup>1</sup> and ultrafine<sup>2</sup> Titanium dioxide (TiO<sub>2</sub>) (2.4 and 0.3 mg/m<sup>3</sup>, respectively).

2. In April 2013, NIOSH reference 1 (NIOSH Current Intelligence Bulletin 65), recommended an REL of 1  $\mu$ g/m<sup>3</sup> 8-hr TWA, for the respirable mass fraction of elemental carbon, single multi-walled carbon nanotubes (CNT) and carbon nanofibers (CNF) using NIOSH Method 5040. In addition to using NIOSH Method 5040, reference 1 recommends taking a duplicate respirable personal sample for electron microscopy analysis (e.g., TEM, SEM) for sizing and counting CNT and CNF structures.

3. Based on the NIOSH RELs for nanoparticles, the Occupational Safety and Health Administration (OSHA), in reference 2 announced their recommended exposure limit of 1  $\mu$ g/m<sup>3</sup> for carbon nanotubes and carbon nanofibers and 0.3 mg/m<sup>3</sup> for nanoscale particles of TiO<sub>2</sub>. By contrast, the NIOSH REL for fine TiO<sub>2</sub> is 2.4 mg/m<sup>3</sup>.

#### III. NIOSH PARTICULATE RESPIRATOR CERTIFICATION

A. NIOSH filter respirator certification procedures in paragraph 84.170 of 42 CFR 84 (reference 3) set forth certification testing requirements for nine classifications of non-powered particulate filtering respirators certified under three classes: N, R, and P. Each class has three levels of filter efficiency: 95%, 99%, and 99.97% (designated 100 in this system). See reference 4 for a detailed explanation of NIOSH filter classifications.

B. NIOSH selected 0.3 micron (300 nm) size challenge particles to test filters because these were considered the most penetrating particle size (MPPS). According to *Single Fiber Filtration Theory*, particles larger than 0.3 micron (>300 nm) aerodynamic mass median diameter are collected most efficiently by impaction, interception, and gravitational settling, while particles smaller than 0.3 micron are collected most

<sup>&</sup>lt;sup>1</sup> NIOSH defines "*fine*" as all particle sizes collected by respirable particle sampling.

<sup>&</sup>lt;sup>2</sup> The term "*ultrafine*" is used to describe nano-sized particles that have not been intentionally produced but are products of processes such as combustion, welding, or diesel engines; whereas nano-sized particles engineered through nanotechnology are referred to as nanoparticles.

efficiently by diffusion or electrostatic attraction. However, none of the filtration mechanisms are as effective at collecting particles around 300 nm in size.

C. NIOSH selected the flow rate of 85 lpm to test single filter respirators, which was believed at that time to simulate the most severe breathing rate likely to be encountered in a work environment. (For dual filtered respirators, the testing flow rate is 42.5 lpm through each filter.)

D. NIOSH 95% efficient filters are protective for most industrial workplace particulate exposures. Because particle sizes in much of industry are large and the work rates commonly encountered in industry are relatively low, 95% filters that pass NIOSH certification testing will be essentially 100% efficient in most workplaces. However, current NIOSH filter testing methods were established in 1995, prior to nanoparticles being considered workplace inhalation hazards.

## IV. NANOPARTICLE FILTER PENETRATION

A. The MPPS for a given respirator filter can vary based on the type of filter (filter diameter, filter density, and electrostatic charge), flow rate, particle size and particle charge, and the condition of the respirator. Other factors influencing the MPPS include variables in filter testing methods, such as whether the challenge aerosol is poly or monodispersed and the type of instrumentation used to measure particles penetrating the filter.

B. In *Approaches to Safe Nanotechnology*, NIOSH provided interim guidance on control technologies, work practices, and personal protective equipment demonstrated to be protective against ultrafine particles and nanoparticles. NIOSH stated that, based on preliminary findings, NIOSH certified respirators should provide the expected levels of protection against nano-size particles if properly selected and fit tested as part of a complete respiratory protection program. However, this publication cites studies showing that the MPPS for electrostatically charged filter media can be much smaller than the 0.3 micron (300 nm) MPPS predicted by *Single Fiber Filtration Theory* and used in NIOSH filtering respirator certification testing. These studies found that the MPPS for electrostatic filters for filtration of nanoparticles. References 5, 6, 7, and 8 also demonstrate deficiencies in the NIOSH filter certification tests for protection against nanoparticles. Additionally, several researchers (references 9, 10, 11, and 12) determined that flow rates other than the 85 lpm used in NIOSH single filter certification tests resulted in increased nanoparticle filter penetration.

# V. ISSUES WITH FILTER CHALLENGE AEROSOL AND DETECTION METHOD

A. Per reference 6, the instrumentation used by NIOSH to measure particle filter penetration during filter testing is two forward-light scattering photometers<sup>3</sup> that simultaneously measure aerosol concentrations before and after the respirator filter. Unfortunately, since 100 nm is the lower limit of particle size detected by NIOSH test

<sup>&</sup>lt;sup>3</sup> These photometers measure the amount of light scattered by a groups of particles, which is proportional to the aerosol mass. For a given wavelength of incident light (780 nm), scattering angle (45°), and particle index of refraction (NaCl = 1.544, DOP = 1.485), the flux of scattered light by an assemblage of particles is proportional to concentration and depends on the particle size distribution.

protocol instrumentation, 100 nm is the smallest particle diameter that measurably contributes to a photometer signal. This results in most of the NaCl particles<sup>4</sup> used to test N-Series filters and a considerable portion of the DOP particles<sup>5</sup> used to test R- and P-Series filters not being large enough to contribute to the photometrically measured concentrations used to certify respirator filtration.

1. In other words, particles smaller than 100 nm in size are present in both NaCl and DOP challenge aerosols; however, these particles essentially do not contribute to the photometric signal used for measuring the concentration of either challenge aerosol penetrating through filters in NIOSH certification testing.

2. Reference 6 concluded that while NIOSH certification testing is effective at determining filtration efficiency against the majority of workplace aerosols, it is limited to providing respirator users with filter performance data for particles greater than 100 nm in physical diameter because NIOSH certification filter test protocols do not measure the contribution to filter penetration made by particles in the nanosize range.

B. References 5, 7, and 8 investigated both the challenge aerosol and the particle detector technology used in NIOSH certification filter testing. Reference 5 explains that the NIOSH N95 filter certification test method uses polydispersed NaCl aerosol and forward light scattering photometry to measure the flux of light scattering from particles penetrating the filter. Reference 5 performed filter penetration testing using specifically sized challenge particles. They accomplished this using monodispersed NaCl aerosols and condensation particle counting (CPC) measurement technology. They compared this monodispersed aerosol/CPC filter test methodology to the current NIOSH N95 respirator certification test. Using the monodispersed aerosol/CPC method, reference 5 determined that the MPPS was 40 nm for the electrostatic N95 filtering facepiece respirators they tested instead of the expected 100 - 400 nm MPPS, which was the case when these respirators were tested by the current NIOSH polydispersed aerosol/ photometry certification method.

1. Having determined that the MPPS was 40 nm, reference 5 tested five N95 electrostatic filtering facepiece respirators with 40 nm particles. Two of these respirators had penetration levels slightly higher than the 5% maximum allowable penetration level for NIOSH N95 respirator certification.

2. The authors explained that NIOSH certified half mask respirators with N95 filters and N95 filtering facepiece respirators should provide expected levels of protection when used in the context of a complete respiratory protection program

<sup>&</sup>lt;sup>4</sup> NaCl filter challenge particles smaller than 100 nm comprise 68% by count and about 8% by mass but essentially do not contribute to the light scatter available for photometric detection. On the other hand, the largest particles only comprise 0.3% of the particle count but contribute 21% of the mass and provide half the light scatter. Approximately 80% of the light scattering is provided by particles 270 nm and larger.

 $<sup>^{5}</sup>$  Ultrafine particles of the DOP filter challenge aerosol make up 10% of the count and about 0.3% of the mass have essentially no contribution to light scatter, whereas the largest 3% of particles by count, comprising 30% by mass provide half the light scatter. Approximately 80% of the light scattering is provided by DOP particles 350 nm and larger.

including proper selection and fit testing. However, in scenarios where the workplace exposure consists of a large percentage of nanoparticles in the MPPS, the employer should take this information into account during the respirator selection process, perhaps by choosing a respirator with higher levels of filtration performance (i.e. class 99 or 100 filtration) or a respirator with a higher APF<sup>6</sup> than a half facepiece respirator, such as a full facepiece respirator.

C. References 7 and 8 demonstrated similar deficiencies with NIOSH filtering respirator certification testing and offered suggestions for improving detection of nanoparticle filter penetration. Reference 8, compared the NIOSH photometric particle detection method to the CPC detection method while measuring filter penetration in NIOSH-approved N-, R-, and P-Series electrostatic filtering facepiece respirators challenged with polydispersed NaCl challenge aerosol. The authors confirmed reference 6 findings that the NIOSH photometric method is not sensitive to measuring nanoparticles because the light scattering signal from nanoparticles is minimal because of their negligible mass and that the NIOSH photometric detection response is mostly triggered by particles larger than 100 nm. In comparison, particle penetration levels measured using the CPC method were much higher than that measured by the NIOSH photometric method.

1. Reference 8 used monodispersed NaCl challenge aerosols that allow testing specific particle size filter penetration. Their experiments, performed using the CPC method to measure monodispersed NaCl aerosols against 10 different size monodisperse NaCl particles in the 20 - 400 nm range, showed that the most penetrating particle size for electrostatic filtering facepiece respirators was 50 nm instead of 300 nm upon which NIOSH filter certification testing is based. They explained that electrostatic filters, which are the predominant type of filter media currently used in respirators, capture particles by both electrostatic attraction and mechanical filtration mechanisms, which result in shifting the MPPS to smaller particle sizes.

2. Reference 7, which was the groundwork for the research reported in reference 8, determined that filtering facepiece respirator nanoparticle penetration measured by the CPC method was two to six times greater than the nanoparticle penetration measured by the current NIOSH forward light scattering photometer method. Based on these results, the authors suggest the need for developing "more challenging" NIOSH filter respirator test methods using a sufficient number of <100 nm size particles and replacing the current NIOSH photometric particle detection method with CPC instrumentation, which is capable of measuring nano-size particles.

#### VI. ISSUES WITH FILTER TESTING FLOW RATE

A. Several researchers (references 9, 10, 11, and 12) determined that flow rates other than the 85 lpm used in NIOSH single filter certification tests result in increased nanoparticle penetration.

<sup>&</sup>lt;sup>6</sup> Assigned protection factor (APF) is the level of protection provided by a class of respirators and only applies when respirators are used within the context of a comprehensive respirator program.

B. Reference 9 compared performance of NIOSH certified N95 filtering facepiece respirators challenged with nano-size aerosols under both cyclic flow test conditions, such as during breathing, and under the constant flow condition used during NIOSH certification testing. This comparison testing was performed at four flow rates (15, 30, 85, and 135 l/min). Per reference 9, although testing at 85 l/min is used by the NIOSH certification program, real breathing rates are likely to be considerably lower in most workplace environments, including healthcare and laboratory facilities as well as many industrial and agricultural settings. Respirators were challenged with monodispersed particles 25, 65, and 99 nm in size and filter penetration measured with CPC instrumentation. The results indicate that tests performed with constant flow may not always be a good predictor of respirator performance under cyclic flow. When the inspiratory flow rates were low (15 - 30 L/ min), the cyclic flow produced higher filter penetration values than the corresponding constant flow filter penetration.

C. Reference 10 demonstrated that filtration performance of a NIOSH approved N95 filtering facepiece respirator dropped with increased flow rates. The maximum penetration dramatically exceeded the NIOSH 5% filter penetration test criterion by 1.30, 2.35, and 3.05 times at flow rates of 135, 270, and 360 l/min, respectively. Also, the MPPS shifted toward smaller sized particles with increased flow rate. Specifically, the MPPS shifted from 46 nm sized particles at 85 l/min to 36 nm sized particles at 360 l/min. The experimental results also showed that performance of N95 respirators decreased slightly with the increase in relative humidity (RH) level due to reduction in electrostatic charge on the filter fiber at higher RH.

D. Reference 11 stated that NIOSH's use of 85 l/min for single filter approval is not representative of real situations. The authors confirmed that filter efficiency of N95 respirators is sensitive to changes in airflow rates. They tested N95 filtering facepiece respirators at breathing rates found in the workplace using polydispersed NaCl nanoparticles ranging in size from 15 to 200 nm and using a scanning mobility particle sizer to measure filter penetration. The airflow rate significantly affected filter efficiency as shown by the particle penetration increasing from an acceptable 2.7% at the 85 l/min NIOSH certification flow rate, to 6.9%, 11.7%, and 15% penetration at airflow rates of 135, 270, and 360 l/min, respectively. Thus, flow rates higher than the 85 l/min used in NIOSH certification testing resulted in filter penetration exceeding the 5% maximum allowable level for NIOSH N95 respirator approval.

#### VII. TOTAL INWARD LEAKAGE

A. Total inward leakage (TIL) is the combination of contaminant leakage into the respirator facepiece through both the filters and through leaks in the respirator sealing surface. References 12 and 13 expected that TIL for nanoparticles would be to be greater than leakage from larger particles. Filter penetration and TIL through artificial leaks were measured for N95, and other filtering facepiece respirators sealed to a breathing manikin placed inside a closed chamber. Polydisperse NaCl or monodisperse sucrose (8 - 80 nm size) aerosols were passed into the chamber. Filter penetration and TIL were measured at 20, 30, and 40 l/min breathing flow rates.

1. Reference 12 reported that as expected, filter penetration for 50 and 100 nm size particles were markedly higher than the penetrations for 400 nm size particles and that particle penetration increased with increasing flow rates.

2. Similarly, reference 13 showed that the MPPS was 50 nm and that there was higher filter penetration and  $\sim$ 2-fold higher TIL measured for these size particles than for 8 nm and 400 nm size particles. This indicated that the TIL for the MPPS (50 nm) nanoparticles was higher than for smaller and larger size particles. Per reference 13, a relatively high concentration of MPPS (50 nm) particles can be expected to leak into respirators where workplace exposure consists of high concentrations of nanoparticles.

### VIII. <u>NANOPARTICLE PENETRATION IN NON-NIOSH APPROVED DUST MASK</u> <u>AND SURGICAL MASKS</u>

A. Dust masks are often confused with filtering facepiece respirators but they are not approved by NIOSH for use as respiratory protection. In reference 14, CPC detection was used to determine particle penetration in seven models of non-NIOSH approved dust masks that were challenged by both poly and monodispersed aerosols. The polydispersed aerosol had a mass median aerodynamic diameter of 300 nm, which NIOSH assumed to be the most filter penetrating sized particles and by monodispersed aerosols challenging the dust masks with eleven different particle sizes ranging between 20 - 400 nm.

1. Only one of the dust masks evaluated in this study was found to have filter penetration on a level low enough to be consistent with NIOSH requirements for class-95 filtering facepiece respirator approval. The rest of the dust mask models evaluated demonstrated exceedingly higher penetration levels than the 5% NIOSH filter penetration requirement for certifying class-95 filtering facepiece respirators. The average filter penetration for these dust masks ranged from 12 to 81.4 %. The variation might be explained by the lack of standard test criteria for dust masks unlike the NIOSH certification protocol used for particulate respirator approval.

2. The authors concluded that non-NIOSH approved dust masks should not be used in workplaces for respiratory protection against inhalation hazards because the level of protection they provide cannot be assured as evidenced by the large variability in filtration performance. Even more importantly, the authors emphasized that users of dust masks should be warned against wearing them for protection against nanoparticulates.

B. Reference 14 also reviewed the literature on surgical and other type masks that were not NIOSH certified and explained that these masks can allow relatively high penetration levels of inert and biological particles. They cited reference 15 whose authors measured particle penetration in non-approved surgical masks and nuisance dust masks. They found that for non-NIOSH approved surgical and nuisance dust masks, penetration levels were approximately 55.85% and 70.90% at flow rates of 30 and 100 l/min, respectively.

# IX. <u>RESPIRATOR SELECTION FOR NANOPARTICLES</u>

A. Navy policy states, per paragraph 1602 of reference 16, that OSHA policy takes precedence over NIOSH criteria documents, which are not mandatory unless adopted in a standard by OSHA or another agency, which the Navy must follow.

B. OSHA minimum respirator - If the exposure is **unknown**, the minimum OSHA respirator requirement for workers exposed to engineered nanoparticles is air-purifying respirators equipped with 100% efficiency (N100, R100, P100) filters. This includes HEPA (high efficiency particulate air) filtering facepiece respirators.

1. In reference 2, OSHA recommended using HEPA filters (N-100, R-100, or P-100) as the default respirator filter for nanoparticle protection. Reference 2 also recommends the guidance in the <u>NIOSH Science Blog, of 7 December 2011</u>, which allows using 95% filters with the exception of using higher efficiency filters for workplaces with a large percentage of nanoparticles. This policy seems contradictory at first glance. However, reference 17, clarified that OSHA policy is to follow NIOSH filter selection guidance with the exception of when the percentage of nanoparticles is unknown then use 100% efficient filters. This OSHA policy radically changes the historical guidance for using 95% filters for most nanoparticle exposures.

C. NIOSH respirator selection for nanoparticles - The authors of reference 5 investigated NIOSH certified N95 respirators and concluded that they should provide expected levels of protection against nanoparticles (consistent with their APF) when used in the context of a complete respiratory protection program including proper selection and fit testing. They recommended; however, that in the unlikely scenario where the workplace exposure consists of a large percentage of nanoparticles in the MPPS, the employer should take this information into account during the respirator selection process, perhaps by choosing a respirator with higher levels of filtration performance (i.e. class 99 or 100 filtration) or a respirator with a higher APF than a half facepiece respirator, such as a full facepiece respirator. Reference 5 contributed to the basis for the NIOSH Science Blog, of 7 December 2011 exception to NIOSH historical guidance for using 95% filtering respirators for most nanoparticle exposures. This exception is for when workplace exposure consists of a large percentage of nanoparticles in the MPPS. In these scenarios, the <u>NIOSH Science Blog, of 7 December 2011</u> recommends respirators with 99 or 100-class filters.

1. The respirator selection guidance discussed above is for protection against nanoparticles in general. NIOSH in reference 1 provides specific respirator selection recommendations for protection against carbon nanotubes (CNT) and carbon nanofibers (CNF) in the form of a respirator selection table. This table, adapted for this document in Appendix A, is very similar to the OSHA assigned protection factor table in 29 CFR 1910.134 (reference 18) with the exception that this table provides respirator filter efficiency guidance. Table 1 recommends either a filtering facepiece or half mask respirator equipped with either 95 or 100% efficiency filters for CNT and CNF workplace concentrations up to 10 times the REL and recommends full face air-purifying respirators equipped with high efficiency filters (N-100, R-100, or P-100) for concentrations up to 50 times the REL. 2. The protection level categories in the respirator selection table of reference 1 are in mass, which does not distinguish the percentage of nanoparticles in the workplace<sup>7</sup>.

D. EPA respirator selection for nanoparticles - In the Environmental Protection Agency (EPA) final rule on multi-walled and single-walled carbon nanotubes (reference 19), the EPA's minimum requirement for respiratory protection is a NIOSH approved full-face respirator equipped with N100 filters for using these nanoparticles in a manner designated by the EPA as a "*significant new use*." Reference 20 revised this respirator requirement to "*NIOSH certified air-purifying, tight-fitting fullface respirator equipped with N-100, P-100, or R-100 filter*."

1. This regulation requires those who intend to manufacture, import, or process single-walled or multi-walled carbon nanotubes for any use designated by the EPA as a significant new use to first notify the EPA before commencing such activities. The EPA will evaluate the intended use and, if necessary, prohibit or limit that activity before it occurs.

2. This regulation exempts multi-walled and single-walled carbon nanotubes that are completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

E. DOE respirator selection for nanoparticles - In reference 21, the Department of Energy (DOE) states that "*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.*"

F. The EPA and DOE policies are included here for completeness and have very little impact on the Navy. Any Navy current use of engineered nanoparticles is anticipated to occur only in a research environment.

G. As emphasized by reference 14, non-NIOSH approved dust masks and surgical masks must not be worn to control occupational exposure. This is especially important for protection against nanoparticles.

# X. <u>SUMMARY AND CONCLUSIONS</u>

A. NIOSH designed respirator filter certification testing to represent the worst case filter penetration conditions, even more severe than likely encountered in a work environment. Recent research on the efficacy of NIOSH filter certification testing verifies that NIOSH certified filtering respirators will ensure expected levels of protection against typical industrial sized particles when respirators are used in the context of a complete

<sup>&</sup>lt;sup>7</sup> Besides measuring mass concentration as determined using NIOSH Method 5040, reference 1 recommends taking a duplicate respirable personal sample for electron microscopy analysis (e.g., TEM, SEM) for sizing and counting CNT and CNF structures. However, reference 1 states that counting CNT and CNF is not currently used in respirator selection, but for use in possible future efforts to control occupational exposures based on number concentrations of airborne CNT and CNF structures. Electron microscopy analysis recommended in reference 1 could be used to determine the percentage of CNTs and CNFs in the workplace for use in deciding between selecting a 95% and higher efficiency filter as discussed in the <u>NIOSH Science Blog, of 7 December 2011</u>.

respiratory protection program. However, these certification tests were developed in 1995, before nanoparticles were ever considered as inhalation hazards in the workplace.

1. Although NIOSH approved filtering respirators are protective against typical industrial sized particles, not all are protective against nanoparticles in the MPPS range (50 to 100 nm). NIOSH's forward light scattering photometric detection method is not effective for detecting nanoparticles penetrating respirator filters during NIOSH certification testing.

2. Also, NIOSH tests single filters at the constant flow rate of 85 l/min, which NIOSH considered the worst-case scenario at the time. However, both higher and lower filter testing flow rates have been found to result in increased nanoparticle penetration. Also, researchers determined that when flow rates were low, cyclic flow produced higher filter penetration values than the corresponding constant flow used in NIOSH filter penetration testing.

3. NIOSH is proactive and in 2005, NIOSH initiated a laboratory research program to better understand respirator performance against nanoparticles. NIOSH nanoparticle filtration research is ongoing and NIOSH has dedicated a <u>website</u> to post findings of this research as results become available. Improved NIOSH filter certification tests are anticipated in the near future that will probably incorporate recommendations provided by the articles cited in this document. These recommendations include:

a. More challenging cyclic flow rates;

b. Challenging filters during certification testing with the recently discovered most penetrating particle size (50 - 100 nm) instead of traditional 300 nm sized particles; and

c. Replacing forward light scattering photometry with ultrafine condensation particle counters that can detect filter particle penetration in the nano-size range.

4. Guidance on respirator filter selection is continually evolving. According to OSHA (reference 17), air-purifying respirators equipped with N100, R100, P100 filters (and HEPA filtering facepiece respirators) are the minimum respiratory protection to reduce exposure to nanoparticles when the percentage of nanoparticles is unknown. This OSHA policy radically changes the historical guidance for using 95% filters for most nanoparticle exposures.

a. The percentage of nanoparticles in the work environment can only be made known through technically sophisticated measurements and analysis (e.g., TEM, SEM). Therefore, the percentage of nanoparticles in most work environments will be unknown and respirator selection defaults to HEPA filters.

b. Even if the percentage of nanoparticles was known in the workplace, OSHA has not indicated the cutoff point for deciding between 95 and 100% efficiency filters. Per reference 17, OSHA's new guidance on respirator selection for protection against nanoparticle exposure is forthcoming.

### XI. <u>REFERENCES</u>

1 National Institute for Occupational Safety and Health (NIOSH): Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers. DHHS (NIOSH) Pub. No. 2013–145. Cincinnati, Ohio: NIOSH, 2013. http://www.cdc.gov/niosh/docs/2013-145/

2 Occupational Safety and Health Administration (OSHA): OSHA Fact Sheet "Working Safely with Nanomaterials". DTSEM FS-3634, 04/2013 https://www.osha.gov/Publications/OSHA\_FS-3634.pdf

3 National Institute for Occupational Safety and Health (NIOSH): 42 CFR Part 84: Respiratory Protective Devices; Final Rules and Notice. Federal Register 60(110):30336–30398. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, June 8, 1995.

http://www.gpo.gov/fdsys/pkg/FR-1995-06-08/html/95-13287.htm

4 National Institute for Occupational Safety and Health (NIOSH): NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 42 CFR 84. DHHS (NIOSH) Pub. No. 96– 101. Cincinnati, Ohio: NIOSH, 1996. http://www.cdc.gov/niosh/docs/96-101/

5 Rengasamy S., Verbofsky R., King W. P., and Shaffer R. E.: Nanoparticle penetration through NIOSH-approved N95 filtering-facepiece respirators. J. Int. Soc. Res. Prot. 24:49–59 (2007)

6 Eninger R. M., Takeshi H., Tiina R., McKay R., and Grinshpun S. A.: What Does Respirator Certification Tell Us About Filtration of Ultrafine Particles? J. Occup. Environ. Hyg. 5:286–295 (2008)

7 Rengasamy S., Miller A., and Eimer B. C.: Evaluation of the Filtration Performance of NIOSH-Approved N95 Filtering Facepiece Respirators by Photometric and Number-Based Test Methods. J. Occup. Environ. Hyg. 8:1, 23–30 (2011)

8 Rengasamy S. and Eimer B. C.: Nanoparticle Filtration Performance of NIOSH Certified Particulate Air-Purifying Filtering Facepiece Respirators: Evaluation by Light Scattering Photometric and Particle Number-Based Test Methods. J. Occup. Environ. Hyg. 9:2, 99–109 (2012)

9 Haruta H., Honda T., Eninger R. M., Reponen T., McKay R., and Grinshpun S. A.: Experimental and Theoretical Investigation of the Performance of N95 Respirator Filters against Ultrafine Aerosol Particles Tested at Constant and Cyclic Flows. J. Int. Soc. Res. Prot. 25:75–88 (2008)

10 Mastofi R., Bahloul A., Lara J., Wang B., Cloutier Y., and Haghighat F.: Investigation of Potential Affecting Factors on perormance of N95 Respirator. J. Int. Soc. Res. Prot. 28:26–39 (2011)

11 Lara J., Mostofi R., Wang B., Bahoul A., Cloutier Y., and Haghighat F.: Investigation of Factors Affecting the Performance of N95 Respirator Filters. J. Int. Soc. Res. Prot. 27 No. 2 (2010)

12 Rengasamy S. and Eimer B. C.: Total Inward Leakage of Nanoparticles Through Filtering Facepiece Respirators. J. Int. Soc. Res. Prot. 27 No. 2 (2010)

13 Rengasamy S. and Eimer B. C.: Nanoparticle Penetration through Filter Media and Leakage through Face Seal Interface of N95 Filtering Facepiece Respirators. Ann. Occup. Hyg. (2012)

14 Rengasamy S., Eimer B. C., and Shaffer R. E.: Nanoparticle Filtration Performance of Commercially Available Dust Masks. J. Int. Soc. Res. Prot. 25:27–41 (2008)

15 Chen C.C. and Willeke K.: Aerosol penetration through surgical masks. Am. J. Infect. Cont. 120:177–184 (1992)

16 OPNAVINST 5100.23 Series. http://doni.daps.dla.mil/allinstructions.aspx?RootFolder=/Directives/05000%20General%20Management%20Securit y%20and%20Safety%20Services/05-100%20Safety%20and%20Occupational%20Health%20Services&View={1FF912B1-1BC6-444A-8943-B769C77880F2}

17 PHONCON OSHA Ms. J. Carter /NAVMCPUBHLTHCEN Mr. D. Spelce of 12 Aug 13

18 Occupational Safety and Health Administration (OSHA): 29 CFR Parts 1910 and 1926 Respiratory Protection: Final Rule. Federal Register 63(5):1278–1279. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, January 8, 1998. <u>http://www.osha.gov/pls/oshaweb/owadisp.show\_document?p\_table=STANDARDS&p\_id=12716</u>

19 Environmental Protection Agency (EPA): 40 CFR Parts 9 and 721: Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules. Federal Register 75(180): 56880–56889. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, September 17, 2010.

20 Environmental Protection Agency (EPA): 40 CFR Parts 9 and 721: Significant New Use Rules on Certain Chemical Substances. Federal Register 78(123): 38210–38223. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, June 26, 2013.

21 U.S. Department of Energy (DOE): "Approach to Nanomaterial ES&H Revision 3a." May 2008.

http://orise.orau.gov/ihos/nanotechnology/files/NSRCMay12.pdf

APPENDIX A <sup>1</sup>	
<b>RESPIRATORY PROTECTION FOR EXPOSURE TO CNT AND CNF</b>	
1–10 μg/m3 (10 × REL)	Any filtering facepiece respirator or air-purifying, elastomeric half-facepiece respirator equipped with appropriate type of particulate filter <sup>†</sup> Any negative pressure (demand), supplied-air respirator equipped with a half-mask
$\leq$ 25 µg/m3 (25 × REL)	Any powered, air-purifying respirator equipped with a hood or helmet and a high-efficiency particulate air filter (HEPA filter) <sup>±</sup> Any continuous flow supplied air respirator equipped with a hood or helmet
≤ 50 μg/m3 (50 × REL)	Any air-purifying full-facepiece respirator equipped with N-100, R-100, or P-100 filter Any powered air-purifying respirator equipped with a tight-fitting half-facepiece and a high-efficiency particulate air filter.
	Any negative pressure (demand) supplied-air respirator equipped with a full-facepiece Any continuous flow supplied-air respirator with a
	tight-fitting half-facepiece Any negative pressure (demand) self- contained respirator equipped with a full-facepiece
$\leq$ 1000 µg/m3 (1,000 × REL)	Any pressure-demand supplied-air respirator equipped with a full-facepiece
*The protection offered by a given respirator is contingent upon (1) the respirator user adhering to complete program requirements (such as those required by OSHA in 29 CFR 1910.134), (2) the use of NIOSH-certified respirators in their approved configuration, and (3) individual fit testing to rule out those respirators that cannot achieve a good fit on individual workers.	
*The appropriate type of particulate filter means: Any 95 or 100 series (N, R, or P) filter. <b>Note:</b> N-95 or N-100 series filters should not be used in environments where there is potential for exposure to oil mists.	
‡Some powered air purifying respirators with a hood/helmet are considered to have an APF of 1000 and thus could be used in situations involving higher airborne concentrations of CNT and CNF (< 1000 $\mu$ g/m3). Contact the respirator manufacturer to determine whether this would apply. Absent such a determination, powered air purifying respirators with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.	
<b>Note:</b> complete information on the selection of respirators can be found at (1) OSHA 3352-02 2009, <i>Assigned Protection Factors for the Revised Respiratory Protection Standard</i> at <a href="http://www.osha.gov/Publications/3352-APF-respirators.html">http://www.osha.gov/Publications/3352-APF-respirators.html</a> , and (2) NIOSH at <a href="http://www.cdc.gov/niosh/docs/2005-100/default.html">http://www.cdc.gov/niosh/docs/2005-100/default.html</a> ].	

<sup>&</sup>lt;sup>1</sup> Appendix A is Table 6–8 is adapted from the following reference:

National Institute for Occupational Safety and Health (NIOSH): Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers. DHHS (NIOSH) Pub. No. 2013–145. Cincinnati, Ohio: NIOSH, 2013. <u>http://www.cdc.gov/niosh/docs/2013-145/</u>