GUIDANCE ON RECOMMENDED MEASURES FOR MITIGATING THE RISK POSED BY ENGINEERED NANOMATERIALS

LIFE NanoRISK

Best practices effectiveness, prevention and protection measures for control of risk posed by engineered nanomaterials

NANO RISK

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Guidance on recommended measures for mitigating the risk posed by engineered nanomaterials

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1 Abbreviations and Acronyms

AC - Administrative controls

ABS - Acrylonitrile butadiene styrene

CAS - Chemical Abstracts Service

CLP - European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances an mixtures

EC - Engineering controls

ECT - Emission Control Technologies

ECHA - European Chemicals Agency

ENMs - Engineered nanomaterials. In this document, the term nanomaterial or engineered nanomaterial (ENMs) is restricted to nanomaterials intentionally produced to have selected properties or composition.

ENPs - Engineered nanoparticles

FAQs - Frequently asked questions

LEVs - Local Exhaustive Ventilation systems

Nano-enabled (products) - products exhibiting function or performance only possible with nanotechnology

NIOSH - US National Institute for Occupational Safety and Health

OECD - Organization for Economic Cooperation and Development

OELs - Occupational Exposure Limits

PEROSH - Partnership for European Research in Occupational Safety and Health

PNC - Polymer nanocomposites

PPE - Personal protective equipment

REACH - Regulation (EC) nº 1907/2006 of the European Parliament and the Council of 18 December 2006

RMM - Risk management measures

RPE - Respiratory protective equipment

SME - Small and medium sized enterprises

SPE - Skin protective equipment

Summary

The use of engineered nanomaterials (ENMs) is growing continuously due to the increasing number of applications of nanotechnology, promoting the development of a new generation of smart and innovative products and processes that have created tremendous growth potential for a large number of industrial sectors.

Due to its potential to develop new added value products, a staggering number of ENMs is already available on the market, however, along with the benefits, there is an on-going debate about their potential effects on the human health or the environment. The uncertainties are extensive since it is now well-established that ENMs exhibit unique physical and chemical properties different from those of the same material in bulk form (Kumar and Dhawan, 2013), affecting their physicochemical and biological behaviour, which can lead to adverse effects to both humans and the environment.

Evidence based data on the effectiveness and performance on current Risk Management Measures (RMMs), including Personal Protective Equipment (PPE) and technical controls such as Local Exhaustive Ventilation (LEV) systems, against ENMs is a key issue to guarantee a high level of protection for human health and the environment.

As nanotechnology applications move from research laboratories to industrial and commercial settings, the likelihood of workplace exposure and industrial releases will tend to increase in the near term, and therefore, producers and users of engineered nanomaterials should take appropriate measures to ensure a safe and healthy work environment, and prevent release of ENMs into the environment.

Scientists agree that if engineering controls (ECs) are well designed, they will be effective in limiting environmental release and workplace exposure. However, these controls need to be supplemented by good practices and the use of appropriate personal protective equipment (PPE), especially relevant when other approaches such as elimination, substitution or modification of is not possible, as could be the case of ENMs.

This guideline on recommended measures and controls for mitigating and control the risk posed by ENMs addresses research institutions, SME industries and large companies, providing recommendations for good occupational health and safety measures following a precautionary approach.

This guideline has been designed and developed taking into account the special needs of the nanotechnology related industry, as well as the requirements laid down on the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The members of the consortium defined the structure of the guidance, covering those aspects considered of special relevance to help to ensure that the risk associated with ENMs and NM-enabled products have been appropriately evaluated and mitigated to an acceptable level.

The guidance developed contains 10 sections, as presented below.

1. Abbreviations and acronyms
2. Summary
3. Introduction: Environmental, health and safety (EH&S) issues in Nanotechnology.
4. Regulations and standards
5. Basics on Risk Management Measures: STOP principle
    - 5.1. Hierarchy of Controls
    - 5.2. Technical measures
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10. Frequently asked questions
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This guidance particularly assists companies in the selection of adequate and experience based personal protective equipment (PPE) and engineering controls (EC) to preventing exposure to nanomaterials and release in the workplace.
The guidance is part of the compendium of deliverables scheduled within the project. This guidance can be obtained via the public website of the project (http://www.lifenanorisk.eu).

Further guidance documents will be published on this website when they are finalized or updated. It is primarily intended for utilisation by small and medium sized enterprises (SMEs) and larger companies involved in the manufacture of polymer-based nanocomposites. The guidance could also be of value to industrial associations, regulatory bodies and relevant international organisations such as the European Food Safety Authority (EFSA), the European Agency for Safety and Health at Work (EU-OSHA) and the Organisation for Economic Co-operation and Development (OECD), as well as international standardisation bodies such as the European Committee for Standardization (CEN).

In detail, key stakeholders are:

- Health and safety advisors
- Occupational hygienists
- Workers and professional users who use ENMs as such, in mixtures or incorporated into articles in research or production processes,
- Researchers
- Experts from industry associations and other stakeholder organizations informing companies about the requirements for the safe handling and use of ENMs on a regulatory basis, especially for risk control purposes,
- Experts from standardization (i.e. ISO committees) and/or regulatory bodies (i.e. ECHA),

The contents of this document are included into the multimedia version of the guidance, being available in the project web site.
This on-line version contains interactive figures, downloadable videos and links specifically designed to support the achievement of the main objective of the guide, the selection of adequate measures to control the exposure to ENMs and prevent release into the environment

To support the proper use of the guide, an evidence based decision tree has been included to guide the user on the identification of adequate measures to achieve a high level of protection of human health and the environment. This decision tree has been developed on the basis the identified uses (IU) and exposure scenarios (ES) at all relevant stages of the life cycle of ENMs used in the polymer nanocomposite industry.

Finally, a detailed instruction sheet containing information on the basic specifications, recommended processes, as well as cleaning and maintenance procedures, has been developed for each of the risk management measures studied within the project.

Further information of specific topics of the guidance and/or details on project outcomes can be requested directly contacting the project coordinator:

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3 Introduction: Environmental, health and safety (EH&S) issues in Nanotechnology

3.1 Nanotechnology: main concepts and overview of current applications on the market

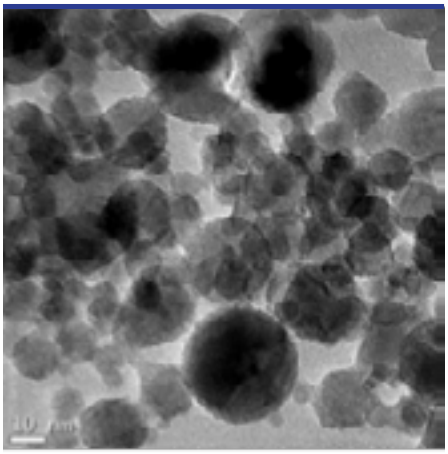
Nanotechnology is a widely applied cross-sectional technology with innovations in almost all industry sectors, with potential applications in a wide range of sectors, from energy (production, catalysis, storage), materials (lubricants, abrasives, paints, tires, and sportswear), electronics (chips and screens), optics, and remediation (pollution absorption, water filtering and disinfection), to food (additives and packaging), cosmetics (skin lotions and sun screens), medicine (diagnostics and drug delivery), and numerous other industrial sectors.

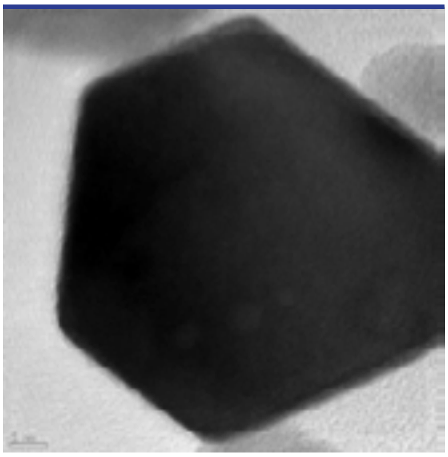
This technology involves the production and use of materials with basic structural units, grains, particles, fibres or other constituent components smaller than 100 nm in at least one dimension, being commonly called "nanomaterials".

The EU adopted a recommendation on the definition of a nanomaterial in 2011 (Recommendation on the definition of a nanomaterial (2011/696/EU)) to enable a coherent cross-cutting reference. According with this recommendation, nanomaterial means:

"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm - 100nm"

The International Organisation for Standardization (ISO) has also worked on definitions of various terms related to nanotechnology. The figure below (Fig. 1) depicts the basic terms defined within ISO/TS 80004-4:2011, which it will be used under the framework of this guideline.





A review of the EU current recommend definition of nanomaterials is expected in 2016, following the consultation of its draft findings with the stakeholders.

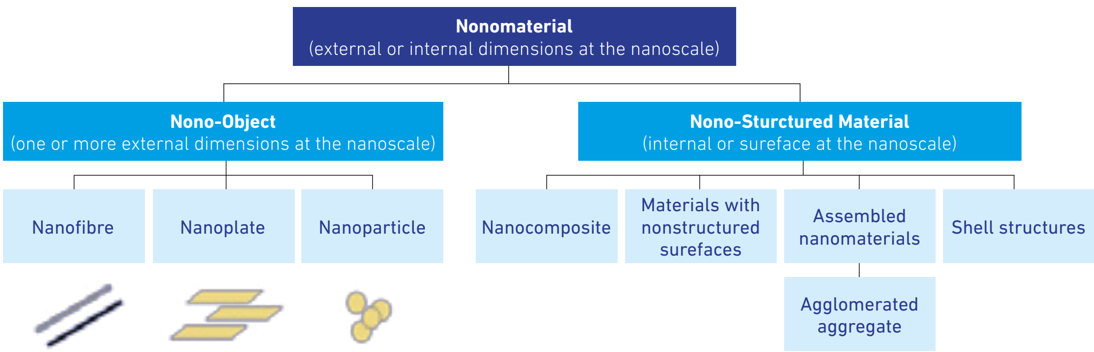


Figure 1. Terminology for materials in the field of nanotechnologies (ISO TS 27687 / ISO TS 80004-4:2011)

Nanotechnology is helping to considerably improve, even revolutionize, many technology and industry sectors, being applied in everyday materials and processes, and covering a wide range of sectors, including electronics, energy, food and beverage, construction, agriculture and medicine, among others.

According to market data from SRI consulting the global quantity of nanomaterials marketed annually is around 11.5 million tonnes, with a market value of roughly 20 bn €. Most of the nanomaterials in the market are produced in quantities above 1 tonne per year, with widespread presence of commodity materials such as carbon black (9.6 million t) and synthetic amorphous silica (1.5 million t). Other nanomaterials with significant amounts on the market include aluminium oxide (200 000 t), barium titanate (15 000 t), titanium dioxide (10 000 t 30), cerium oxide (10 000 t), and zinc oxide (8 000 t).

By 2020, the increasing integration of nanoscale science and engineering knowledge and of nanosystems promises mass applications of nanotechnology in industry (M. C. Roco, 2011). A mass application of nanotechnology is expected after 2020 in areas such as health care, energy, electronics and materials. At present, the bio-medical industry is one of the largest sectors in which nanomaterials have made major contributions, mainly in healthcare industry, with significant developments being done in other sectors such aselectronics and energy as well. The main applications of nanomaterials depicted in figure 2.

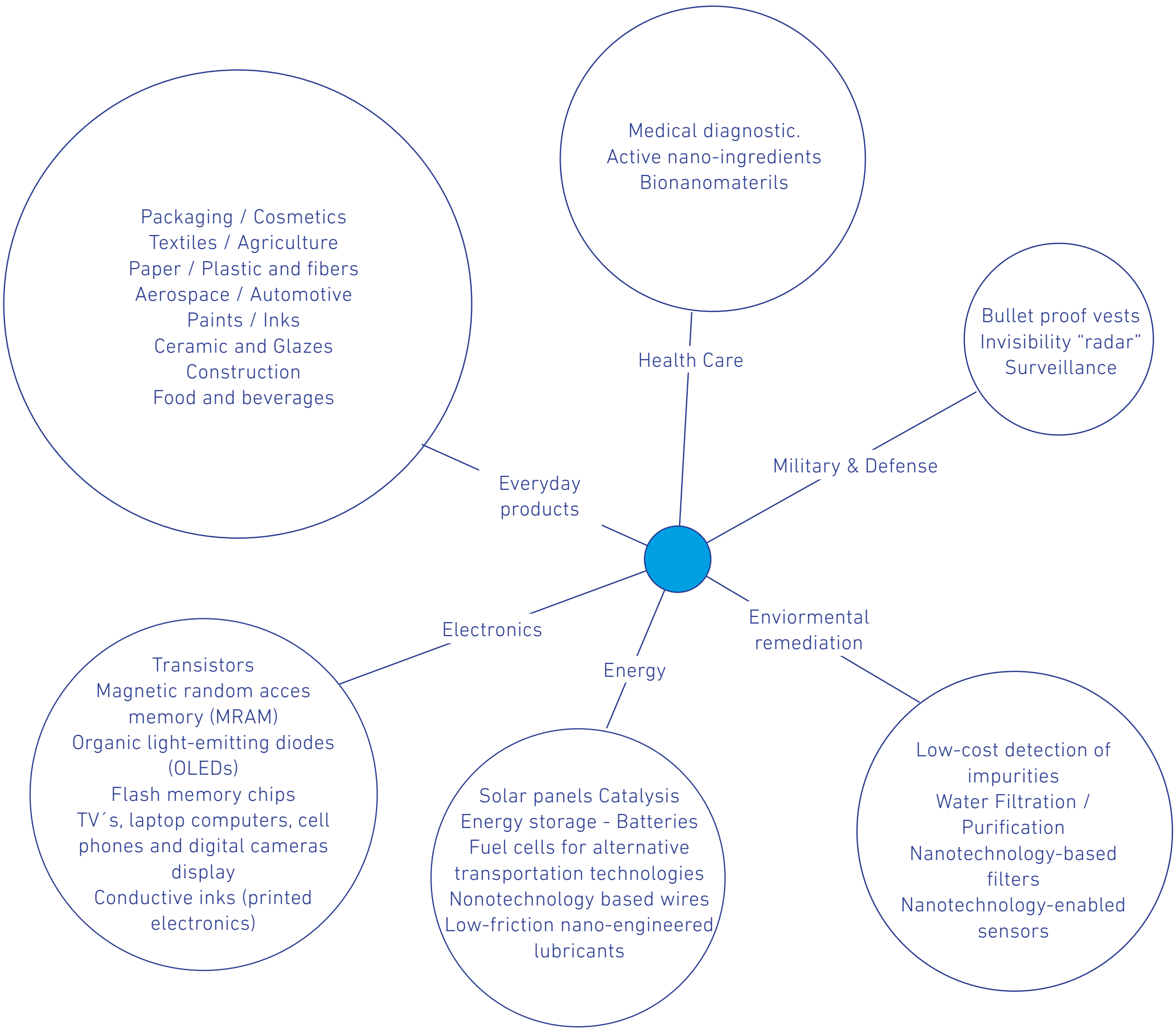


Figure 2. Main industrial applications of nanomaterials

One of the most relevant applications of the nanotechnology is the development of polymer nanocomposites (PNCs), where the use of ENMs such as carbon nanotubes (CNTs), nanoclays, graphene, Silver or ZnO, among others, allow the achievement of noticeable improvements in mechanical, thermal, electrical, and rheological properties of widely used polymers. The novel properties offered by the addition of ENMs in polymeric materials has resulted in a continuous growth in the market, being expected to witness substantial growth owing to growth in end-use applications including aerospace engineering, automotive industry, construction, renewable power generation, military and food (Grand view research, 2015).

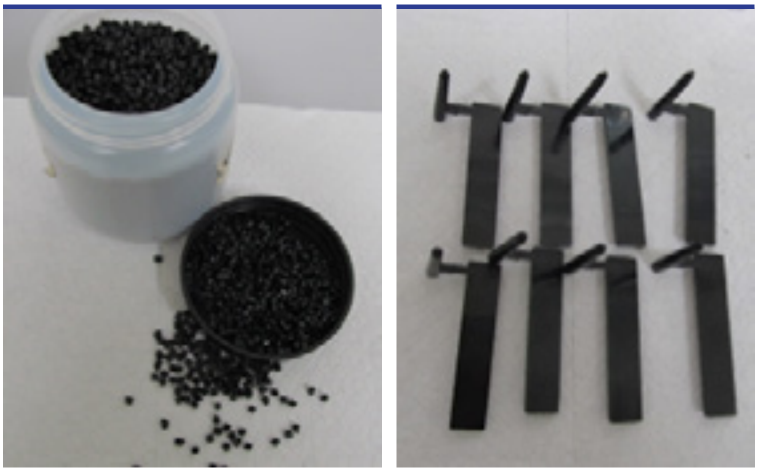


Figure 3. Left: Extruded grains of ABS-CNTs nanocomposites. Right. ABS-CNTs Testing samples.

The activities conducted under the framework of the NanoRISK project focussed on representative ENMs and processes in the polymer nanocomposite industry, and especially in the use of carbon-based nanomaterials, metals, and metal oxides to develop packaging and construction materials, automotive components, electrical wire and cables.

This sector is selected in view of the rising demand of added valued polymer based products in end-use applications such as food packaging materials and automotive parts, both key drivers for polymer based nanocomposites.

Examples of ready to use applications of ENMs developed by the members of the NanoRISK consortium are shown in the following figures (Figure 3 / Figure 4).

Figure 4. Left: Testing samples of PP-nanoclay nanocomposites. Centre: Extruded wire of nanocomposite SEBS-Graphene. Right: PMMA-TiO2 Testing samples

A number of advances have recently been made in the area of polymer based composites, however, several cross cutting issues need to be addressed to promote a continuous growth of such applications on the market, including: 1) the establishment of a regulatory framework for ENMs and nano-enabled products, considering a clear and easy-to-follow human and environmental safety framework for the development along the innovation chain from initial idea to market; 2) the development of standards, considering regulatory testing and good practices; 3) an increase of the level information regarding the use and functions of ENMs in products, as well as safety issues, promoting a transparent and open communication process among stakeholders.

3.2 Environmental, Health and Safety Considerations for Nanotechnology

3.2.1. Overall view of the Hazards of ENMs on Human Health and the environment

As stated previously, nanotechnology is an emerging science with broad applications and vast potential to create new materials and products. However, in contrast with the benefits of this technology, concern has been raised about potential adverse effects to human and the environment.

For a comprehensive risk management, information is needed with respect to the intrinsic properties of the ENMs (hazards), and likelihood of exposure (exposure/release) in a specific compartment (i.e. workplace, freshwater, marine water, sediments or soils, sewage treatment plant and air), and dose-response data (i.e. DNEL- Derived No-Effect Level, PNEC - Predicted No-Effect-Concentration).

Major investments have been done so far on the **characterization of the toxicological profile** of the first generation of ENMs including data on relevant human health endpoints such as acute toxicity, skin irritation and sensitisation, genotoxicity or carcinogenesis. However, the Organization for Economic Cooperation and Development (OECD) recognizes that the current test guidelines were not specifically designed for the testing of ENMs and the guidance provided on these guidelines is considered insufficient for testing ENMs (Porredon Guarch C. et al, 2014). Due to this situation, toxicity studies are being published in a wide range of test method, tested concentrations and cell cultures, making difficult the comparison of toxic effect observed for a same kind of ENM.

Research initiatives are underway to address knowledge gaps in human exposure and health effects of nanotechnology. However, establishing a conclusive link between human health outcomes and ENMs exposure requires rigorous epidemiologic studies, which are currently missing

In relation to the understanding of the **possible exposure** arising from all life cycle stages of the production, use and disposal of ENMs, the amount of research activities focused on the evaluation of the likelihood of exposure has increased in the last decade in parallel with the increased interest of the industry on the production and use of ENPs for developing new added value products (C.Fito-López et al, 2015).

In the occupational context, **it has been demonstrated that workers are potentially exposed to ENMs** with novel sizes, shapes, and chemical properties, at levels far exceeding ambient concentrations (Yokel et al, 2011).

Workers may be exposed to nanomaterials via three main routes: inhalation, ingestion or through skin penetration. The most common studied potential risk arises from airborne nanoparticles being released into the workplace, inhaled by workers and potentially depositing in the respiratory tract and lungs. Nanomaterials may also be unintentionally ingested via hand-to-mouth transfer or contaminated food or water, where they may potentially cross the gut wall, enter the bloodstream and subsequently reach other parts of the body.

Several approaches have been proposed and discussed by relevant organizations such as the US National Institute for Occupational Safety and Health (NIOSH) or the partnership for European Research in Occupational Safety and Health (PEROSH) to achieve a quantitative assessment of the level of exposure in the workplace. Most of these strategies are based on four main steps, including 1) identification of the potential sources of emission (e.g. dedicated questionnaires), 2) definition of the measurement strategy, including instrumentation and metrics, 3) evaluation and characterization of the background levels of ENPs, describing sources of ENPs and characteristics, and 4) data processing.

A suite of real-time monitoring devices is already available, and new devices are likely to become available on the market in the near future. The most employed devices include: portable condensation particle counters (CPCs) in the size range of 10 to 1000 nm, portable optical particle sizers (OPS) in the size range of 0.3 to 10 μm, transportable surface area monitors in the size range of 10 nm to 1000 nm, and high sensibility particle sizers depending on the time resolution needed such as the SMPS-Scanning mobility particle sizer (<30 s) or the FMPS-Fast mobility particle sizer (1 s).

Figure 5. Real time instrumentation applied to evaluate the likelihood of exposure in workplaces

The combined use of these instruments will provide valuable information on the levels of release and exposure to ENPs, including particle number concentration (particles/cm3), size distribution and surface area (μm2/cm3), all relevant metrics for risk assessment.

The use, production and disposal of ENMs also raise concerns about their environmental impact, considering that ENMs can be released to the air, soil or water in common industrial processes and/or accidental events, and ultimately accumulate in the soil, water or biota, endangering living organisms and ecosystems. In this regard, recent ecotoxicological studies pointed out adverse effects on key species and communities, including the inhibition of seed germination and root growth (Lin 2007), oxidative stress in algae and daphnids (Hund-Rinke, 2009), harmful effects on freshwater fish (Handy et al., 2008), DNA damage for several benthic species from the marine environment as well as relevant effects towards crustaceans and bacteria (Heinlaan et al., 2008) and protozoa (Mortimer et al., 2010).

Despite this situation, it is currently not possible to precisely asses the ecological impacts of the release of ENMs into the environment, which is mainly due to the lack of understanding of the inherent physicochemical properties of ENMs and mechanisms driving exposure and release, as well as the scarce existing knowledge on the transport, transformation, degradation and possibly accumulation of ENMs in the environment upon release, all of them of paramount importance for characterizing and evaluating whether a potential risk for humans and the environment is present.

Finally, concerning the adequacy of common **Risk Management Measures (RMM)**, scientists agree that if engineering controls are well designed they will be effective in limiting the exposure to airborne ENMs in the workplace. Current knowledge indicates that a well-designed LEV system with a HEPA filter should effectively remove NMs due to the fact that the high-diffusion behaviour of NMs increases their opportunity to come in contact with filter elements, but limited studies have reported the efficacy of filter media typically found in control systems in capturing NMs.

In relation to PPE, very few studies have reported the filtration performance of CE-marked respirators against NPs. Based on the studies conducted by the National Institute for Occupational Safety and Health (NIOSH), certified respirators provide an acceptable degree of protection, with the mean penetration levels in the 40 nm range for all respirator models tested. Similarly, a limited number of studies have reported data on protective clothing and gloves efficiency against ENMs. However, some clothing standards like the ASTM standard F1671–03 (ASTM 2003) and ISO standard 16604 (ISO 2004b) incorporate testing with nanoscale particles and therefore provide some indication of the effectiveness of protective clothing with regard to nanoparticles.

3.2.2. Overall view of Risk assessment and risk characterization methodologies on a regulatory basis

There is a legal obligation to adequately assess and manage the potential risks of ENMs. In this sense, it has been acknowledged that **the existing risk assessment paradigm developed for traditional chemicals should also be applied to ENMs** (OECD, 2012). Nevertheless, these steps need specific considerations in practice when applied to NMs (e.g. metric to use, exposure assessment methodology etc.), introducing new challenges for regulators, as well as all other stakeholders.

Several experts from the European NanoSafety Cluster, an initiative of the directorate-general for research and innovation (DG RTD) to maximise the synergies between the existing projects addressing all aspects of nanosafety, are currently working on the definition of a risk assessment framework for ENMs. This framework is based on the chemical safety assessment (CSA) process defined by regulation (EC) No 1907/2006 (**REACH**).

According to REACH, the main requirements under REACH regarding the Chemical Safety Assessment are:

- To perform a complete **Hazard assessment** based on the physicochemical, toxicological and ecotoxicological properties of the substance, in whatever size, shape or physical state;
- To define the **levels of exposure** under reasonable conditions of use;
- To **characterize the risk** by comparing the levels of exposure and threshold levels below which risks for human health and for the environment are considered to be controlled.

Unfortunately, the data for a proper science based Risk Assessment of ENMs are limited. This is why the development of methods and tools to generate such nano-specific data has become a dynamic area of research.

> Under REACH framework, if risks are under control, the chemical safety assessment ends here.
> If risks are not under control, the chemical safety assessment has to be refined, either by obtaining more data on the properties of the substance, changing the conditions of manufacturing or use, or making more precise exposure estimations.

Proper characterisation of any nanoforms is a prerequisite to the proper determination of hazards and risks of the ENMs. Data on the zeta potential, agglomeration/aggregation state, surface area and particle size distribution are of special relevance for risk assessment purposes.

The majority of standard endpoints used in **regulatory hazard assessment remain appropriate for ENMs in the context of supporting data for toxicological and environmental risk assessment**. However, changes on sample preparation and dosimetry have been foreseen for most of the tests (OECD, 2012).

Regarding exposure assessment, occupational, consumer, and environmental exposure to NMs should be characterized during the entire product life-cycle, and particular attention should be given to the potential release of nanoforms at different stages (manufacture, use and disposal).

ECHA acknowledges that measuring ENM exposure is a complicated task and no single approach can currently be used nor recommended, given that the most appropriate choice depends on the substance-specific information and the measuring techniques available (Best practice for REACH registrants, 2014). In occupational settings for example, evidence of technical measurement difficulties related to background nanoaerosols has been reported in several studies.

Similarly, regarding environmental exposure, detecting and quantifying ENMs in complex matrices (e.g. soil or sediments) is challenging, particularly for those ENMs made of chemical constituents that are highly abundant in the natural environment (e.g. many metals and metal oxide ENMs, carbon materials, etc.).

4 Regulations and standards

This chapterprovides a brief outline of the key European legislations, regulations and standards of relevance that apply to personal protective equipment.

4.1 Regulatory aspects

The regulatory challenge is to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained. According to the EU news & policy debates web page, a lack of knowledge and understanding of the health and environmental risks associated with nanomaterials highlights the need for more regulation of the sector.

In general, current regulatory activities are still focused on reviewing whether, why, and when currently existing nanomaterials are hazardous, and whether and how humans or the environment are exposed to these hazards. Many European countries have state-specific activities on regulation of nanomaterials mainly related to occupational safety and health aspects, chemicals, and foods (Observatorynano, 2012. Of all of the EU member states, France, Germany, Switzerland, the Netherlands, and the UK have been the most proactive in establishing specific requirements on manufacturers and importers of nanomaterials into its internal markets.

Information on how **EU regulation applies to ENMs** can be found in the Commission Communication on Regulatory Aspects of Nanomaterials and in the Commission Staff Working Document . These documents conclude that **current legislation may need to be adapted** as the depth of scientific knowledge on ENMs increases. In Europe, regulations regarding nanomaterials are based at present on existing laws and regulations applicable to chemicals. The regulatory frameworks that are found applicable according to the Second Regulatory Review on Nanomaterials (October 2012) are depicted in figure 6.

Figure 6. Regulatory framework of nanomaterials and nanoproducts.

[1]http://ec.europa.eu/research/industrial_technologies/nanotechnology-redirect.html
[2]http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52008SC2036

According to the information given in the abovementioned Communication, all ENMs are considered as chemical substances and must meet the requirements laid down on **REACH** regulation and regulation (EC) No 1272/2008 (**CLP** - classification, labelling and packaging).

Besides REACH regulation, several statutory instruments are in place to ensure an appropriate level of protection of workers. The general framework is provided by the regulation on occupational safety and health of workers **(Directive 89/391/EEC - OSH "Framework Directive" of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work).**

Special emphasis shall be done concerning the selection of risk management measures (RMMs) to avoid the potential risk posed by the use of ENMs.

The aim of this framework directive is to ensure high level of protection of workers at work, including those exposed to nanomaterials through the **implementation of risk management (preventive) measures** to guard against exposure to risks, and through provision of information, consultation, balanced participation and training of workers and their representatives.

From a regulatory point of view, the **use of risk management measures** is regulated by a number of EU directives focussed on the enhancement of the health and safety at work, like Directive 89/656/EEC, on the minimum health and safety requirements for the use by workers of personal protective equipment. In this sense, the Council of the European Union has adopted a new regulation on personal protective equipment, which will repeal Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and, like the latter, defines legal obligations to ensure that personal protective equipment on the European market provides the highest level of protection against hazards. For more detail, refer to the official web site of the EC: http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective equipment/index_en.htm.

This legislation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market, in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union, and establish the conformity assessment procedures which have to be followed by manufacturers. These procedures are linked to the degree of risk involved.

It shall be noted that the European legislation on Personal Protective Equipment established that CE-marking is mandatory for Personal Protective Equipment. By means of this CE-marking the manufacturer claims that the product meets the essential health and safety requirements, and so that the product is placed on the market in conformity with the legislation.

Concerning the use of **ENMs in products**, the provisions laid down on community regulations on areas such as medicinal products, plant protection and biocidal products, cosmetics, food, or feed additives apply. All product legislation imposes a risk assessment and the adoption of risk management measures. Therefore, nano-enabled products and ENMs used as active ingredients are not excluded from this obligation.

Environmental regulation relevant in the nanotechnology and nanomaterials context relates in particular to integrated pollution prevention and control (IPPC), the control of major accident hazards involving dangerous substances (Seveso III), the water framework directive and a number of waste directives.

The most relevant piece of regulation is REACH, aimed at ensuring a high level of relevant protection of human health and the environment. The main steps to be considered to ensure the compliance with the REACH regulation and relevant product specific regulations are depicted in the figure below (figure 7).

A number of activities are underway to support the definition of a scientific based regulatory framework for ENMs and nano-enabled products. These activities have been initiated by organisations such as the International Organization for Standardization (ISO) and the Organization for Economic Cooperation and Development (OECD) to support a globally harmonised development.

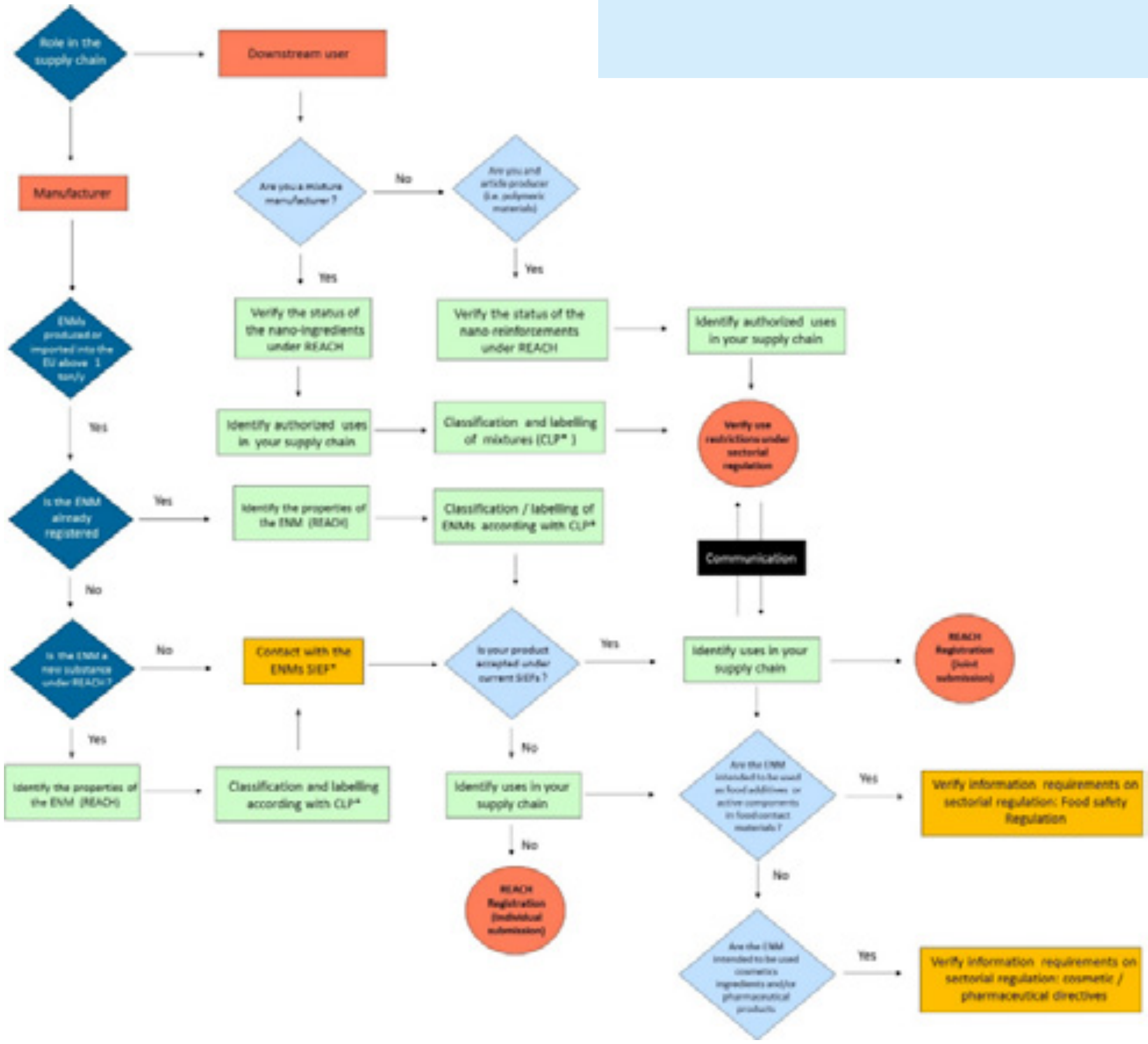


Figure 7. Regulation Flowchart for EU-based companies producing and/or using ENMs

*CLP: European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures / * SIEF: Substance information exchange forum (SIEF)

4.2 Standards for personal protective equipment

To meet legislation requirements, manufacturers must ensure that their products meet the European legislation (New Approach Directives). A set of **harmonised European Standards for Personal Protective Equipment (PPE)** have been developed as one of the means of demonstrating conformity of equipment with the basic requirements of the Personal Protective Equipment Directive. Only PPE that meets these requirements is entitled to carry the CE marking and to be made available in the EU.

The legisltation may contain design or performance requirements for the different types of equipment. For more detail, refer to the official web site of the EC: http://eur-lex.europa.eu/legal-content/ES/TXT/?uri=uriserv:OJ.C_.2015.412.01.0010.01.SPA&toc=OJ:C:2015:412:TOC

The following sections lists the most relevant standards according with the scope and goals of the project.

4.2.1 Respiratory protection standards

A) Harmonized standards

• Generals standards

- EN 132:1998. Respiratory protective devices- Definitions of terms and pictograms.
- EN 133:2001. Respiratory protective devices - Classification.
- EN 134:1998. Respiratory protective devices - Nomenclature of components.
- EN 135:1998. Respiratory protective devices - List of equivalent terms.

• Selection and use

- EN 529:2005. Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document.

• Face pieces

- EN 136:1998, EN 136/AC: 1999, EN 136/AC:2003. Respiratory protective devices – Full-face masks - Requirements, testing, marking.
- EN 140:1998, EN 140/AC: 1999. Respiratory protective devices. Half masks and quarter masks. Requirements, testing, marking.
- EN 142:2002. Respiratory protective devices - Mouthpiece assemblies -Requirements, testing, marking.
- EN 1827:1999+A1:2009. Respiratory protective devices - Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only - Requirements, testing, marking.
- EN 148-1:1999. Respiratory protective devices. Threads for facepieces. Part 1: Standard thread connection.
- EN 148-2:1999. Respiratory protective devices. Threads for facepieces. Part 2: Centre thread connection.
- EN 148-3:1999. Respiratory protective devices. Threads for facepieces. Part 3: Thread connection M 45 x 3.

• Filtering devices

- EN 143:2000, EN 143/AC: 2002, EN 143:2001/AC:2005, EN 143:2000/A1:2006. Respiratory protective devices - Particle filters - Requirements, testing, marking.
- EN 14387:2004+A1:2008. Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking.
- EN 12941:1998, EN 12941/A1:2003, EN 12941:1998/A2:2008. Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood - Requirements, testing, marking.

- EN 12942:1998, EN 12942/A1:2002, EN 12942:1998/A2:2008. Respiratory protective devices
- Power assisted filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking.
- EN 149:2001+A1:2009. Respiratory protective devices - Filtering half masks to protect against particles
- Requirements, testing, marking.
- EN 405:2001+A1:2009. Respiratory protective devices - Valved filtering half masks to protect against gases or gases and particles - Requirements, testing, marking.

• Test methods
- EN 13274-1:2001. Respiratory protective devices - Methods of test - Part 1: Determination of inward leakage and total inward leakage.
- EN 13274-2:2001. Respiratory protective devices - Methods of test - Part 2: Practical performance tests.
- EN 13274-3:2001. Respiratory protective devices - Methods of test - Part 3: Determination of breathing resistance.
- EN 13274-4:2001. Respiratory protective devices. Methods of test - Part 4: Flame test.
- EN 13274-5:2001. Respiratory protective devices - Methods of test - Part 5: Climatic conditions.
- EN 13274-6:2001. Respiratory protective devices - Methods of test - Part 6: Determination of carbon dioxide content of the inhalation air.
- EN 13274-7:2008. Respiratory protective devices - Methods of test - Part 7: Determination of particle filter penetration.
- EN 13274-8:2002. Respiratory protective devices - Methods of test - Part 8: Determination of dolomite dust clogging.

B) Related standards (non-harmonized)
- ISO 16900-2:2009. Respiratory protective devices. Methods of test and test equipment. Part 2: Determination of breathing resistance.
- ISO 16900-4:2011. Respiratory protective devices. Methods of test and test equipment. Part 4: Determination of gas filter capacity and migration, desorption and carbon monoxide dynamic testing.
- ISO 16972:2010. Respiratory protective devices. Terms, definitions, graphical symbols and units of measurement.
- ISO/TS 16974:2011. Respiratory protective devices. Marking and information supplied by the manufacturer.
- ISO 16976-1:2007. Respiratory protective devices. Human factors. Part 1: Metabolic rates and respiratory flow rates.
- ISO 16976-2:2010. Respiratory protective devices. Human factors. Part 2: Anthropometrics.
- ISO 16976-3:2011. Respiratory protective devices. Human factors. Part 3: Physiological responses and limitations of oxygen and limitations of carbon dioxide in the breathing environment.

4.2.2 Protective gloves standards

• Generals standards
- EN 420:2003+A1:2010, EN 420:2004+A1:2010, ERRATUM: 2011. Protective gloves - General requirements and test methods.

• Protective gloves against chemicals and micro-organisms

- EN 374-1:2004. Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements.
- EN 374-2:2004. Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration.
- EN 16523-1:2015. Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact.
- EN 374-4:2013. Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals.

4.2.3 Protective clothing standards

• Generals standards

- EN ISO 13688:2013. Protective clothing - General requirements (ISO 13688:2013).

• Protective gloves against chemicals and micro-organisms

- EN 943-1:2015. Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols - Part 1: Performance requirements for Type 1 (gas-tight) chemical protective suits.
- EN 943-2:2002. Protective clothing against liquid and gaseous chemicals, including aerosols and solid particles - Part 2: Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET).
- EN 14605:2005+A1:2009. Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]).
- EN ISO 13982-1:2005, EN ISO 13982-1:2005/A1:2011. Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) (ISO 13982-1:2004).
- EN ISO 13982-2:2005. Protective clothing for use against solid particulates - Part 2: Test method of determination of inward leakage of aerosols of fine particles into suits (ISO 13982-2:2004).
- EN 13034:2005+A1:2009. Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).
- EN 14325:2004. Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages.

4.2.4 Eye protection standards

A) Harmonized standards

- UNE-EN 165:2006. Personal eye-protection. Vocabulary.
- UNE-EN 166:2002. Personal eye protection. Specifications.
- UNE-EN 167:2002. Personal eye protection. Optical test methods.
- UNE-EN 168:2002. Personal eye-protection. Non-optical test methods.

B) Related standards (non-harmonized)

- UNE CR 13464:1999. Guide to Selection, Use And Maintenance Of Occupational Eye And Face Protectors.

5 Basics on Risk Management Measures

5.1. Hierarchy of Safety and Health Controls

Risks should be reduced to the lowest reasonably practicable level by taking preventative and protective measures, following the so called hierarchy of control. Therefore, wherever reasonably practicable, exposure to hazardous particles and liquids, including ENMs, by main routes (inhalation, dermal and ingestion) should be **eliminated or controlled to the lowest reasonably practicable level.**

The hierarchy of control is a systematic approach to manage safety in workplaces by providing a structure to select control measures to eliminate or reduce the risk of certain hazards that have been identified as being caused by the operations of the company. The hierarchy of control involves the following steps:

- Elimination
- Substitution
- Technical measures - Engineering controls (ECs)
- Organizational measures (use of administrative controls)
- Personal Protective Equipment (PPE)

A non-exhaustive list of risk management measures classified according with the hierarchy of controls and objectives to be achieved with each measure is depicted on table 1.

Table 1. Risk management measures classified according to the hierarchy of controls

		APPLICATION			
PRIORITY	OBJECTIVE	CHEMICAL AGENT	PROCESS	WORKPLACE	WORKPLACE
1	Risk elimination	Substitution by less hazardous chemicals agents	Process substitution Use of intrinsically safe equipment (1)		Automatization Robotization Remote control
2	Risk reduction / control	Partial substitution of the chemical agents Change in physical state (2)	Process containment Segregation Preventive maintenance Local Exhaust General dilution ventilation Spillage measures	Housekeeping Dilution ventilation Control of sources of ignition	Good practices Supervision Reduced timetable
3	Worker protection				Respiratory, dermal and eye protection

(1) Applicable to eliminate safety risk such as fire or explosion
(2) Examples: Handling of a solid material in wet, pastes or gel, or encapsulated can reduce the risk of via ingestion and inhalation.

For the same level of priority, the measures identified on the left column of the table are preferred attending to the hierarchy of controls. The selection of the risk management measures to be implemented should be carried out in view of the results of the risk assessment conducted by a competent person knowledgeable of the operative conditions and exposure situations.

The hierarchy of controls is also considered by the STOP principle, a risk management approach based on the implementation of strategic, technical, organizational and personal measures.

The STOP principle priority gives priority to strategic measures (S), including elimination and substitution, technical measures (T), organizational and administrative measures (O), and personal protection (P). Within this principle, if it is not practicable to eliminate the risks, then the risks need to be reduced through **substitution** of processes or substances giving less hazardous results, or the implementation of **technical measures**, being the last level of control the provision of personal protective equipment (PPE). In most cases a combination of substitution, technical measures, organizational measures and personal protective equipment (PPE) are chosen to effectively control the risks.

The table below provides an overview of the measures defined under the STOP principle.

Table 2. STOP principle basic measures

STOP concept
The STOP principle establishes priorities in the following order:
(S) Strategic measures
(T) Technical measures
(O) Organizational measures
(P) Personal measures

PRIORITY	OBJECTIVE	CHEMICAL AGENT
1	**S** measures (Strategy)	Substitution of processes or substances Redesigning / Modifying processes Low-emission forms or processes
2	**T** measures (Technical)	Enclosing/isolating Local Exhaust Ventilation General dilution ventilation Setting/design of operation
3	**O** measures (Organizational)	Training Work instructions Strategic planning
4	**P** measures (Personal)	Respiratory protection Dermal protection Eye protection

In view of the table, if the potential hazard cannot be eliminated or substituted with a less hazardous or non-hazardous substance, then technical measures ECs should be installed and tailored to the process or job task, and while other more effective controls are being developed or installed, or if there are no other more effective way to control the hazard or the controls are not sufficient to reduce the hazard to an appropriate level, personal protective equipment (PPE) shall be employed.

In general, these measures must be combined to obtain the required level of protection. The elimination and substitution (S measures) are rarely possible in practice, therefore technical and personal measures shall be implemented. Existing technical measures and personal protective equipment are described in detail in this guidance, including recommended measures when working with ENMs.

5.2 Technical measures

Technical Measures
When strategic measures are not a viable option, the most desirable alternative for controlling occupational exposure is to employ technical measures.

Technical measures protect workers by limiting the propagation (i.e. isolation and machine guards) or by removing, catching or neutralizing harmful substances (e.g., general ventilation, local exhaustive ventilation, substance neutralization, or air purification). These measures are commonly known as engineering controls, acting on the trajectory between the source and the worker. Technical measures are divided into two main categories, including ventilation and non-ventilation controls.

5.2.1 Non Ventilation control

Non-ventilation controls cover a range of technical measures designed to reduce or eliminate process emission rate, and can be used in conjunction with ventilation systems to provide an enhanced level of protection.

> **Non-ventilation controls**
> The use of non-ventilation controls in the industry is limited, however, in some cases is a be cost- effective alternative to traditional ventilation systems.

These measures range from enclosures, seals, jigs and handling aids. One of the most common systems are glove box containment and glove bags, which can be used as a non-ventilation control around small-scale powder processes. Other non-ventilation control approaches have been used in a variety of industries, including the use of water-spray delivery systems or continuous liner systems.

5.2.2 Ventilation

Types and specifications of ventilation systems

Ventilation systems used in industrial plants are of two generic types, including supply systems, used to supply tempered air to the workspace, and exhaust systems, used to remove contaminants generated in a space. We consider here only exhaust systems, commonly used in industrial settings to reduce employee exposure to airborne contaminants (dust, mist, fume, vapour, gas) in the workplace.

These systems are classified in two generic groups: general exhaust ventilation systems "dilution ventilation" and local exhaust ventilation (LEV) systems. Local exhaust ventilation systems are the preferred method to control the exposure to harmful substances in workplace air. Most systems have the following parts:

- Hood: This is where the contaminant cloud enters the LEV.
- Ducting: This conducts air and the contaminant from the hood to the discharge point.
- Air cleaner or arrestor: This filters or cleans the extracted air. Not all systems need air cleaning.
- Air mover: The 'engine' that powers the extraction system, usually a fan.
- Discharge: This releases the extracted air to a safe place.

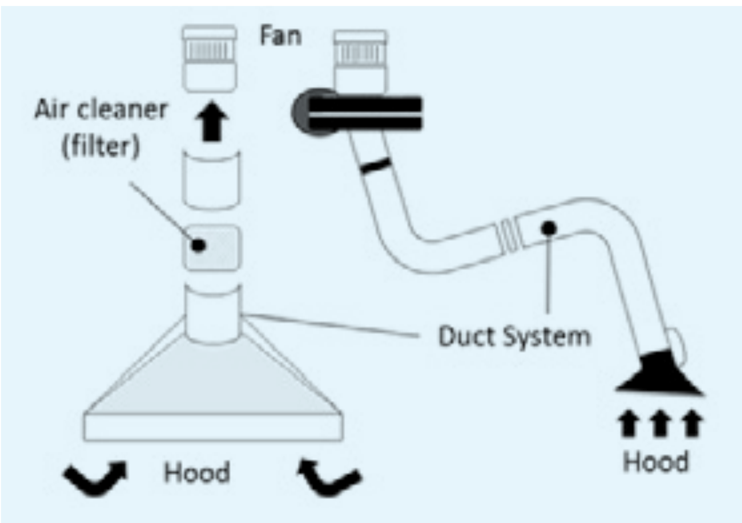


Figure 8. Structural parts of LEV systems

Hoods have a wide range of shapes, sizes and designs (figure 9). They control contaminant clouds in three different ways according their classification: enclosing hoods; receiving hoods; and capturing hoods.

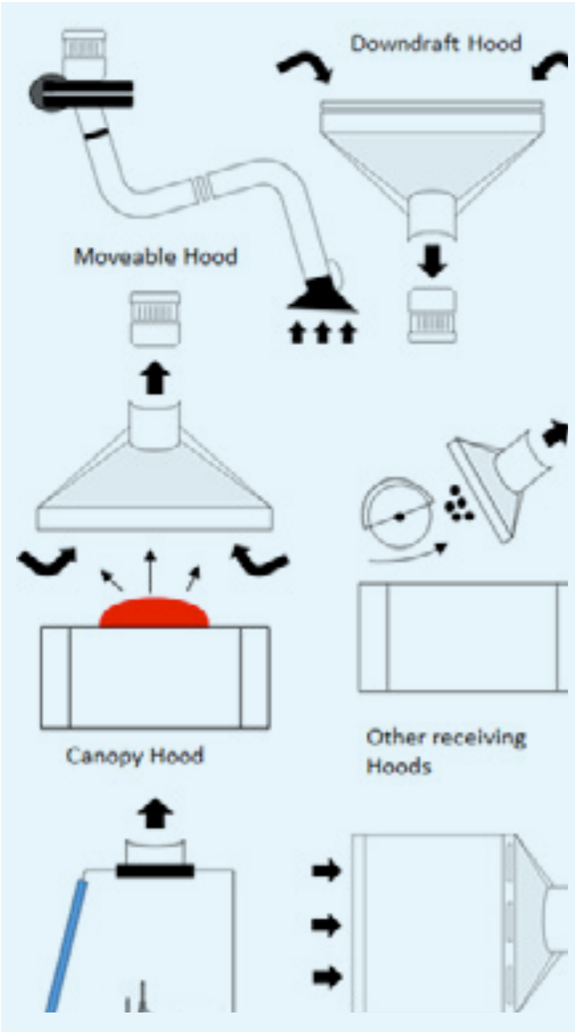


Figure 9. Local exhaust ventilation hoods

• **Enclosing Hoods:** completely or partially enclose the process and contaminant generation point.

- Laboratory Glove Box (complete enclosure)
- Down-flow room (complete enclosure)
- Horizontal/downward laminar flow booth
- Laboratory Hood (partial enclosure)
- Walk-in booths
- Paint spray booth (partial enclosure)

• **Capturing Hoods:** these hoods are located next to an emission source without surrounding (enclosing). The process, source and contaminant cloud are outside the capturing hood. Capturing hoods are also known as exterior, external or captor hoods. Some examples are:

- Movable LEV systems (extendable arms)
- ULPA filtered down flow booth
- Fixed capturing hoods
- On-tool extraction

• **Receiving Hoods:** these hoods are designed to "receive" or catch the emissions from a source that has some initial velocity or movement. The contaminant cloud is propelled into the hood by process-induced air movement.

The face of the hood must be big enough to receive the contaminant cloud and the extraction empties the hood of contaminated air at least as fast as it is filled. For example, a type of receiving hood called a canopy hood receives hot rising air and gases (figure 10).

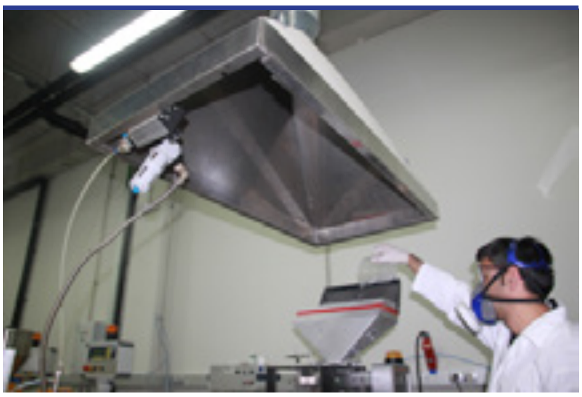


Figure 10. Canopy Hood in ITENE facilities

The selection of the right type of hood depends on the process, the contaminant, its hazards, the sources to be controlled, and exposure benchmarks of the respective nanomaterial. Detailed information on the types and specifications of the hoods is provided below.

Performance and effectiveness of ventilation systems

There is limited information on the effectiveness of LEVs regarding nanomaterials. Currently available LEV are designed to capture inhalable particles, with a size range from less than 0.01 µm up to 100 µm aerodynamic diameter, clouds of respirable particles that can penetrate deeply into the lungs, with an upper size limit of about 10 µm.

Particles above 100 µm have been demonstrated to be "non-inhalable" as they are too large to be breathed in. They fall out of the air and settle on the floor and surfaces near the process.

Figure 11 proposes some indicative ranges for the effectiveness of the various types of LEV.

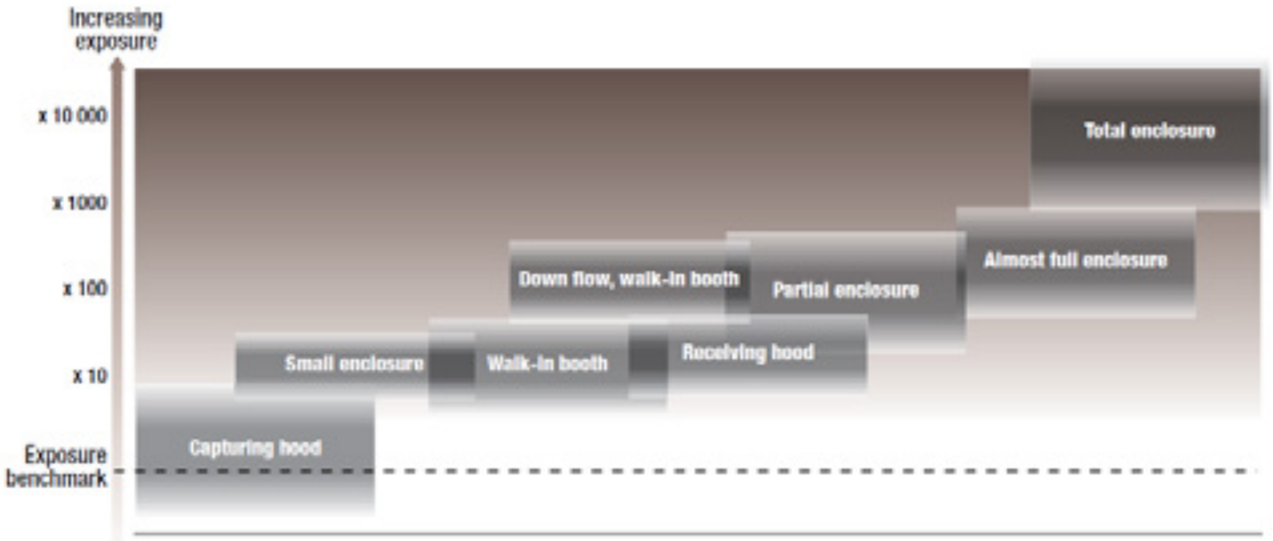


Figure 11. Effectiveness of various types of LEV (HSE,2011)

A complete description of relevant parameters related with the effectiveness of LEV systems is provided within the following points.

- **Capture efficiency**: LEV systems work effectively when the airborne contaminant cloud is contained, received or captured by the hood. Capture velocity is the necessary air velocity at any point upstream of the hood required to overcome opposing air currents, thereby capturing contaminated air. For contaminated air to be captured, it must be moving at a velocity at or above the capture velocity in order to be drawn into the hood. This value is a good indication of how well a hood performs in terms of capturing contaminates and controlling worker exposures. By increasing capture velocity, the hood effectiveness to capture contaminants is increased likewise.

- **Face Velocity:** The average velocity of air at the open front face of a hood or booth directly measured or calculated.

- **Hood design:** Hood selection and design are critical to the performance of an LEV system, and must match the process, the source, production and how the operator carries out the process. To function effectively, any LEV hood needs a minimum face velocity to capture, contain or receive airborne contaminant clouds. An LEV hood, especially the larger designs such as partial enclosures, also needs a minimum face velocity to resist the effects of workroom draughts and general air turbulence. The minimum required will vary depending upon the circumstances.

- **Usability:** LEV system designed for long-term working by operators of different sizes should be comfortable and usable. The design shall be based on good ergonomic principles and safe use, including for instance easy access in case of total or partial enclosures and materials handling.

- **Airflow:** the face velocity shall be sufficient to contain the contaminant cloud. A key issue is to choose a volume flow rate able to clear the hood of the realistic worst-case volume flow rate of contaminant cloud.

- **Filtering elements:** LEV used to control dust, mist or fume should be fitted with a high efficiency particle arrestor (HEPA) filter. The filter seating needs to be checked every time it is changed, and the system needs.

Good design and being fit for purpose are the crucial initial considerations to ensure the effectiveness of the system. The degree of containment around the emission point is also of prime importance. The hood should be structured and placed at the emission point so as to entrain/contain the emission.

Moreover, the flow rate within the ducting must be sufficient to transport the contaminant to the filtering system and on to the exhaust. In a system with many duct branches to individual hoods, there may be a header system. Whether simple or complex, the ducting structure and dimensions will influence the air-flow rate.

Performance evaluation

The control effectiveness can be determined using qualitative assessment methods. HSE (2011) also described how to control gas, vapour, dust, fume and mist in workplace air using local exhaust ventilation (LEV). It describes a variety of qualitative and quantitative methods which can be used to assess LEV performances. These methods are described below.

Qualitative assessment methods

Observation: Observation includes judging the adequacy of make-up air. Inspection within ducts etc. Requires an endoscope, fibre-optic camera or boroscope.

Making particle clouds visible

This method is based on the reproduction of the 'Tyndall effect' by producing a powerful parallel beam of light which makes fine particles visible. The user should move the lamp to illuminate different parts of the cloud and indicate the full cloud size and behaviour.

LEV effectiveness

Maintenance, examination and testing are of prime importance to guarantee a safe working environment.
Effectiveness of LEV system can be identified through experimental measurements (qualitative or quantitative) and computational fluid dynamics (CFD) simulation models.

Making air movement visible using smoke generators

This method is based on the use of a smoke generator to produce a variable amount of smoke that can support a proper identification of the size, velocity and behaviour of airborne contaminant clouds, confirm containment within a hood, identify draughts, or show the general movement of air.

Quantitative assessment methods

Quantitative methods produce a reproducible measurement of performance. Measurements alone do not provide direct evidence of control effectiveness, but the records are available for future comparison, as benchmarks. Methods include:

• **Full enclosures**

Measure the static pressure between the interior of the enclosure and the workroom. The pressure in the interior must be lower than the workroom (HSE, 2011).

• **Partial enclosures**

Measure the face velocity. Readings should not vary excessively. Fume cupboards should also be further tested according to appropriate standards (HSE, 2011).

• **Receiving hoods including canopies and capturing hoods**

Measure the face velocity. For larger hoods, measure at several points over the face. Readings should not vary excessively. Measure the hood static pressure and the static pressure of the plenum as well as in the duct. Measure the air velocity in the duct (straight section) (HSE, 2011).

• **Capturing hoods – Slots**

Measure the air velocities at equidistant points along the entire length and average the readings. Readings should not vary excessively. Measure the hood static pressure and the static pressure of the plenum as well as in the duct. Measure the air velocity in the duct (straight section) (HSE, 2011).

5.3. Organizational measures

Organizational measures are actions that used alone or in combination with other controls are targeted to reduce workers' exposure to hazards. Although are preferred to the PPE implementation in the hierarchy of controls, organizational measures are not usually chosen due to the difficulty of implementation, maintenance and limitations since the hazard itself is not actually removed or enough reduced. A non-exhaustive list of administrative controls is provided in the figure below:

Work practices
Development and implementation of standard operating procedures (SOPs)
Focused workplace training and education on the SOPs
Establishment of good housekeeping plans
Maintenance and storage of equipment in good conditions
Preparation and training for emergency response

Good housekeeping
Correct stockpiling and storage for a more effective use of space
Dust and Dirt Removal
Adequate, clean and well maintained employee facilities
Maintain Light Fixtures
Spill Control
Tools and Equipment more efficient by preventive clean-up and maintenance

Personal Hygiene practices
Washing hands after handling material and before eating, drinking or smoking
Avoiding touching face (lips, nose, eyes) with contaminated hands

Education and trainning on PPE
When PPE is necessary
Which PPE is necessary
How to properly put it on, adjust, wear it and take it off
The limitations of use of the PPE
Proper care, maintenance, useful life and disposal of PPE

Emergency Preparation
Practice their emergency response skills regularly
Prevent fatalities and injuries
Reduce damage to buildings, stock, and equipment
Protect the environment and the co-workers

Figure 12. Examples of Organizational measures

5.4. Personal protective equipment

Personal Protective Equipment is defined as "any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards". There are many types of personal protective equipment, each of them with specific applications and use requirements: i.e. Respiratory (to protect against adverse health effects caused by breathing contaminated air), Eye and face (to protect from the hazards of flying fragments, hot sparks and chemical splashes), and skin (should be used when an exposition to harmful substances can occur).

Use of personal protective equipment
The selection of a determined PPE must be done according to the estimated risk level. According with the hierarchy of controls, PPEs must be used only as a last option, when engineering and/or administrative controls do not offer adequate protection and not in substitution of these.

The **level of protection** afforded by personal protective equipment can be defined as the capacity of the equipment to provide protection from serious injuries or illnesses resulting from contact with chemical, radiological, physical, electrical, mechanical, or other hazards.

No single combination of PPE is capable of protecting against all hazards. Thus, PPE should be used in conjunction with other protective methods, including exposure control procedures and equipment.

The following subchapters provide an in depth description of the main characteristics and performance of those PPEs studied under the scope of the project, including respiratory protective equipment, chemical protective gloves, and protective clothing.

5.4.1. Respiratory protection equipment (RPE)

Respiratory protective equipment (RPE) is a device that protects an individual from the inhalation of harmful airborne substances and/or an oxygen-deficient atmosphere. There are two distinct types of respiratory protective devices, including filtering devices (air purifying) and breathing apparatus (air supplied).

Table 3. Specifications for particle filters

FILTER TYPE	SPECIFICATIONS
P1	Filters at least 80% of airborne particles
P2	Filters at least 94% of airborne particles
P3	Filters at least 99.95% of airborne particles

P1=low efficiency filters   P2=medium efficiency filters   P3=high efficiency filters

Table 4. Main materials used in respiratory protective equipment

RPE PART	SPECIFICATIONS
Face piece	Elastomeric compounds: Butyl IRR, EPDM & natural rubber
Inner Mask	Thermoplastic Elastomer (TPE)
Face seal	Silicone
Visor	Polycarbonate (PC) coated on both sides for scratch & solvent resistance
Head Harness	Natural Rubber (NR)
Valve Discs	Silicone
Visor Frame (Mask)	Polybutylene terephtalate PBTE (thermoplastic polyster) reinforced

• Filtering devices (air purifying): these devices purify the ambient air to be breathed using filters able to remove contaminants in the air. These respiratory protective devices consist of two main components, a face piece and filter(s).

The filter can be for protection against particles (particle filters), gases/vapours (gas filters) and for protection against particles and gases/vapours (combined filters).

Depending on the specifications of the filter (see table 3), the filtering devices can be used for protection against particles (particle filters), gases/vapours (gas filters) and for protection against particles and gases/vapours (combined filters).

Breathing apparatus (air supplied): these devices supply the wearer with breathable air (e.g. compressed air), or breathable gas, (e.g. compressed oxygen) from an uncontaminated source. These respiratory protective devices consist of two main components, a face piece and a means of supplying uncontaminated breathable air or gas.

According to the source of air or breathable gas these devices they are classified as:

- Fresh air hose breathing apparatus. This equipment has a face piece connected to an air supply hose, the upstream end of which should be anchored outside the contaminated atmosphere.
- Compressed air line breathing apparatus. Equipment where air supply is performed through a source of clean compressed breathing air.
- Self-contained breathing apparatus. They are equipment in which air source is a pressure vessel carried by the user himself.

Figure 13. Examples of filtering devices: 1. P3 Filter; 2. Full-Mask; 3. Half-mask; 4. Disposable mask.

Figure 14 shows examples of the different types and models of respiratory protective equipment.

The protection factor is defined as the capacity of the respiratory protection device to reduce the levels of exposure to acceptable levels. This protection factor (PF) is commonly calculated as the ratio between the breathing zone concentration of the contaminant outside the face-piece and the concentration inside the face-piece of the contaminant in a correctly functioning protective device.

This PF depends of the fit factor (FF), which represents a quantitative measure of the fit of a particular respirator to an individual, and the filter efficiency, which is measured according with European standards such as EN 143 and EN149.

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This PF depends of the fit factor (FF), which represents a quantitative measure of the fit of a particular respirator to an individual, and the filter efficiency, which is measured according with European standards such as EN 143 and EN149.

5.4.2. Chemical protective gloves

Appropriate hand protection must be worn when hands are exposed to hazards such as skin absorption of harmful substances, severe cuts, lacerations or abrasions, punctures, chemical or thermal burns and harmful temperature extreme. This chapter focusses specifically in protective gloves against chemicals. Chemical protective gloves are designed to protect against a wide variety of chemicals, including protective gloves that offer splash protection for minimal chemical exposure and products that provide protection for applications involving full chemical immersion.

Protective gloves against chemicals and micro-organisms are impermeable to air and manufactured in a wide range of elastomers, including nitrile, polyvinyl chloride (PVC), neoprene, polyvinyl alcohol (PVA), natural rubber latex, laminated film, butyl or Viton®/butyl gloves. The level of protection of the glove against a chemical depends mainly on the type of material and the specific chemical.
This level of protection is determined based on the resistance to penetratrion (i.e. movement of a chemical and/or micro-organism through porous materials, seams, pinholes or other imperfections in a protective glove material), and the material's resistance to permeation of a chemical in laboratory conditions. This parameter is measured in terms of a passing time or Breakthrough time (see Table 4). This Breakthrough time, in minutes, serves to classify the glove material into six classes or levels, from Class 1 to 6. The manufacturer should refer in its prospectus to the chemical tested and to the permeation classes obtained.

Considering penetration, a glove shall not leak when tested with an air and water leak test, and shall be tested and inspected in compliance with the acceptable quality level. Permeation is different from penetration. Penetration occurs when the chemical leaks through seams, pinholes and other imperfections in the material. Permeation occurs when the chemical diffuses or travels through intact material.

Table 4. Classification of chemical protective gloves according to their resistance to permeation, measured in minutes

BREAKTHROUGH TIME (1)	CLASS OR LEVEL OF PERFORMANCE
> 10 minutes	1
> 30 minutes	2
> 60 minutes	3
> 120 minutes	4
> 240 minutes	5
> 480 minutes	6

(1) Do not confuse the breakthrough time with time recommended use of a glove. The breakthrough time is obtained in laboratory test conditions and constant contact with the chemical. Therefore, this data should only be used as a reference when selecting a glove according to the exposure conditions.

5.4.3. Chemical Protective clothing

Chemical protective clothing is garments specifically designed to shield or isolate individuals from the chemical, physical, and biological hazards that may be encountered during hazardous materials operations. Depending on the design, there are two main types of protective clothing:

- Partial body garments such as jackets, sleeves, pants, aprons, hoods, leggings, etc., that cover only part of the body, and
- Overalls and suits, covering the whole body and can lead hood or not.

Protective clothing against chemicals is made of different polymeric materials or textiles, being classifies in several types depending on tightness offered to liquids, dust and gases. In this sense, CEN has identified six levels of protection (Types) to facilitate the choice of chemical protective clothing. It should be noted that for chemical protective clothing, not only material but also suit's design plays a fundamental role in protecting. Of this latter will depend the tightness of the equipment, i.e., the resistance to enter chemicals, in its different presentation forms (powders, liquids and gases) through seams and joints. Table 5 shows these six levels of protections and related physical forms of the chemical for which they are intended.

Table 5. Types of suits and use for which they are intended

	PHYSICAL FORM OF THE POLLUTANT				
	VAPOUR, GAS	LIQUID JET	SPRAYED LIQUID	SMALL SPLASHES	DUST, PARTICLES FIBERS
TYPE	Clothing type 1a, 1b, 1c y 2	Clothing type 3	Clothing type 4	Clothing type 6	Clothing type 5
PICTOGRAM					

Performance of protective clothing (types 1-6) to obtain exposure reduction values are carried out according standard tests in the laboratory (quantitative or pass/fail) for repellence, retention, and penetration, permeation, or pressure/jet.

The CE marking means that chemical protective clothing meets the requirements of the PPE Directive. However, it does not mean chemical suits of the same Type are suitable for the same risk situation. This is why it is essential to look at the results of the tests carried out on the material used to make the garment.

In the case of chemical protective clothing, permeation and penetration are of special relevance. Permeation resistance describes the resistance of materials used in protective clothing to permeation by liquid or vapour chemicals with either continuous or intermittent contact. Penetration resistance and repellency measure the indexes of penetration, absorption and repellency of protective clothing material exposed to liquid chemicals, mainly of low volatility.

5.4.4. Eye and face protection

Eye and face protection must be provided whenever necessary to protect against chemical, environmental, or mechanical irritants and hazards.

Several types of eye protectors currently exist, including:

- Safety glasses
- Safety goggles (tight-fitting eye protection)
- Face shields: usually transparent sheets of plastic that extend from the eyebrows to below the chin and across the entire width of the employee's head.

An appropriate protector or combination of protector must be selected on the basis of the hazards that workers may be exposed to, considering flying particles, dust, sparks, or injuries optical radiation, among other potential hazards.

Figure 14. Examples of eye protection: 1. Safety glasses; 2. Safety goggles; 3.Face shields

5.5. Environmental Emission Control Technologies

Emission control technologies include a range of technologies and techniques that can be used to control the release of pollutants from individual or diffuse sources into air, water or land. At industrial scale, normally wastewater discharge together with emissions to air are of highest environmental relevance as these flows contains most of the potential pollutants employed during the process. In addition, generated solid waste is of environmental relevance since it could be source of release of hazardous substances by air emissions or leachates that could contaminate air, soil and water compartments. The table below provides an overview of the main emission control technologies applied in industrial settings.

Table 6. Non-Exhaustive list of common emission control technologies

COMPARTMENT	MEASURES	DESCRIPTION
AIR	Clothing type 3	Cyclones use centrifugal force to remove particulate matter from a gas stream (solid particles or liquid droplets)
	Clothing type 3	Wet Scrubbers use a liquid stream to remove solid particles from a gas stream by impacting these particles with water droplets either through water spraying into the gas or through violent mixing of water with the gas stream.
	Electrostatic precipitators	Particle control device that uses electrical forces to move the particles out of the flowing gas stream and onto collector plates. The particles are given an electrical charge by forcing them to pass through a corona, a region in which gaseous ions flow
	Wet electrostatic precipitators	Modified electrostatic precipitators that collect the charged particles on the wet collecting surface washing the electrodes with liquid.
	Fabric filters (bag houses)	Fabric filters operate in a manner similar to a household vacuum cleaner. Dust-laden gases pass through fabric bags where the dry particulates are captured on the fabric surface.
WATER	Microfiltration	Microfiltration (MF) is a pressure-driven process in which a membrane is applied to separate particles from an aqueous solution
	Ultrafiltration	Ultrafiltration (UF) a pressure-driven separation process in which a membrane of a pore size between 1 nm and 100 nm is applied.
	Reverse osmosis	Reverse osmosis (RO) is a process based on the use of closed, nonporous membranes acting in the form of a physical barrier for the hydraulic flow, allowing selective permeation of the solvent (mostly water) and partial or total retention of the other dissolved substances (mostly salt).
	Nanofiltration	Nanofiltration (NF) is a membrane separation process with a cut-offs being between 180 and 2000 Dalton.

COMPARTMENT	MEASURES	DESCRIPTION
WATER	Electrodialysis	Electrodialysis is an electrochemical process whereby electrically charged particles, ions, are transported from a raw solution (retentate, diluate) into a more concentrated solution (permeate, concentrate) through ion-selective membranes by applying an electric field.
	Activated sludge	The activated sludge is a process to treat wastewater streams using a biological floc composed of bacteria and protozoa in aerobic conditions.
	Membrane bioreactor	Wastewater treatment processes where a perm-selective membrane such as microfiltration or ultrafiltration is integrated with a biological process (activated sludge process).
	Membrane distillation	Membrane distillation (MD) is a process in which a microporous, hydrophobic membrane separates aqueous solutions at different temperatures and compositions.
	Advanced oxidation	Advanced oxidation processes (AOPs) are a set of chemical treatment procedures designed to remove organic (and sometimes inorganic) materials in water and wastewater by oxidation using ozone (O3), hydrogen peroxide (H2O2) and/or UV light.
	Activated carbon adsorption	Activated carbon filtration is a commonly used technology based on the adsorption of contaminants onto the surface of carbon granules, or the retention of contaminants in the small pores of the activated carbon.
	Filtration assisted crystallization technology	FACT is a novel hybrid process based on heterogeneous crystallization and filtration, being currently used for removing at least one constituent from a solution.
	Assisted gravity settling	Use of coagulants to assist flocculation and enhance solid removal form wastewater streams.
SOIL / LAND	Landfilling	Disposal of waste on ground. Hazardous wastes are disposed in holes or trenches in ground lined with impervious plastic sheeting to prevent leakage or leaching of dangerous substances into soil and water supply.
	Fast crystal growth	New technique intended to artificially induce the fast crystal growth of amorphous/nanophase form into large ones, hence to make the precipitation of particles easier and reduce their adsorption capacities.
	Incineration	Common process that involves the combustion of organic substances contained in waste materials and converts the waste into ash, flue gas, and heat.
	Phytomining / Phytoremediation	Treatment technique based on the use of plants that selectively concentrate specific metals from the environment into their tissue.

It should be noted there are a wide range of emission control technologies that already exist.To determine the most appropriate technology to controlling a process stream, it is necessary to identify and characterize what contaminants need to be removed or controlled. Moreover, the selection of the technology should consider the information published in the Best Available Techniques (BAT) reference documents, the so-called BREFs, that have been adopted under the current EU environmental regulation (Directive 2008/1/EC) and the Industrial Emissions Directive (IED, 2010/75/EU).

Special attention is given to the air pollution control technologies to the extent that the activities within NanoRISK are focused on the control of the exposure to airborne particles. Table 7 provides detailed information on the efficiency and applicability of common air emission control technologies.

Table 7. Applicability and efficiency of common air emission control technologies

MEASURES	DRY DUST	WET DUST	EFFICIENCY (%)	DESCRIPTION
Settling chamber / Gravitational separator	✕	✕	10-90 Not suitable for removal of nanoparticles	Reasonably suitable for the removal of large and midsized particles (> 15 µm)
Cyclone / Dust cyclone / Wet cyclone / Multi-cyclone / Vortex separation	✕	✕	Dust (< 1 µm) :5 Dust (6-10 µm): 50 Dust (> 10 µm): 90 Dust (> 50 µm): 99. The minimum particle size removed by cyclones is 5– 25 µm and 5 µm in multicyclones	Normally used as pre-separator to take away the largest dust load (particles >5 µm), followed by, for example, a scrubber or fabric filter. Very small fractions can be removed by a series of multiple cyclones.
Scrubbing (general) / Wet dust remover / Wet dust scrubber	✕	✕	99 (fine dust)	Other components such as heavy metals and inorganic chemicals can be removed simultaneously
Spraying tower / Rotational scrubber / Dynamic scrubber	✕	✕	PM_{10}: 70-99	The scrubber is primarily applied for separating very small dust particles (< PM10). Other easily soluble water components such as HF, HCl and SO2 can also be efficiently removed.
Venturi-scrubber / Venturi-scrubber / Whirl scrubber			50-99 PM_{10}: 70-99 $PM_{0,3}$ to $PM_{0,5}$: <50	Venturi-scrubber is primarily applied for the removal of fine dust (PM10). It can be applied for the removal of small particles (< 1 µm) from a gas stream, although the efficiency generally decreases with particle size. The efficiency is particularly low with components that are not easily humidified.
Fabric filter (filtering dust separator) / Tube filter/ Bag filter	✕		99.95 Dust (> 2,5 µm)	Primarily used for the removal of dust and particles up to <PM2,5.
Absolute filter / HEPA-filter / surface filter / cartridge filter / micro filter	✕		PM-PM0.1-PM0.01: 99.99-99.999	Applicable for the removal of dust between PM0.12 and PM0.3 and for toxic or dangerous particles. Two variants: HEPA (High Efficiency Particle Air) filter: 99.97% minimal removal efficiency for fine dust > 0.3 micrometer; ULPA (Ultra Low Penetration Air) filter: 99.9995% minimal removal efficiency for fine dust > 0.12 micrometer
Two-stage dust filter	✕			
Demister / Aerosol filter / Deep bed filter		✕	<99 Dust, drops and aerosols	
Dry electrostatic precipitator / Electrostatic precipitator (ESP) / Dry E-Filter / Dry ESP / Dry electrostatic precipitator / Electro filter		✕	97- >99.9 PM_1: > 97	Removal efficiencies are lowest for particles with a diameter of 0.1 to 1 µm
Wet electrostatic precipitator / Wet E-filter / Wet ESP / Wet Electrostatic precipitator / Electro-filter			97-99 Dust, aerosols	Very small particles can be removed. It also collects particles with high resistivity as well as sticky particles, mists or explosive dusts The lower efficiency of ESPs on nanoparticles can be addressed by the use of an association of an ESP and a FF or the use of an agglomerator.
Acid gas scrubber / Acid scrubber	✓	✓		
Alkaline gas scrubber	✓	✓		
Catalytic incinerator	✓			

It should be noted that removal efficiencies of dust control measures for particles <μm are in general: Absolute filter > Wet ESP > Dry ESP > Wet scrubber (Kupiainen and Klimont, 2004), achieving high removal efficiencies (up to 95% to 99.99%). However, when comparing removal efficiencies, it has to be taken into account that, apart from the characteristics of the dust, other parameters like dust load, flow rate or fluctuations may have a large impact on overall and size-specific removal performance. Moreover removal rates largely depend on the specific design of the dust collector (such as chosen filter material and ESP dimensioning), and in the end investment and operating costs.

More detailed information of air and water emission technologies is provided in the annex section.

6 Effectiveness of common risk management measures against occupational exposure to ENMs

6.1. Current knowledge on the effectiveness of PPE and LEVs

Current knowledge on the effectiveness of personal protective equipment and technical measures against nanomaterials is still scarce. However, a number of initiatives, including EU funded research projects and studies from research organizations across the scientific community are starting to appear.

The EU funded projects NanoMICEX (FP7- 280713), Scaffold (FP7- 280535), NanoREG (FP7- 310584), and GUIDEnano (FP7- 604387) are the most relevant sources of information concerning the performance of risk management measures against nanomaterials. On the other hand, institutions such as IRSN (Institut de Radioprotection et de Sûreté Nucléaire) and INRS (Institut National de Recherche et de Sécurité) in France are very active on the publication on new data on the effectiveness of personal protective equipment.

Knowledge on the measures that concern waste management is far less advanced, with few references in peer reviewed publications. Concerning personal protective equipment, the protection of the respiratory track has been prioritized due to the relevance of the inhalatory route in the workplace. Data on the performance of chemical protective gloves and protective clothing is available to a limited number of fabrics, mainly nitrile and polyethylene for chemical protective gloves and protective clothes respectively.

A number of studies have been identified under the framework of the project. Table 9 summarizes the most relevant studies published so far concerning respiratory protection equipment.

Table 8. Published studies on respiratory protection equipment

PPES	TYPE	ENM	SIZE (NM)	EFFICIENCY (ENMS)	CERTIFIED EFFICIENCY	REFERENCE
FILTERING FACEPIECE RESPIRATORS (FFP)	N95 (free of oil aerosols)	NaCl	20–500	P95 > 85 %	> 95 %	Gao S, et al. 2015
	P95 (oil resistant)			N95 > 91 – 99 %		
	N95	NaCl	10–400	98.79 - 99,10%	> 95 %	Vo E, et al. 2015.
	P100			99.77 - 99,98%	> 99.97 %	
	FFP1	NaCl	93-1600	93.60 – 95.00%	> 78 %	Lee SA, et al. 2016
	FFP2			91.90 – 93.50%	> 92 %	
	FFP3			86,50 – 93.90%	> 98%	
	N95	NaCl	7 – 289	96,90%	> 95 %	Ramirez JA, et al. 2016
	N95			94,70%		
	N95	NaCl	50 - 200	81,10%	> 95 %	Huang et al; 2007.
	FFP1			94,20%	> 78 %	
	N95	NaCl	8 - 400	98,47%	> 95 %	Rengasamy et al; 2011b,
	P100			99,23%	> 99.97 %	
	FFP2			65,30%	> 92 %	
	FFP3			97,80%	> 98%	
	N95 A	NaCl	10 - 600	94 - 95,00%	> 95 %	Bałazy, A. et al. 2006
	N99	vNaCl	< 0,1 μm	95,50 – 97.40	> 99 %	Eninger, R. M., et al.. 2008.
	N95 B			96,60%	> 95 %	
	N95	NaCl	45-52	97,30%		Mostofi et al; 2011;
HALF-MASK RESPIRATOR		NaCl	100-40	>99,49%	> 95 %	Vo E, et al. 2015
				99.98 - 99,99%	> 99.97 %	

Table 9. Published studies on protective clothes

PPES	TYPE	ENM	SIZE (NM)	EFFICIENCY (ENMS)	CERTIFIED EFFICIENCY	REFERENCE
PROTECTIVE CLOTHES	Cotton fabric	Graphite	35 - 40	F.F.E: 73,00%	>70 %	Golanski L, et al. 2009
	HD Polyethylene textile			F.F.E: 99,40%	> 99.7 %	
	Cotton fabric	TiO2	9 - 90	F.F.E: 73%	>70 %	Golanski L, et al. 2010,
	HD Polyethylene textile	Pt	9 - 19	F.F.E: 99,40%	> 99.7 %	
	Woven and fibrous fabrics	NaCl	100- 500	F.F.E: 50 - 80%	> 97 %	Huang S.H, et al. 2007
	Nonwoven fabrics (A,B,C)	NaCl	14 – 400	F.F.E: A, B, C >99%	> 99.7 %	Ben Salah, et al 2016
	Woven fabrics (D, E)			F.F.E: 91.5%	> 97 %	

Table 10. Published studies on protective gloves

PPES	TYPE	ENM	SIZE (NM)	EFFICIENCY (ENMS)	CERTIFIED EFFICIENCY	REFERENCE
PROTECTIVE GLOVES	Nitrile	TiO2 NPs	5nm	Penetration observed	Only for liquids	Vinches et al. 2011
	Nitrile / Neoprene /Latex/ Vinyl	Graphite	40 nm	No penetration		Golanski et al. 2009a
	Latex / Nitrile	Silver	90 nm	Penetration observed		Park et al. 2011
	Nitrile and latex glove	NanoclayAl2O3		No penetration		Ahn et al.

Table 11. Publishes studies on local exhaustive ventilation (LEV)

PPES	TYPE	ENM	SIZE (NM)	EFFICIENCY (ENMS)	REFERENCE
TECHNICAL MEASURES (VEMTILATION)	Movable LEV system	Ag	300 nm	> 99 %	L. Old, M.M. Methner et al, 2008.
		Mn	300 nm	> 99 %	
		Co	300 nm	> 99 %	
	Constant-velocity hood	Aluminum oxide (Al2O3)	200 nm	Good performance observed	S. J. Tsai, et al, 2010.
	Constant-flow hood			Low performance	
	Biological safety cabinet	MWCNTs	10-50 nm outer diameter and 1-20 μm length	Good performance	Lorenzo G. Cena and Thomas M. Peters, 2011
	Filters used in fumehoods (HEPA)	Ag	10 nm	> 99.99 %	Seong Chan Kim, et al, 2007

The data retrieved form the literature revealed an evident lack of standardized methods to experimentally measure the effectiveness of common risk management measures. This situation limits the comparability of studies and stresses the need for standardized approaches to evaluate the effectiveness of common personal protective equipment and technical measures.

Within NanoRISK, the task conducted within action B1 focused on the development and validation of standard operating procedures to support a robust, reproducible and reliable assessment of the performance of RMM against nanomaterials. Chapter 6.2 summarizes proposed testing strategies.

The data published so far suggest a good level of performance for respiratory protective equipment, where most of the data retrieved from peer reviewed publications showed efficiencies above the threshold levels defined in reference harmonized standards.

In the case of protective clothing and chemical protective gloves, there are still a lot of unknowns as to whether or not traditional protective measures provide a proper level of protection against ENMs. The information retrieved from the literature highlight two main challenges linked with the body protection. The first is to understand the external parameters that can influence the penetration of nanoparticles through commonly issued fabrics. The second is to consider the variations on the surface properties of the materials used protective gloves and protective clothing, which results in high variations on the performance results.

6.2. Testing approaches followed under NanoRISK

The activities conducted within NanoRISK focused on the evaluation of the effectiveness of common risk management measures to prevent or minimize exposure to engineered nanomaterials (ENMs). The selection of risk management measures studied under the scope of the task was conducted considering the needs and opinions of the industry. Table 12 depicts the types of RMMs selected under the scope of the tasks.

Table 12. RMMs studied under the scope of LIFE NanoRISK

EXPOSURE ROUTE	RMM TYPE	MEASURES	NanoREG Selection
Inhalation	PPE	Respiratory protective equipment (RPE)	Filtering Facepiece (FFP) Half-Face mask (HM) Full-Face mask (FM)
Dermal	PPE	Chemical protective gloves (DPE-Gloves)	Nitrile Latex Neoprene Vinyl / Butyl
Dermal / Body	PPE	Protective clothing	Disposable Protective coveralls Ventilated / pressurised protective suit Laboratory coats
Eye	PPE	Eye protection	Safety glasses Safety googles (tight-fitting eye protection)
All	ECs	Ventilations systems	Ventilated Laboratory Hood (partial enclosure) Movable LEV systems (extendable arm) Custom-fabricated enclosures

Only personal protective equipment and technical measures available on the market were considered under the scope of the project.

Experimental studies were conducted to evaluate the effectiveness of respiratory protective equipment, chemical protective gloves, protective clothing and local exhaust ventilation systems against ENMs. Standard operation procedures (SOPs) were developed based on current EN standards, and r approaches retrieved from peer reviewed publications.

A set of 8 SOPs were finally developed, including 3 for respiratory protection (masks, filters), 3 for protective clothing (coats, gloves), and 2 for engineering controls (LEVs). The list of protocols is depicted below.

1. Determination of inward leakage of nanoparticles
2. Determination of total inward leakage of nanoparticles
3. Determination of particle filter penetration by nanoparticles
4. Determination of inward leakage of aerosols of nanoparticles into suits
5. Determination of resistance to penetration by spraying a liquid solution of nanoparticles
6. Determination of permeation to nanoparticles in gloves
7. Determination of particle capture efficiency of Movable LEV systems
8. Determination of Ventilated Laboratory Hood effectiveness

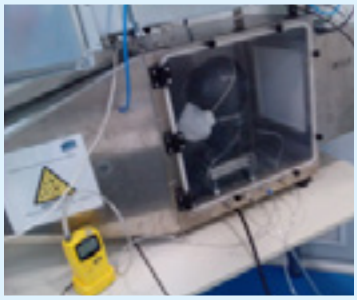
The list of performance factors evaluated to study the level of protection provided by PPE and ventilation is depicted in table 13. This level of protection "performance factor" is defined as a product (risk management measure) characteristic which tells us quantitatively how capable the product is in reducing the risk (directly or indirectly). Within the project, the performance factors to be studied were determined by studying literature and current standards.

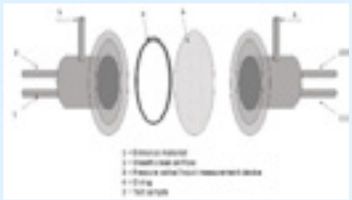
Table 13. Performance factors studied within NanoRISK project

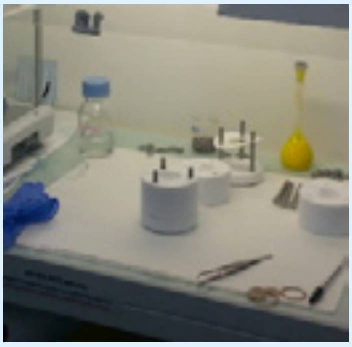
MEASURES	RMM TYPE	NanoREG Selection
Respiratory protective equipment (RPE)	Filtering Facepiece (FFP)	Total Inward Leakage (TIL) Nominal protection factor (NPF)
	Half-Face mask (HM) Full-Face mask (FM)	Inward Leakage (IL) Total Inward Leakage (TIL) Nominal protection factor (NPF)
Dermal protective equipment	Chemical protective gloves (DPE-Gloves	Permeation Penetration Nominal protection factor (NPF)
Eye protection	Protective clothing	Total Inward Leakage (TIL) Nominal protection factor (NPF)
Ventilation	Safety glasses Safety googles	Total Inward Leakage (TIL)
	Local Exhaustive ventilation	Capture efficiency (Cf)

An overview of the most relevant experimental approaches followed under NanoRISK are depicted in the table 14.

Table 14. Experimental set up for RMM testing under NanoRISK

RMM	PF	DESCRIPTION	SET UP PICTURES
Respiratory Protective Equipment (RPE)	Inward Leakage (IL) / Total inward leakage (TIL)	**Scope:** characterization of the TIL, defined as the penetration of particles into the RPD, including face seal, valves and gaskets, and penetration through the filter. IL refers the penetration of particles into the RPE excluding filters. **Objective:** evaluation of the level of protection provided by filtering face pieces, half and full masks against airborne nanoparticles. **Reference substance:** NaCl particles (50 – 80 nm) **Set up (1) – Evaluation the total inward leakage and inward leakage with a test head** ENMs are conducted to the testing furnace, where a Sheffield head carrying a respirator is placed. The Sheffield head is a manikin head with internal pipes, which let to collect the air from the inside of the mask **Set up (2) – Evaluation the total inward leakage on human subjects** Subjects are placed on a treadmill and while walking, they are asked to do a list exercises defined in current EN standards. In both set ups, the concentration of ENMs is measured inside and outside the RPD tested by means of direct reading devices (CPC, OPS, P-Track, SMPS). **Performance factor:** particle penetration (P) $P(\%)=1{,}25{*}C_2/C_1{*}100$ Where, C1: test concentration C2: average concentration measured inside the face piece 1,25 is a correction factor due to the retention of sodium chloride in the lungs **Reference standard:** UNE-EN 13274-1 2001	 
Filter penetration		**Scope:** characterization of the penetration of ENMs through chemical protective clothing (CPC) during exposure to an aerosol flow. **Objective:** evaluation of the level of protection provided by protective clothing against airborne nanoparticles. **Reference substance:** NaCl particles (50 – 80 nm) **Set up:** tests can be performed using a mannequin (static) or volunteers (dynamic). Three points of the suit are selected to measure the concentration inside, which is then compared with the concentration outside the suit. A sheath flow of clean dry air is supplied inside the suit at the same flowrate as the measuring devices are suctioning in order to no create depression or a false result. The sleeve ends of the suit, as well as seams, closures, zips, etc. are sealed to avoid penetration through opened parts and only test the suit material. **Performance factor:** particle penetration (P) $P(\%)=C_2/C_1{*}100$ Where, C1 NaCl concentration before the filter; C2 average concentration measured after the filter. **Reference standard:** UNE-EN 13274-7 2008	 

RMM	PF	DESCRIPTION	SET UP PICTURES
Protective clothing	Particle penetration	**Scope:** characterization of the penetration of ENMs through chemical protective clothing (CPC) during exposure to an aerosol flow. **Objective:** evaluation of the level of protection provided by protective clothing against airborne nanoparticles. **Reference substance:** NaCl particles (50 – 80 nm) **Set up:** tests can be performed using a mannequin (static) or volunteers (dynamic). Three points of the suit are selected to measure the concentration inside, which is then compared with the concentration outside the suit. A sheath flow of clean dry air is supplied inside the suit at the same flowrate as the measuring devices are suctioning in order to no create depression or a false result. The sleeve ends of the suit, as well as seams, closures, zips, etc. are sealed to avoid penetration through opened parts and only test the suit material. **Test conditions (Human Subjects):** - 3 min standing - 3 min walking - 3 min squatting. - 3 measurement probes: chest, waist and knee - Six suits tested **Performance factor:** Total average inward leakage (TILA) reported as a ratio of the test particle concentration inside the suit and the test chamber (For all six suits, all the exercises and all 3 probes) Nominal protection factor = $100/(TIL_A)$ **Reference standard:** UNE-EN ISO 13982-2 2005	 
Chemical protective gloves	Particle penetration	**Scope:** characterization of the penetration of airborne nanoparticles through glove material. **Objective:** evaluation of the level of protection provided by chemical protective gloves against airborne nanoparticles. **Reference substance:** NaCl particles (50 – 80 nm) **Set up:** a specimen is cut from the glove and clamped into a test cell as a barrier membrane. The "exterior" side of the specimen is exposed to airborne NaCl nanoparticles, and concentrations are measured at both sides of the glove and compared. **Performance factor:** particle penetration (Pn (%) The percentage of penetration is calculated from the measurements at each side of the glove, considering Cout the concentration right before the glove and Cin after the glove sample. $P_n (\%)=C_{in}/C_{out}*100$ **Reference standard:**EN 16523-1:2015	

RMM	PF	DESCRIPTION	SET UP PICTURES
Chemical protective gloves	Permeation	**Scope:** characterization of the permeation of nanoparticles diluted in a water based solution through the glove material by permeation mechanisms. **Objective:** evaluation of the level of protection provided by chemical protective gloves against nanoparticles dispersed in water or solvents. **Reference substance:** water dispersed ZnO NPs (45 – 56 nm) **Set up:** to test permeation to liquid dispersions of nanoparticles, a Teflon cell is required. In this case, a circular sample of the glove is placed in rest between the liquid dispersion and a filter sampler that will be analyzed after 1 hour of being in contact. **Performance factor:** particle permeation **Reference standard:** : ISO/CD 19918	
(LEV) systems – Ventilated Laboratory Hood	Containment	**Scope:** characterization of the containment effectiveness of ENMs of a Ventilated Laboratory Hood. **Objective:** ensure that Ventilated Laboratory Hoods are capable of providing a minimum level of protection (containment) when handling ENMs. **Reference substance:** NaCl particles (50 – 80 nm) **Set up:** The test method is based on the generation and dispersion of nanosized NaCl inside the work space of a fume cupboard. The containment factor is defined as the ratio of calculated concentration of tracer gas in the work space of the fume cupboard to the measured concentration in the inner or outer measurement plane. The method proposed is based on the use of a injector is positioned inside the work space of the fume cupboard, as well as 9 sampling probes arranged in a grid at the inner measurement plane. **Performance factor:** Capture efficiency (Cf) estimated comparing the concentration at 100% aerosol capture C100 and the measured mean concentration Cm at different sampling points: Cf = (C100 – Cm)/ C100*100 **Reference standard:** UNE-EN 14175-4:2005 / ASHRAE 52 2007	

RMM	PF	DESCRIPTION	SET UP PICTURES
(LEV) systems - movable capturing hood	Capture efficiency	**Scope:** characterization of the capture efficiency of ENMS using a movable capturing hood. **Objective:** ensure that movable capturing hoods are capable of providing a minimum level of protection when handling ENMs. **Reference substance:** NaCl particles (50 – 80 nm) **Set up:** Nanoparticle capture efficiency of a capture hood is tested by atomising an aqueous solution of NaCl (50 nm). The aerosol is released through several diffuser pipes at the work area. First 100% aerosol capture is obtained by placing the diffuser pipes as close as possible to the exhaust duct inside the exhaust hood. With a CPC aerosol concentration shall be measured inside the duct. The concentration at different diffuser distances are compared with the concentration levels during the 100% aerosol capture experiment. **Performance factor:** Capture efficiency (Cf) is the ratio of measured concentration of tracer gas in the duct of the capture hood with 100% aerosol capture (at 0 cm height) to the measured concentration of tracer gas in the duct of the capture hood with the hood positioned at a specific height above the work surface. **Reference standard:** UNE-EN 1822 / ASHRAE 52 2007	

6.3. Protection factors and performance levels based on the studies conducted within NanoRISK

The studies conducted under the framework of NanoRISK focussed on the evaluation of the effectiveness of commonly used personal protective equipment and local exhaustive ventilation systems against ENMs, including dry particles in the nanometer range or dispersed in water. Detailed information on the experimental set up and results is provided in deliverables D.B1 and D.B3.

6.3.1. Respiratory protection

A wide range of test were conducted by the research team form ITENE within the project, including assays using a test head (static) and assays on human subjects (dynamic). These last is based on current EN standards, where several subjects complete a set of exercises designed to evaluate the protection provided by a respirator device. Filter penetration studies were also conducted following the SOPs developed within the project. The following table summarizes the results retrieved form the experimental activities conducted.

Table 15. Efficiencies of different kinds of masks and particulate filters tested for NaCl NPs.

RPD	SPECIFICATIONS	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Filters	P2 Filter	Efficiency	94 %	99.83 %	NaCl
	P3 Filter	Efficiency	99.95 %	99.97 %	NaCl
Half Mask	New Mask P3 Filter	Efficiency	99.95%	99.47 ± 0.83 %	NaCl
	Aged Mask P3 Filter	Efficiency	99.95 %	99.77 ± 0.29 %	NaCl
Full Mask	New Mask P3 Filter	Efficiency	99.95%	99.73 ± 0.25 %	NaCl
	Aged Mask P3 Filter	Efficiency	99.95 %	99.78 ± 0.16 %	NaCl
Disposable	FFP1	Efficiency	80%	75.63 %	NaCl
	FFP3 (Model a)	Efficiency	99%	99.77 ± 0.29	NaCl
	FFP3 (Model b)	Efficiency	99%	95.63 ± 4.39	NaCl

Table 16. Efficiencies of different kinds of masks and filters tested for SiO2 NPs.

RPD	SPECIFICATIONS	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Half Mask	P2	Efficiency	94 %	96.26 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2
	P2	Efficiency	94 %	97.67 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2
	P2	Efficiency	94 %	99.98 %	SiO2
	P3	Efficiency	99.95 %	99.55 %	SiO2
	P2	Efficiency	94 %	98.12 %	SiO2
	P3	Efficiency	99.95 %	99.48 %	SiO2
	P2	Efficiency	94 %	96.26 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2

The results showed that Full and Half Mask Respirators provided adequate performance levels of filtration efficiency against NMs. Total inward leakage (TIL) ratios determined in relevant studies suggest that face seal leakage, and not filter penetration, is a key parameter to be considered when working with nanoparticles.

6.3.2. Skin Protective Equipment

Several tests were conducted to evaluate the effectiveness of common dermal protective equipment against ENMs, including chemical resistant gloves and protective clothing. In the case of protective clothing, as for respiratory protection, tests for the resistance against penetration of ENMs can be performed with human subjects when the aerosolized material is NaCl, to exam the suits in movement, or with a mannequin with any other material. The results of the evaluation of the effectiveness of chemical protective gloves and chemical protection suits are presented in this section.

Table 17. Average Efficiencies (% Penetration "Inward Leakage") of recommended protective coveralls against chemicals (Category III) using NaCl NPs .

SPE	POSITION	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Protective coverall (PE) High performance for liquids	Knee	T.I.L (%)	< 15 %	< 3 %	NaCl
	Waist	T.I.L (%)		< 6 %	NaCl
	Chest	T.I.L (%)		< 10 %	NaCl
	Global	T.I.L (%)		< 7 %	NaCl
Protective coverall (PE) Types: 3,4,5,6	Knee	T.I.L (%)	< 15 %	< 4 %	NaCl
	Waist	T.I.L (%)		< 3 %	NaCl
	Chest	T.I.L (%)		< 12 %	NaCl
	Global	T.I.L (%)		< 6 %	NaCl

Table 18. Efficiencies of chemical protective gloves against ENMs

SPE	MATERIAL	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Disposable protective gloves	Nitrile Thin	I.L (%)		0.040	NaCl
	Nitrile Thick	I.L (%)		0.006	NaCl
	Vinyl	I.L (%)		0.103	NaCl
	Non powder Vinyl	T.I.L (%)		0.013	NaCl
	Non powder Latex	I.L (%)		4.64	NaCl
Protective coverall (PE) Types: 3,4,5,6	Neoprene / Natural Latex	T.I.L (%)		1.63	NaCl
	PVC	I.L (%)		3.17	NaCl
	Butyl II	I.L (%)		-	NaCl

In view of the table, performance depends strongly on the material of the glove, and although generally there are no pores in their surface, some small defects or gaps can be enough to offer a way in to the glove.

6.3.3. Eye protection

In the case of eye protection, only safety goggles were tested since are considered the only ocular protection that offers a closed arrangement. The goggles tested were of two kinds. A simple pair of goggles that can be bought in a hardware store, with small holes on the sides to allow ventilation, and a specialized pair of goggles with screen coated to be scratch resistant on the outside and permanent anti-fog on the inside, plus UV protection. The results of the evaluation of the effectiveness are presented in the table 19.

Table 19. Efficiencies of safety goggles against ENMs

SPE	SPECIFICATIONS	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Conventional		I.L (%)		57.79 %	NaCl
Tight-fitting goggle		I.L (%)		20.07 %	NaCl

6.3.4. Local Exhaustive ventilation

Three independent tests were performed to test the containment effectiveness of Ventilated Laboratory Hoods. To support the understanding of the experimental results, the test is based on the use of test gas injector, which consists of a punctured hollow stainless steel (SS) cylinder. A single jet atomizer is connected to the injector to generate 50 nm NaCl particles. A sampling grid made of SS sampling tubes are connected to 9 particle counters (CPC) using conductive tubing to measure particle number concentration simultaneously.

The measurements with the nine CPCs are performed at the intersection of two horizontal and three vertical equally spaced lines (outermost 130 mm, lines in between <600 mm, figure x) and compared with the generated particle number concentrations.

At the exhaust of the injector about 35,000 particles per cm3 were measured. Highest particle number concentrations were measured at sampling position 5 as can be seen in figure 16.

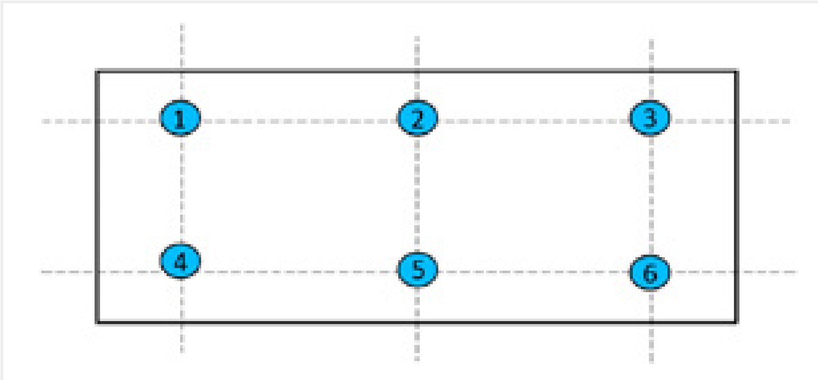


Figure 15. Six measurement positions (top) with particle number concentrations in pt/cm3 (below) during three test (A,B,C)

Average particle number concentration of all three tests and positions was about 300 particles per cm^3 resulting in an efficiency of 99.04 ± 0.36%.

Test A	21	19	21
	688	891	30
Test B	2	7	11
	953	1553	26
Test C	3	6	9
	184	1660	8

Figure 16. Six measurement positions (top) with particle number concentrations in pt/cm3 (below) during three test (A,B,C)

• Movable capturing Hood

Nanoparticle capture efficiency of a mobile capture hood (Nederman Filtercart Carbon, 750-900 m3, HEPA >99,97%) is determined inside the test chamber (zero particle background). An emission source is simulated using diffuser pipes connected to a six jet atomizer generating 50 nm NaCl particles. Particle measurements are performed inside the sampling duct of the capture hood and in the surrounding area.

Particle number concentration at 100% aerosol capture is compared with the particle number concentration at different capture hood-diffuser distances to calculate the efficiency. The results of the capture efficiency experiments are shown in table 20.

Table 20. Results capture efficiency experiments

TILTED CAPTURE HOOD		VERTICAL CAPTURE HOOD	
DISTANCE DIFFUSER PIPES – CAPTURE HOOD (CM)	EFFICIENCY WITH TILTED CAPTURE HOOD (%)	DISTANCE DIFFUSER PIPES – CAPTURE HOOD (CM)	EFFICIENCY WITH VERTICAL CAPTURE HOOD (%)
0	100 ± 14	0	100 ± 5
15	79 ± 4	5	79 ± 6
50	72 ± 2	20	53 ± 43
65	63 ± 5	45	82 ± 2
-	-	70	66 ± 20

The results of the tilted capture hood show a decrease in efficiency when the distance increases from 0 to 65 cm. With a vertically positioned hood, efficiency decreases gradually at 5 cm and drops significantly at 20 cm. At 45 cm a more or less similar efficiency is measured compared with 5 cm efficiency. The drop at 20 cm is probably the result of considerable turbulence when the capture hood is positioned at this distance.

7 List of measures for the safe handling and control of exposure

7.1. List of measures for controlling occupational exposures to ENMs

The motivation of the NanoRISK project was to define a compendium of proper measures to prevent, reduce and control the exposure to ENMs in the workplace and likelihood of unintentional releases of ENMs during production, use, and end-of-life treatments.

This chapter provides a set of recommended measures that can be used to reduce the potential levels of exposure to ENMs in the workplace health based on the knowledge generated within NanoRISK. These measures follow the principles of the hierarchy of controls, including: 1) substitution, 2) technical measures, 3) organizational measures, and 4) personal protective equipment.

7.1.1. Substitution

The first recommended approach is to select less hazardous ENMs. To this end, the following specifications should be considered:

- Specific toxic effects of the bulk form
- Particle Shape and Aspect Ratio
- Size and Surface Area
- Physical form (powder/ liquid / solid matrix)
- Physical properties: solubility and dustiness

We consider substitution as a means for reducing the risk at source. In this regard, the abovementioned properties play a major role in the toxicological potential of ENMs, being recommended a thorough review of such properties before their use or selection.

The following table shows a proposed toxicity ranking based on peer reviewed publications.

Table 21. Toxic categories based on relevant physicochemical Properties of nanomaterials (Source: ITENE)

	EXTREMELY TOXIC	VERY TOXIC	MODERATELY TOXIC	SLIGHTLY TOXIC	NON-TOXIC
Effects of the bulk form	Carcinogenic, mutagenic and reprotoxic substances	Mutagenic and reprotoxic substances	Skin irritation / sensitizer. Mutagenicity (cat. 2)	Skin sensitizer	Non classified
Particle Shape and Aspect Ratio	Fibres > 10 μm	Fibres > 5 μm Spherical	Fibres < 2 μm Non-spherical*	Spherical	-
Particle diameter	1-10	11-40	41 -100	100 - 300	-
Physical form	Powder	Powder / Liquid	In liquid	In solid	-
Solubility	Low solubility	Hardly soluble	Partially soluble	Soluble	Soluble
Dustiness	High dustiness	Moderate dustiness	Low dustiness	Very Low dustiness	Very Low dustiness

It is rarely possible to substitute the nanomaterial, as it is often the specific material's properties that the researchers are trying to exploit or research. However, in some cases it has been possible to replace fullerenes, carbon nanotubes, quantum dots and different metallic oxides with materials that are presumed to be less risky.

According with table 21, it is highly recommended to select soluble ENMs, with very low dustiness potential and non-classified as hazardous in bulk form. When substitution with potentially less hazardous ENMs is not possible, try to introduce best practices based on the toxic categories depicted in table 21. Examples of source reduction measures based on substitution principles are:

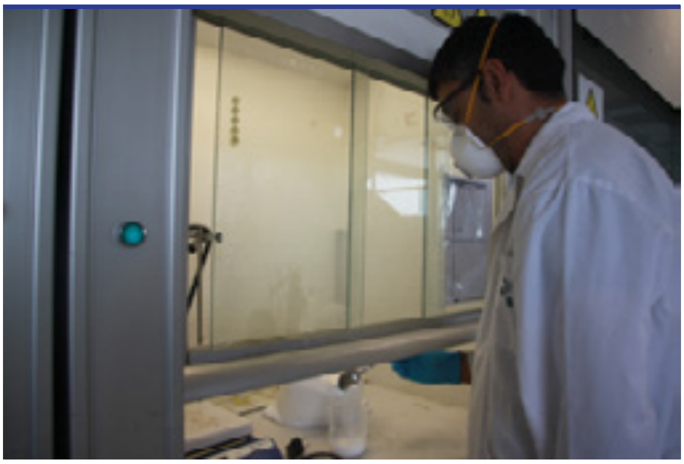
- Reduce the amount of nanomaterial as much as possible;
- Try to use ready-for-use materials/products to avoid further preparation prior to use at the work place Preferably use ENMs in a matrix (i.e. dispersion, suspension, paste, palletized or encapsulated);
- Choose those work methods that generate as little aerosols as possible (low-dust processing methods): i.e. cutting instead of sawing and brushing/rolling instead of spraying.

7.1.2. Technical measures: Exhaust ventilation

The need for technical exposure mitigation has been accentuated by all specific nanomaterial guidelines, including physical and technical solutions in the work process to isolate, encapsulate and shield the process, as well as using mechanical ventilation and filters (locally and/or centrally).

Technical measures are likely the most effective and applicable control strategy for most nanomaterial processes. In most cases, they should be more feasible than elimination or substitution and, given the potential toxicity of many ENMs, should prove to be more protective than administrative controls and PPE.

Local Exhaust ventilation is the most common technical measure used for controlling occupational exposures to air contaminants, including ENMs. The use of general ventilation is limited to low toxicity sources that are usually diffused throughout the workplace and where the workers are a sufficient distance from the source(s). The use of Local Exhaust Ventilation (LEV) systems is preferred to general ventilation and should be considered when working with ENMs.



The data retrieved from the literature, and studies conducted within the project revealed that:

• General ventilation “dilution” can be used for non-hazardous exposures, but isn’t acceptable for ENMs.

• LEV systems are a primary method for controlling occupational exposures to ENMs. The most relevant and most often used LEV types for ENMs are enclosing and capturing hood.

It should be noted that there is always more than one approach that can be applied to any process and therefore it is important that the various technical measures are collated and their suitability assessed before a solution is selected.

The following table includes a list of recommended measures considering relevant activities in the life cycle. These activities include material unpacking, synthesis, bag filling, weighing, mixing, spraying and machining of parts that contain ENMs.

Table 22. List of technical measures for controlling occupational exposures to ENMs from laboratory to large scale facilities (Source: ITENE).

STAGE / PROCESS	LABORATORY	PILOT PLANTS	INDUSTRIAL SETTINGS (MEDIUM SCALE PRODUCTION)	INDUSTRIAL SETTINGS (LARGE SCALE PRODUCTION)
Material Unpacking (Dry Powder)	Ventilated Laboratory Hood (partial enclosure) Local exhaust enclosure (Glove Box)	HEPA filtered down flow booth	Custom-fabricated enclosures HEPA filtered down flow booth	Custom-fabricated enclosures HEPA filtered down flow room
Material Unpacking (Liquid dispersions)				
Material Unpacking (Dry Powder)	Ventilated Laboratory Hood (partial enclosure)	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth (or rooms) / Non ventilated enclosure for low Slightly or non Toxic ENMs	
Weighing (Dry Powder)	Ventilated Laboratory Hood (partial enclosure) Local exhaust enclosure (Glove Box) Biological safety cabinet	HEPA filtered down flow booth Walk-in hood	Custom-fabricated enclosures HEPA filtered down flow booth	Custom-fabricated enclosures HEPA filtered down flow booth
Weighing (Liquid dispersions)				
Transferring				
Sonicating	Ventilated Laboratory Hood (partial enclosure)	Ventilated Laboratory Hood (partial enclosure)	Fully enclosed operation	
Mixing (Dry Powder)	Ventilated Laboratory Hood (partial enclosure) Local exhaust enclosure (Glove Box)	HEPA filtered down flow booth	Custom-fabricated walk-in booths	Custom-fabricated walk-in booths
Mixing (Liquid dispersions)		Movable LEV systems (extendable arms)		
Production (physical and chemical synthesis)	Ventilated Laboratory Hood (partial enclosure)	Ventilated enclosure located inside a downflow room Receiving hood (hot process)	Fully enclosed reactor	Fully enclosed reactor
Packing / bag filling	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth Ventilated collar-type exhaust hoods Continuous liner product off-loading system	Custom-fabricated enclosures Downdraft Hood Ventilated collar-type exhaust hoods Continuous liner product off-loading system	Custom-fabricated enclosures Downdraft room Ventilated collar-type exhaust hoods Continuous liner product off-loading system
Spraying	Ventilated Laboratory Hood + built-in water wash down systems	Walk-in hood	Custom-fabricated walk-in booths	Custom-fabricated walk-in booths (built-in water wash down systems)
Machining (sawing , grinding, etc)	Ventilated Laboratory Hood (partial enclosure) Movable LEV systems (extendable arms)	Custom-fabricated Movable LEV systems (extendable arms)	Movable LEV systems (extendable arms) Custom-fabricated walk-in booths (Wet suppression)	Movable LEV systems (extendable arms) Custom-fabricated walk-in booths (Wet suppression)
Compounding / injection molding	Custom-fabricated Movable LEV systems	Canopy hood - Receiving hood (hot process)	Canopy hood - Receiving hood (hot process)	Fully enclosed operation

A proper maintenance of the technical measures depicted in the table must be conducted, including additional system checks to ensure adequate system performance. The following table depicts a list of technical measures that can be used in relevant activities in the life cycle of ENMs.

Table 23. List of technical measures for controlling occupational exposures to ENMs in relevant operations in production facilities (Source: ITENE)

	VENTILATED TECHNICAL MEASURES									NON VENTILATED TECHNICAL MEASURES	
	Laboratory fume hood or cupboard	Local exhaust enclosure (Glove Box)	Receiving hood (hot process)	Movable LEV systems	Walk-in hood / booth	HEPA filtered down flow booth	Ventilated collar-type exhaust hoods	HEPA filtered down flow rooms	Custom-fabricated enclosures (fully – partial)	Continuous liner product off-loading system *	Inflatable seals
Material Unpacking	×	×				×		×	×		
Weighing (Dry Powder and liquid dispersions)	×	×			×	×	×	×			
Transferring	×				×				×		
Sonicating	×								×		
Mixing (Dry Powder and liquid dispersion)	×	×		×	×			×			
Synthesis (Dry/ liquid)	×		×						×		
Packing / bag filling	×					×	×	×	×	×	×
Spraying					×	×				×	
Machining	×			×	×				×		
Compounding / injection molding			×								

The selection of technical measures not only depends on the stage of the life cycle and/or related operations, being necessary to consider the toxicity potential and dustiness of the ENM handled.

It shall be noted that the selection of the technical measures should be based on the specific workplace conditions and results of the risk assessment conducted by a competent person knowledgeable of the operative conditions and exposure situations.

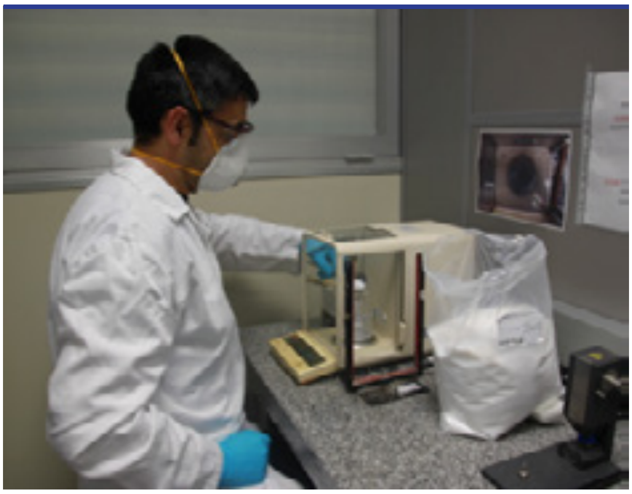
The following table summarizes a list of recommended technical measures that can be used when dealing with ENMs in the workplace.

Table 24. List of recommended technical measures when working with ENMs (Source: ITENE)

PROTECTION LEVEL	TECHNICAL MEASURES
Highly recommended (High protection)	Local exhaust enclosure (Glove Box) HEPA filtered down flow booth Custom-fabricated enclosures HEPA filtered down flow room Ventilated Laboratory Hood + built-in water wash down systems (sprays) Negative pressure rooms
Acceptable level of protection (non-hazardous ENMs)	Ventilated Laboratory Hood (partial enclosure) Biological safety cabinet (small amounts of ENMs) Walk-in hoods Ventilated collar-type exhaust hoods Movable LEV systems (extendable arms) Receiving hood (hot process) Work processes in furnaces (High cost)
Not recommended	Biological safety cabinet (Amounts above 100 g) Ventilation by dilution

7.1.3. Organisational protection measures

As stated previously, organisational protective measures consist of various policies and requirements that are established at an administrative level to promote safety in a dedicated facility of a SME, large company, or private and public laboratories. They may include:



- Restricting access to areas in which particularly hazardous ENMs are used;
- Requiring prior approval and additional control measures for certain particularly hazardous operations or activities;
- Posting appropriate signs to identify specific hazards within an area;
- Training in good practice work routines;
- Preparing work instructions and directions on handling daily work routines, spills, accidents, cleaning, personal hygiene, fire, downtime, maintenance, etc.

The following recommended organisational measures have been defined within the NanoRISK project considering laboratory, pilot plant and large scale facilities.

Laboratory scale facilities

- Make an inventory of the ENMs used / synthetized in your laboratory.
- Provide information on the properties of the ENMs being handled in the laboratory, including:
  - a) Identity and main specifications of the ENMs handled, including at least product and chemical name, size distribution, shape and physical state.
  - b) Hazards: classification of the ENMs handled according with the information provided in safety data sheets and/or available information on specific properties to support hazard categorization.
  - c) Update the information available
- Make an inventory of activities and operation where a potential exposure or unintentional release is likely to occur.
- Provide adequate training, procedures and work instructions for handling ENMs and related waste.
- Avoid handling of ENMs in dry particle forms when possible, especially in open air areas.
- Switch on existing laboratory fume hoods or ventilated enclosures before starting operations.
- Avoid surfaces on which dust can be deposited. Ensure that laboratory benches and other surfaces, which come into contact with powders where ENMs, are dry before starting operations.
- Do not clean up with a dry brush or compressed air. Use wet wiping methods or HEPA-filtered vacuum cleaner (if needed) for cleaning operations in the laboratory.

Industrial facilities (Pilot to large scale facilities)

- Make an inventory of the ENMs produced and/or used in your company
- Provide information on the properties of the ENMs being handled in the company, including:
  - a) Identity and main specifications of the ENMs handled, including at least product and chemical name, size distribution, shape and physical state.
  - b) Hazards: classification of the ENMs handled according with the information provided in safety

data sheets and/or available information on specific properties to support hazard categorization.

- Make an inventory of the activities and processes where a potential exposure or unintentional release is likely to occur.
- Provide workers with adequate training on the safe handling of ENMs to reduce the likelihood of exposure, including:
  a) Procedures and work instructions
  b) Instructions on how to prevent exposure following the hierarchy of controls
  c) Instructions on waste management, cleaning and maintenance operations
- Avoid handling of ENMs in dry particle forms when possible, especially in open air areas.
- Switch on exiting local exhaustive ventilation (LEV) systems before starting operations.
- Avoid surfaces on which dust can be deposited. Ensure that the facilities that come into contact with powders where ENMs are dry before starting operations.
- Encourage workers to clean work areas at the end of each work shift using either HEPA-filtered vacuum cleaner or wet wiping methods. Do not clean up with a dry brush or compressed air.
- Policies and procedures must be readily accessible and focus on training for all relevant employees.

7.1.4. Personal Protective Equipment (PPE)

According to the hierarchy of controls, the use of PPE is the least desired option for controlling worker exposure, being used when engineering and administrative controls are not feasible or effective in reducing exposures to acceptable levels.

Use of Respiratory protection equipment
In order to reduce exposures to ENMs, RPE must be able:
To Filter nanomaterials (1 – 100 nm)
To seal adequately to the user's face.

In view of the data retrieved from the literature and the results achieved within the project, respiratory protection equipment, chemical protective gloves, protective clothes, and safety googles can provide an acceptable level of protection to ENMs if they are properly selected and used. However, there are still some challenges when dealing with ENMs associated with the fitting factor (face seal leakage) of respiratory protection equipment or the degradation potential of solvents where ENMs are dispersed in the case of protective gloves and clothing.

The selection of personal protective equipment should be based on a comprehensive personal protection implementation program developed after the thorough analysis of the existing operations and processes, and hazard potential of the ENMs to be handled.

This chapter provides a list of personal protective equipment when dealing with ENMs in laboratory scale facilities and occupational settings. These recommendations should be advised by each company's own hazard assessments.

Respiratory protection equipment

Several studies have shown that respirators tested and certified under the current NIOSH and EU certification test methods provide expected levels of filtration efficiency against ENMs. However, total inward leakage (TIL) ratios determined in relevant studies suggest that face seal leakage, and not filter penetration, is a key parameter to be considered when working with ENMs.

The studies conducted within NanoRISK concluded that in general particulate respirators must be used to

help reduce exposure during nanomaterial production and handling process. It should be noticed that the RPE must be suitable for the task conducted and must be face-fitted for the individual.

The following table provides a list of RPE considering relevant activities in the life cycle.

Table 25. List of Respiratory Equipment types to be used in relevant activities at laboratory scale (Source: ITENE)

RPE TYPE		FILTER TYPE	Unpacking (Liquid/Solid)	Unpacking (Bonded /Coated)	Weighing (Dry particles)	Weighing (Liquid dispersion)	Transferring (Solid – dry)	Transferring (Liquid dispersion)	Sonicating	Production (physical and chemical synthesis)	Mixing (Dry Powder)	Mixing (In Luiquid)	Packing /bag filling	Machining operations (sawing , grinding, etc)	Maintenance operation (reactors)	Cleaning operations (reactors)	General cleaning operations
Filtering devices (air purifying)	Filtering Face piece	P1		✖													
		P2		✖													
		P3	✖	✖													
	Half-Face mask	P1															
		P2			✖				✖				✖				
		P3			✖	✖	✖		✖	✖	✖	✖	✖	✖			
		Combined				✖		✖		✖		✖					✖
	Full-Face mask	P1															
		P2				✖							✖				
		P3				✖	✖	✖		✖	✖	✖	✖	✖	✖	✖	✖

Table 26. List of Respiratory Equipment types to be used in relevant activities in industrial facilities (Source: ITENE)

RPE TYPE		FILTER TYPE	Unpacking (Liquid/Solid)	Unpacking (Bonded /Coated)	Weighing (Dry particles)	Weighing (Liquid dispersion)	Transferring (Solid – dry)	Transferring (Liquid dispersion)	Sonicating	Production (physical and chemical synthesis)	Mixing (Dry Powder)	Mixing (In Luiquid)	Packing /bag filling	Machining operations (sawing , grinding, etc)	Maintenance operation (reactors)	Cleaning operations (reactors)	General cleaning operations
Filtering devices (air purifying)	Filtering Face piece	P1		✖													
		P2		✖													
		P3	✖	✖	✖	✖			✖								✖
	Half-Face mask	P1															
		P2		✖		✖		✖	✖				✖				
		P3		✖	✖		✖	✖		✖	✖	✖	✖				✖
		Combined				✖		✖		✖		✖		✖	✖		
	Full-Face mask	P1															
		P2											✖				
		P3								✖	✖	✖	✖	✖			
		Combined				✖		✖		✖		✖			✖	✖	✖
Air supplied	Half Face	N/A														✖	
	Full-Face	N/A													✖	✖	
	Helmets/Hoods	N/A														✖	

It should be noted that the use of RPE must be complemented with dermal protective equipment, safety goggles, and exhaust ventilation. The following recommendations on the use of RPE are based on the choices defined in tables 25 and 26.

Disposable mask

- Disposable mask are only recommended for material unpacking operations and weighting of small amount of ENMs at laboratory scale.

- Disposable masks (no less than FFP3 AFP 20 standard) are suitable as a precautionary measure during general cleaning operations.

- Disposable masks (no less than FFP3 AFP 20 standard) are suitable as a precautionary measure in partially enclosed operations such as weighing operations and sonication in fumehoods.

Half Mask respirators

Half mask particulate respirators (P3) are suitable in the following operations:
- Weighing of ENMs in powder form (amounts below 500 g)
- Transferring/pouring of ENMs from small containers in partially enclosed operations
- Sonication operations in industrial facilities in partially enclosed operations
- Mixing operations in small containers (5 L / 5 Kg) in partially enclosed operations
- Packing operations of ENMs in dry form in partially enclosed operations
- Machining operations such as sieving, sawing and grinding using safety googles and movable capturing hoods.
- General cleaning operations

Full - Mask respirators

Full mask particulate respirators (P3) are suitable in the following operations:
- Weighing of ENMs in powder form (amounts above 500 g)
- Transferring/pouring of ENMs from containers (> 500 g) in partially enclosed operations
- Discharge operations (gravity) from tanks
- Sonication operations in industrial facilities in partially enclosed operations
- Mixing operations in containers above 5 L / 5 Kg in partially enclosed operations
- Harvesting operations after production stage
- Packing / bag filling operations of ENMs in dry form in partially enclosed operations
- Working areas containing free airborne nanomaterials
- Machining operations such as sieving, sawing and grinding using safety goggles and movable capturing hoods

PPE manufacturers continue working in innovations to provide better protection factors when dealing with ENMs. Recent publications and guidelines include recommendations to be considered when selection a RPE to reduce exposure during nanomaterial production and handling, including:

1. Use of RPE equipped with highly charged microfibers. Much of the RPE manufacturers have available in their product catalogue half mask and full-face respirators incorporating electrostatically charged fibers (electret media).
2. A key parameter to ensure the effectiveness of respiratory protective equipment is the face seal. It is highly recommended to use RPE offering innovation in face seal, ranging from new silicone based materials to inflatable seals. Moreover, the use of a double flange face piece for full-face piece respirators is thought to be both more comfortable and to fit better, because it didn't slip and because the second flange offered a backup seal in case of leakage through the first flange
3. Strap attachment and design can play an important role in the effectiveness of respirators. Five adjustable straps on a full face mask appear to be the minimum number to ensure a seal. It is recommended to avoid a strap across the ears. In this sense, the strap must pass either above or below, with further adjustment generally required because a strap will remain anchored on the back of the worker's head only at certain points.
4. The incorporation of an adhesive sealing material in the face seal has also been reported to increase the fitting factor and reduce the total inward leakage.

It shall be noticed that a wide range of material properties are important to good design, including mechanical, chemical and physical properties, comfort, ability to withstand degradation, thermal conductivity, transparency, compatibility with other parts of the respirator, cost and speech transmission.

Skin protection equipment (SPE)

Most of the studies published recommend wearing chemical protective gloves and protective clothes when working with ENMs.

Use of Skin protection equipment

In order to reduce exposures to ENMs, SPE must be able:

To be resistant to particle penetration and permeation.

To provide protection considering the resistance "compatibility" of the material with ENMs and solvents in which ENMs are dispersed.

The overlap of gloves with other protective clothing and the correct way in which they are put on and removed are of prime importance for the avoidance of possible skin contact.

Double nitrile gloves are recommended.

Air-Tight polyethylene clothes are found to be more resistant to penetration and permeation than cotton or polyester. Concerning chemical protection gloves, the preferential material is nitrile, followed by latex and chemical resistant triple polymers.

The permeation time and the chemical compatibility of the glove/ clothing material with the respective nanomaterial should also be taken into account.

A no-exhaustive list of recommendations concerning chemical protective gloves retrieved from published guidelines and peer reviewed publications is detailed below:

Table 27. Recommended chemical protective gloves

MATERIAL	CATEGORY	APPLICATIONS	CONTACT PERIOD
Nitrile	III	Dry powder ENMs in liquid using nitrile gloves with extended sleeves ENMs in solvents, oils, greases, and some acids and bases.	Incidental Extended (thicker reusable glove)
Latex	III	ENMs in powder or in water suspension Not use with ENMs in organic solvents	Incidental
Butyl rubber	III	ENMs in water / solvents Not recommended with dry dispersions	Extended
Neoprene	III	ENMs is liquid dispersions (if corrosive)	Extended
Cotton	III	Not recommended	-

The following table provides a list of chemical protective gloves to be used under different operations when dealing with ENMs.

Table 28. List of chemical protective gloves to be used in relevant industrial activities (Source: ITENE)

Gloves Type	Unpacking (Solid)	Unpacking (water dispersion)	Unpacking (in solvents)	Unpacking (Bonded /Coated)	Weighting (Dry particles)	Weighing (Liquid dispersion)	Weighting (in solvents)	Transferring (Solid – dry)	Transferring (Liquid dispersion)	Mixing (Dry Powder)	Mixing (In Luiquid)	General cleaning operations	Splashes	Spray	Airborne particles (solid)	Water dispersions	Solvent dispersions
Nitrile	✕	✕	✕		✕	✕	✕	✕	✕	✕	✕	✕	✕	✕	✕	✕	✕
Latex	✕	✕			✕	✕		✕							✕	✕	
Butyl rubber		✕	✕			✕	✕		✕		✕	✕	✕	✕		✕	✕
Neoprene			✕			✕			✕		✕	✕		✕		✕	
Cotton				✕													

In the case of protective clothing, the use of the use of non-woven materials made by synthetic textile fibers is highly recommended. The most common type of material used when dealing with ENMs in occupational settings is made of non-woven high density polyethylene textile. Only in some situations where the likelihood of exposure is low and the ENMs handled are non-toxic, the use of cotton or cotton-polyester materials may provide sufficient protection.

A no-exhaustive list of recommendations concerning protective clothing retrieved from published guidelines and peer reviewed publications is detailed below:

Table 29. List of protective clothing to be used in relevant industrial activities (Source: ITENE)

PROTECTION LEVEL	TECHNICAL MEASURES	EN TYPE	EXPOSURE	EXAMPLES
Disposable Protective coveralls (Full Body Suit)	Polypropylene/ Polyethylene Laminate	3	Strong and directional jets of ENMs dispersed in liquids	
		4	Liquid aerosols of ENMs	
		5	Airborne ENMs (dry particles or fibres)	
			Light spray -splash	
Ventilated / pressurised protective suit	Polymeric materials	EN 1073-1 (Class 4)	Radioactive particules – Radioactive Labelled ENMs	
		EN 1073-1 (Class 5)	Radioactive contaminations	
Disposable Lab. coats	Spunbonded polypropylene		Non recommended (Used for Non-Hazardous dust and light liquid splashes)	
Laboratory coats	Polypropylene Breathable SMS Fabric	6	Light duty protection against non-hazardous spray -splash	
Protective Oversleeves	Microporous PE Laminate		Wearer's arms against light liquid splashes and non-hazardous airborne ENMs.	
Aprons	PVC		Light splash (Non recommended for ENMs)	
Protective Overboot	Microporous PE Laminate		Airborne ENMs Light liquid splashes containing ENMs	

In view of the information retrieved from literature and results from the project, the following recommendations can be defined:

• Particulate protection clothes are mostly made from non-woven fabrics. Porous fabrics are used for particulate protection and coated/laminated fabrics are used for liquid and gas protection.

• Non-microporous PE Laminate offers a good barrier against hazardous ENMs in dry form or dispersed in liquids (water / solvents). This fabric offers excellent barrier protection for sub-micron particles, with up to 99% holdout of < 0.5 micron particles.

• Microporous PE Laminate offers a good barrier against hazardous ENMs in powder and liquid splashes.

• Avoid the use of protective clothing made with cotton fabrics. Woven protective clothing materials offer poorer protection than membrane materials. Additional protection against chemicals may be necessary under certain circumstances.

• Breathability of material is another important factor to be considered. To achieve an effective protection, protective clothing materials that can provide a combination of high barrier performance and thermal comfort is essential.

The following table provides an exhaustive list of specific types of protective clothes that can be used to prevent occupational exposure to ENMS under different situations:

Table 30. List of protective clothing types to be used against ENMs in relevant operations (Source: ITENE). Legend: (R) Recommended; (A) Expert advice needed before use ; (NR) Not recommended; (C) Complementary to recommended

		Full Body Protective coveralls			Laboratory coats		Complementary garments		
Operations	Exposure / Hazard	Microporous Polyethylene Laminate	Non-microporous Polyethylene Laminate	Polypropylene (SMS-SMMMS)	Spun bonded PP Lab. coats	PP Breathable SMS Fabric	Protective Oversleeves	Aprons	Protective Overboot
Material Unpacking (Dry powders)	Airborne particles in the nanometer scale	R	R	R	NR	A	C	C	C
Material Unpacking (Liquid dispersions)	Hazardous nano-aerosols	R	R	R	NR	A	C	C	C
Material Unpacking (Bonded / Coated)	Airborne particles	R	R	R	A	A	C	C	C
Weighing (Dry Powder)	Airborne particles in the nanometer scale	R	R	A	NR	A	NR	NR	C
Weighing (Liquid dispersions)	Hazardous nano-aerosols	A	R	A	NR	A	NR	NR	C
Transferring / Pouring (Dry)	Airborne particles in the nanometer scale	R	R	A	NR	A	NR	NR	C
Transferring / Pouring (Liquid)	Hazardous nano-aerosols	A	R	A	NR	A	NR	NR	C
Sonicating	Airborne particles in the nanometer scale	R	R	R	NR	A	NR	NR	NR
Mixing (Dry Powder)	Airborne particles in the nanometer scale	R	R	A	NR	NR	NR	NR	NR
Mixing (Liquid dispersions)	Hazardous nano-aerosols-Hazardous liquids	A	R	A	NR	NR	NR	NR	NR
Harvesting (Pilot-Industrial reactors)	Airborne particles in the nanometer scale	A	R	A	NR	NR	NR	NR	C
Harvesting (small reactors in laboratories)	Airborne particles in the nanometer scale	R	R	A	NR	A	NR	NR	C
Packing /Bag filling of Hazardous ENMs at laboratory scale (<1 Kg)	Airborne particles in the nanometer scale	R	R	A	NR	A	NR	NR	C
Packing /Bag filling of Hazardous ENMs at laboratory scale (<1 Kg)		A	R	A	A	A	NR	NR	NR
Spraying	Hazardous nano-aerosols	A	R	A	NR	NR	C	C	C
	Non Hazardous nano-aerosols	A	A	R	NR	A	C	C	C
Light duty cleaning	Airborne particles, spills, liquids	R	R	R	NR	R	NR	NR	NR
General industrial cleaning		R	R	R	NR	A	NR	NR	NR
Machining	Airborne particles	R	R	R	NR	A	C	NR	C

Eye protection equipment (SPE)

Safety glasses or goggles are considered to be the appropriate level of eye protection for working with ENMs. Safety glasses should be the minimal eye protection to be worn when appropriate engineering controls (e.g. nano-cabinet or glove box) is being used.

According with the American Industrial Hygiene Association (AIHA), close-fitting safety glasses with side shields provide protection in low hazard, low exposure situations when the ENMs will not become airborne.

Tightfitting, dustproof (i.e., non-vented) safety goggles are recommended in situations involving hazardous ENMs and high exposure potentials. A full face shield is recommended when conducting tasks posing potential for any generation of aerosol and/or droplets.

The risk management measures selected must provide an acceptable level of protection in each activity where a potential exposure to ENMs is expected. Respiratory protective equipment, chemical protective gloves and protective clothing must offer a good barrier against hazardous particles in the nanometer scale (i.e. airborne nanoparticles), liquid splashes, nano-aerosols and liquids (i.e. jets).

The selection of the protective equipment should be based on the specific workplace conditions and results of the risk assessment conducted by a competent person knowledgeable of the operative conditions and exposure situations.

The following table includes a list of different PPE that can be used when dealing with ENMs in the workplace.

Use of eye protection equipment

ILaboratories and other spaces where ENMs are handled must be equipped with an eyewash station.

Safety goggles offer an increased eye protection compared to safety glasses and should be used when:

- Appropriate technical measures are deficient or not available.
- A large amounts of ENMs are being used.
- A suspension of ENMs in solvents / water is being generated and splash or aerosol generation is possible.

Table 31. Recommended PPE when working with ENMs (Source: ITENE)

PROTECTION LEVEL	PERSONAL PROTECTIVE EQUIPMENT
Highly recommended (High protection)	Full Face particulate respirators (P3) Half Face particulate respirators (P3) Nitrile gloves – Double glove for large exposure periods Full body protective coverall (EN type 4-6) made of PE laminated with built-in hood. Tight-fitting, dustproof (i.e., non-vented) safety goggles
Acceptable level of protection (non-hazardous ENMs)	Half-Face particulate respirators (P2) Neoprene gloves / Butyl gloves Full body protective coverall (EN type 4-6) made of polypropylene with or without built-in hood. Laboratory coats (Non-woven) Dustproof safety goggles
Not recommended	Filtering Face piece (FFP3) Latex / Cotton / PVC gloves Laboratory coats (cotton / Spun bonded polypropylene) Safety glasses

Table 32. List of chemical protective clothing to be used according with the type of hazard (Source: ITENE)

SOURCE	PERSONAL PROTECTIVE EQUIPMENT	PROTECTION
Weighing	Airborne ENMs (dry particles or fibres)	Half Face particulate respirators (P3) Nitrile – Latex gloves (Nitrile preferred) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 5) for large amounts Dustproof safety goggles
	Liquid aerosols of ENMs (Irritating nano-aerosols)	Half Face respirators (combined - P3) Double Nitrile gloves (with sleeves) Butyl rubber (ENMs in solvents) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 4-6) for large amounts Tight-fitting safety goggles
Weighing	Airborne ENMs (dry particles or fibres)	Half Face particulate respirators (P3) Nitrile – Latex gloves (Nitrile preferred) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 5) for large amounts Dustproof safety goggles
Mixing	Airborne ENMs (dry particles or fibres)	Full Face particulate respirators (P3) for continuous operations Half Face particulate respirators (P3) for intermittent operations Nitrile – Latex gloves (Nitrile preferred) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 5) for large amounts Dustproof safety goggles (if half mask is used)
	Liquid aerosols of ENMs (Irritating nano-aerosols)	Full Face respirators (combined - P3) Double Nitrile gloves (with sleeves) Butyl rubber (ENMs in solvents) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 3-4-6) for large amounts Tight-fitting safety goggles (if half mask is used)
	Light spray -splash	Half Face mask respirators (Combined - P3) Nitrile(Nitrile preferred) Butyl rubber (ENMs in solvents) Full body protective coverall (EN type 4 & 6) Tight-fitting safety goggles
Spraying operations	Liquid aerosols of ENMs (Irritating nano-aerosols)	Full Face mask respirators (Combined - P3) Half Face particulate respirators (P3) for intermittent operations Nitrile Butyl rubber (ENMs in solvents) Full body protective coverall (EN type 3-4-6) Tight-fitting safety goggles (if half mask is used)
	Light spray -splash	Full Face mask respirators (Combined - P3) Half Face particulate respirators (P3) for intermittent operations Nitrile Butyl rubber (ENMs in solvents) Full body protective coverall (EN type 4 & 6) Laboratory coats (Non-woven) for lab-scale operations Tight-fitting safety goggles (if half mask is used)
Machining	Airborne ENMs (dry particles or fibres)	Full Face particulate respirators (P3) for continuous operations Half Face particulate respirators (P3) for intermittent operations Nitrile – Latex gloves (Nitrile preferred) Laboratory coats (Non-woven) in Ventilated Laboratory Hoods Full body protective coverall (EN type 5) for large amounts Dustproof safety goggles (if half mask is used)
	Airborne agglomerates / aggregates	Full Face particulate respirators (P3) Neoprene gloves Laboratory coats (Non-woven) for lab-scale operations Full body protective coverall (EN type 5) for large amounts Dustproof safety goggles (if half mask is used)
	Large fragments / particles	Filtering Face piece (FFP3) for intermittent operations Half Face particulate respirators (P3) for continuous operations Latex / Cotton / PVC gloves Laboratory coats (cotton / Spun bonded polypropylene) Dustproof safety goggles Safety glasses for low energy operations

Remember

PPE alone should not be relied to provide protection against hazards, but should be used in conjunction with proper technical measures and taolired defined organizational measures.
Consider and evaluate the working conditions under which the operations are carried out, including a thorough evaluation of the type and level of risk to workers and co-workers. The toxic properties of the ENMs must be determined; in particular, the ability of the ENM to cause acute effects by inhalation or dermal contact, or systemic effect due to chronic exposures (i.e. mutagenic – carcinogenic potential).
Careful consideration must be given to comfort and fit. Particular attention should be given in fitting devices for respiratory and eye protection against ENMs in powder and chemical splash.
It is important that all PPE be kept clean and properly maintained. PPE should be inspected, cleaned, and maintained at regular to ensure protection.

7.2. Personal protective equipment selection charts

The selection of personal protective equipment can be conducted according to the actuation sequence presented in the figure below.

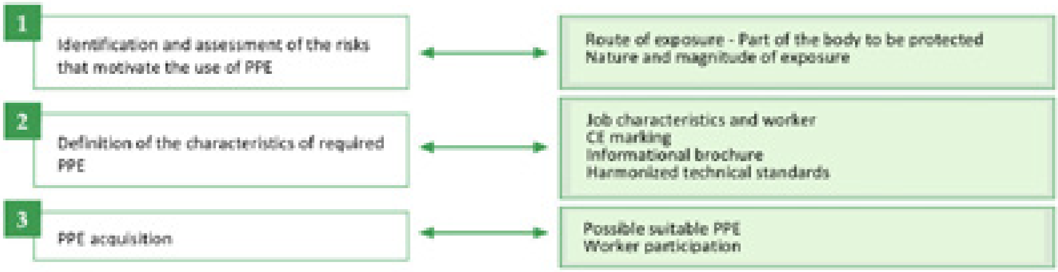


Figure 17. Criteria for the selection of PPE

1. Identification and assessment of the risks that motivate the use of PPE

This first step is to determine the equipment to be used. Depending on the type of exposure, it may be necessary to use one or more PPE. In any case, the type of them come determined by the route of entry of contaminants into the body of professionally exposed workers. In general, it can establish the existence of three basic situations.

If during the course of labor activity, there are several routes of exposure, it will be necessary to resort to the use of various protective equipment simultaneously or the use of a multi-risk equipment. An example of characteristic combination is presented in the table below.

Table 33. Route of exposure and equipment to use

ROUTE OF EXPOSURE	EQUIPMENT TO BE USED
Inhalation	Respiratory protective devices
Dermal	Protective gloves Clothing Footwear
Eye contact	Protection glasses

Table 34. Coexistence of routes of exposure and use of personal protective equipment

ROUTE OF EXPOSURE	RECOMMENDED EQUIPMENT
Route of exposure	Combination of equipment Multi-risk equipment
Inhalation + eye contact	Half mask + filter + protection glasses Full face mask + filter

2. Definition of characteristics of required PPE

PPE should be appropriate to the risk against which they will protect. The sequence of action based on technical parameters that should be considered for different types of equipment is shown in the following decisions diagrams.

A) Respiratory protective devices

The selection of a respiratory protective equipment (RPE) depends on the data provided in the risk assessment, should especially take into account the following:

- Oxygen concentration throughout the duration of the work or exposure.
- Chemical hazardous, including asphyxiants, and physical state of the pollutant (dust, fiber, smoke, gas, steam, etc.).
- Maximum concentration that can be found in the atmosphere and Threshold Limit Value.
- Adaptation of the equipment to the work environment, to the user and to the characteristics of the task
- Other risks (e.g. splashes, sparks, fire...) that are related to work and can influence the selection and use of equipment.

The figure shows a diagram of a possible sequence of action to follow in the selection process of RPE. It can be seen that there are certain factors that lead inescapably to the use of insulating equipment, among which can be highlighted oxygen deficiency, ignorance about contaminants or immediately dangerous to life or health (IDLH) atmospheres.

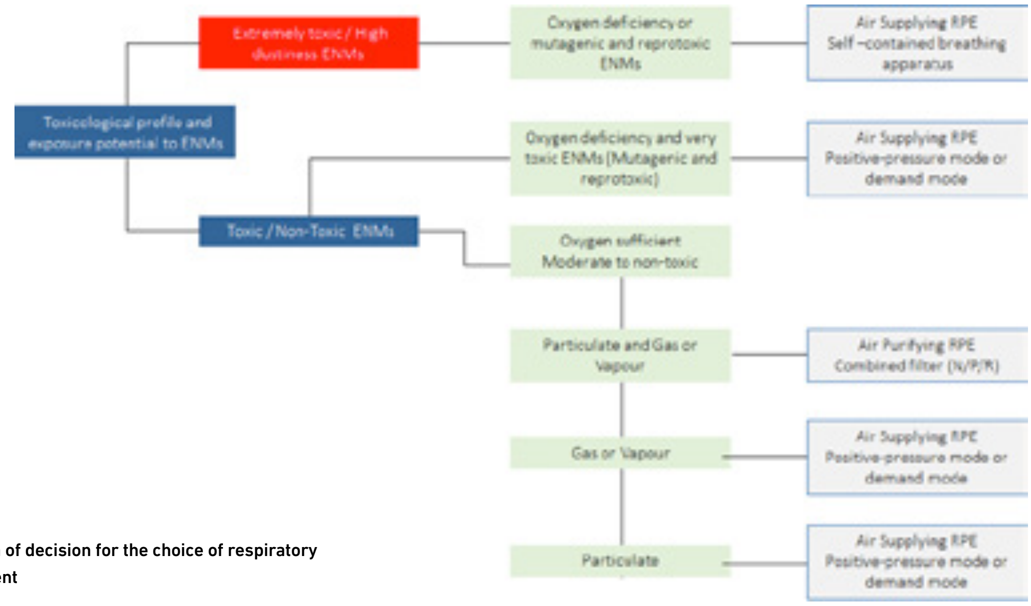


Figure 18. Diagram of decision for the choice of respiratory protective equipment

B) Protective clothing

For chemical protective clothing, the material of manufacturing and the costume design play a key role in the protection. Of the costume design will depend the tightness of the equipment, i.e., the resistance to entry of chemicals, in its different presentation forms (powders, liquids and gases) through seams and joints. The classification of chemical protective clothing that make European standards, in its various types, is based on this tightness (see table 6).

The choice of one or another type of clothing depends on the exposed part of the body and the form of presentation of the contaminant. The figure includes a diagram of decision for selection.

Figure 19. Flow chart for the selection of protective clothing

C) Protective gloves

The level of protection of the glove against a chemical depends mainly on the type of material and the specific chemical. This level of protection is determined based on the material's resistance to permeation of the product through it in laboratory conditions and this parameter is measured in terms of a time of passage or Breakthrough time.

This Breakthrough time, in minutes, serves to classify the glove material into six classes or levels from Class 1 through 6 (see Table 5). The manufacturer should refer in the informative brochure to chemicals tested and to classes of permeation obtained.

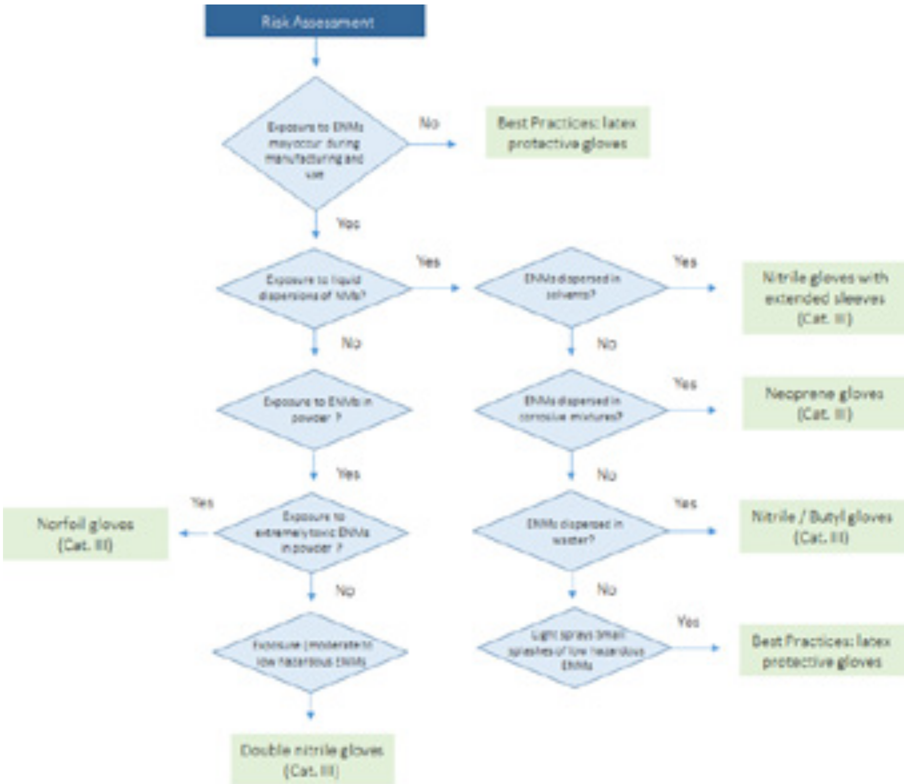


Figure 20. Flow chart for the selection of chemical protective gloves

3. PPE acquisition

The PPE that you select must meet the product safety legislation that is applicable to it (Royal Decree 1407/1992), which in practice means for the user that the equipment must have the CE marking.

Complementarily, among different PPE to respond effectively to the level of risk according to the criteria presented in the previous section, you should select the one that offers a better level of adaptation to both the user and the tasks performed at the workplace. Therefore, it is essential to have the opinion of employees about the various possible solutions. Testing "in situ" is key to support the adoption of the final decision.

7.3 Emission Control Technologies and procedures

Several technologies are starting to appear intended to capture and remove ENMs from air and water streams generated in occupational settings. These technologies are key to control the unintended release of ENMs into the environment, especially freshwater, soil and air. This last compartment is of special relevance due to the wet deposition phenomena, a process in which atmospheric chemicals are accumulated in rain, snow, fog, mists and are then deposited onto soils, water, vegetation, and other non-biotic structures.

Concerning water streams, ENMs can enter wastewater steams at several places in the life cycle: at the production location, at the location where the NMs are used into products and at the location where the

final product is used. In all cases the NMs will have to be removed from the wastewater by the wastewater treatment systems, implemented by the companies or in a central wastewater treatment plant (WWTP), or will otherwise enter to the environment. Hence, efficient removal is particularly important in view of increasing long-term persistence and evidence for considerable ecotoxicity of specific ENMs.

The studies conducted within NanoRISK show that the use current adsorption and filtration technologies can be effective in removing a wide range of ENMs, which might have different properties such as different zeta potentials, surface charge and unpredictable behaviour under the operating conditions of the wastewater treatment system. Ultrafiltration, nanofiltration and reverse osmosis can be used to remove ENMs from wastewater considering the specific properties of the ENMs release, including particle size distribution, speciation, and surface chemistry.

Control of unintended air emission of ENMs
Wet electrostatic precipitators and scrubbers are recommended. Data published on peer reviewed publications show capture efficiencies higher than 90%.

Concerning unintended emissions of ENMs into air, common technologies designed to collect and remove particulate matter are being re-designed. The electrostatic precipitator is used for removing particles, and it has been used satisfactorily to trap and remove dust particles from the exhaust gas stream of an industrial process. However, conventional electrostatic precipitators cannot remove submicron particles and the collection efficiency drops less than 40% when the particle size is less than 1 µm. Scrubbers can also be used to remove some particulates and/or gases from industrial exhaust streams.

Finally, removal of ENMs from soils is still a challenge. Several techniques are applied to remove ENMs from soils, including common techniques such as landfilling. Promising efficiencies of novel techniques such as phytoming and fast crystal growth have been retrieved from peer-reviewed publications. A non-exhaustive list of control technologies for each compartment is collected on table 35.

Table 35. Non-exhaustive list of recommended control technologies to remove ENMs

WATER	AIR	SOIL
Waste water treatment plant • Controls the release of nanomaterials via treated effluent that is discharged into surface waters. **Activated sludge:** • Uses a biological floc composed of bacteria and protozoa in aerobic conditions to remove organic pollutants through three components: 1. A reactor in which the microorganisms are aerated and in contact with the pollutants, 2. Liquid-solid separation 3. Sludge recycling system. **Nanoporous membranes:** • Consists of a regular organic or inorganic framework supporting a regular and porous structure of sizes < 100 nm. • Most nanoporous materials can be classified as bulk materials (activated carbon and zeolites) or membranes (cell membranes). **Electrofiltration, microfiltration and nanofiltration:** • Combines membrane filtration and electrophoresis in a dead-end process for separation of colloidal substances. • Minimizes the film formation on the filter membrane through the application of an electric field.	**Electrostatic precipitator:** • Used for removing particles, cleaning of flue gas from large-capacity factories, combustion furnaces, and thermal power plants. • Wet electrostatic precipitator reaches > 90% of removal efficiency for NPs with diameters 80- 600 nm. **Scrubber:** • Pollution control device that use liquid to wash unwanted pollutants from a gas stream to remove some particulates and/or gases from industrial exhaust streams	**Incineration:** • Involves the combustion of organic substances contained in waste materials • Converts the waste into ash, flue gas, and heat which must be cleaned of gaseous and particulate pollutants before they are dispersed into the atmosphere • A post treatment system such as gas cleaning system as filter and acid washing flue gas or electrostatic precipitator and a scrubber must be coupled • Residues normally end up in landfills, thus the problem of nanoparticles is transferred to the following stage. **Landfilling:** • Can be applied directly to untreated residues containing nanowaste as well as to sludge and ashes from the prior processes of water treatment and incineration. **Fast crystal growth:** • Is an alternative to incineration for the treatment of industrial sludge containing amorphous/nanophase metal oxides or hydroxides or stabilize ash from the incinerator **Phytomining / Phytoremediation:** • Plant and harvest vegetation that selectively concentrate specific metals from the environment into their leafs • Some plants are natural hyperaccumulators, in others the property can be induced

8 Health Surveillance

This chapter provides an overview of recent developments concerning exposure and health monitoring of workers who might be expose to nanomaterials. The current situation is that there is a huge lack of data of the exposure of nanomaterials in human. The health effects of nanomaterials exposures are largely unquantified and currently there are not any reports of any correlated human disease that is caused by nanomaterial exposure. Specific health endpoints on which human studies should be focused are similarly not well elucidated or agreed upon and chronic effect studies with adequate latency are unlikely to be completed in the near future.

8.1. Health Surveillance

Health surveillance and medical screening offer important means for assessing the health of exposed workers, which can be used to identify adverse health outcomes resulting from exposure. At the time of writing, although health hazards caused by ENMs have not been confirmed in humans, evidence accumulating from animal studies suggest that exposure to some ENMs could be harmful (Liou et al. 2016).

Health Surveillance
Initial epidemiological studies found biological changes that might be indicative of disease in nanomaterial-handling workers.

According with Bergamaschi (Bergamaschi et al.2015), evaluation of the possible health effects from exposure to NMs requires a stepwise approach considering the knowledge of the likelihood of a known exposure, tracking changes of such characterized exposure over time by exposure registries, conducting targeted epidemiological investigations, and possibly applying selected biomarkers.

To date, scientific knowledge about the health effects of most nanomaterials is limited, and the number of epidemiological studies of workers´ exposure to ENMs is scarce, with no more than 15 studies completed worldwide. Hence, there is a need to assess the risk of potentially adverse health effects among workers handling ENMs, and to recommend biological markers, as well as preclinical and clinical outcomes that might be useful for their periodic examination to prevent late/delayed effects and identify failures of disease prevention (Bergamaschi et al . 2015; Schulte et al. 2008).

Several initiatives to support the health surveillance in relation to ENMs are starting to appear. In 2014, a detailed guidance was developed under the framework of the FP7 funded project Scaffold. Recently, the French Institute of Public Health Surveillance conducted an epidemiological surveillance study on work stations potentially causing exposure to ENMs (EpiNano).

This French national epidemiological surveillance program aims at surveying mid- and long-term health effects possibly related with occupational exposure to either CNTs or $TiO2$ nanoparticles. This program proposes the use of an on-site technical logbook to identify those work areas where a potential exposure to ENMs is likely to occur, in site exposure assessments to identify specific task (job-exposure matrix), and the identification of workers of concern.

The information retrieved within EpiNano will be introduce in a exposure registry containing information on the levels of exposure in several operations during the production, processing or use of ENMs in occupational settings.

A recommended approach to support the health monitoring of workers who might be expose to ENMs is presented below. This approach is based on the recommendations of NIOSH, the health council of the Netherlands, and information retrieved from peer reviewed publications, and considers 5 main steps:

Step 1. Identification of the ENMs and/or nanoenabled products used at the workplace.
Step 2. Evaluation of the potential exposure to ENMs to elucidate the likelihood of exposure to ENMs based on the analysis of the process and the compilation of information by means of questionnaires.
Step 3. Evaluation of the level of exposure by means of modelling approaches or measurement campaigns.
Step 4. Complete a risk assessment considering recommended exposure levels (RELs) for ENMs.
Step 5. Health Monitoring by means of biomarkers - biomonitoring

These steps are described in the flowchart below. Recommended approaches to support the exposure assessment are also included (figure 21).

Figure 21. Flow chart of recommend health monitoring procedure on workers exposed to ENMs

The person assigned to conduct the health monitoring of workers should be a qualified health care professional who is informed and has knowledge of the working areas where a exposure risk has been identifies, routes of exposure, and potential effects of ENMS used.

NIOSH proposed a set of recommendations for the medical screening of workers exposed to CNT or CNF, including:

- An initial evaluation, consisting of occupational and medical history conducted by a qualified health professional, with an emphasis on the respiratory system
- A physical examination with an emphasis on the respiratory system
- A spirometry test
- A baseline chest X-ray
- Other examinations or medical tests deemed appropriate by the responsible healthcare professional
    - These should be based on factors such as work-related symptoms noted at evaluation
    - Results of hazard information (e.g. toxicity information) and exposure
- Periodic evaluations
    - Periodic analysis of the medical screening data collected at a workplace by an epidemiologist or other specialist

NIOSH does not recommend specific medical screenings for workers potentially exposed to other ENMs, because there is currently insufficient scientific and medical evidence on health effects.

More observational studies in occupationally exposed workers are needed to carry out strictly controlled epidemiological studies. Epidemiological studies must consider biological biomarkers (BM) as indicators of exposure-specific disease outcomes.

Health Surveillance

It is recommended to include a regular follow-up examination of the respiratory and the cardiovascular system in workers likely to be exposed to ENMs.

Concerning biomonitoring, scientists are developing non-invasive methods to measure biomarkers in blood, urine, and breath in order to identify individuals at risk, and then intervene using disease prevention and early detection strategies. Biomonitoring can help determine the relationship between exposure and disease, and target prevention or remediation efforts more appropriately.

Biomonitoring can be used as a tool for occupational health by identifying potential hazards of nanoparticles, indicators of exposure or early disease. It is based on the identification of biomarkers, which are regarded as early biological signs which are indicative of an actual or potential condition. Biomonitoring measures personal environmental exposures to toxic substances by measuring the substances or their metabolites in human specimens, such as blood or urine rather than inferring exposure from chemical concentrations in air, water or soil.

The already published nanotoxicology literature includes clues about exploratory biomarkers that can be used to establish biologically plausible statistical associations between exposure and health effects. Table 36 suggest a list of exploratory biomarkers used in current epidemiological studies conducted in workers exposed to ENMs.

Table 36. Exploratory biomarkers retrieved from published epidemiological studies of ENMs

RESPONSE	EXPLORATORY BIOMARKERS
Cardiovascular effect	VCAM- Vascular cell adhesion molecule ICAM - Intercellular adhesion molecule hsCRP - Highly sensitive C-reactive protein MPO - Myeloperoxidase Paraxonase
Pulmonary effects	Serum pneumoproteins (CC16) Surfactant associated protein B (SP-B) FENO – Fractional exhaled nitric oxide Krebs Von den Lungen 6 (KL-6) Macrophage inflammatory protein-1β Sputum IL-1 β Interleukin-8 (IL-8)
Oxidative stress	Decresed antioxidant enzymes (SOD, GPX) EBC markers of lipids oxidation (MDA, HNE, HHE, 8-Isoprostane, n-hexanal, C6-C12) DNA and protein oxidation markers (8-OHdG, 8-OHG, 5-OHMeU, 3-NOTyr, 3-NOTyr, o-Tyr)

Considering the potential risk for cancer from exposure to ENMs (and demonstrated for some nanomaterials) and previous dramatic experiences with too late surveillance of occupational exposures to similar substances (e.g. to asbestos), there is an urgent need to define and implement adequate scientifically sound biomonitoring methods and programme for exposure to nanomaterials. The design of human biomonitoring studies should be based on:

- The route of exposure
- Information on the bio-distribution and kinetics in vivo in animal studies of the nanomaterials to which workers are exposed
- The known mode of action of nanomaterials to which workers are exposed

Instruction sheets

Respiratory protection equipment

TYPES

- FFR- Particulate Filtering Face piece Respirators (Filtering half mask)
- Half Mask Respirators (Filters: P1/P2/P3)
- Full Face Masks (Filters: P1/P2/P3)
- Particulate filters (Cartridges)

CERTIFICATION AND TESTING

- EN 13274-1:2001. Respiratory protective devices. Methods of test. Determination of inward leakage and total inward leakage
- EN 13274-7:2008 Respiratory protective devices. Methods of test. Determination of particle filter penetration
- EN 149 / EN 140 / EN 136 / EN 143

MAINTENANCE AND CLEANING

- Inspect respirators for cleanliness and damage before each use.
- Filtering face piece respirators can be reused by the same worker, but only if the respirator is working properly, its shape remains unchanged, and the filter material is not physically damaged or soiled.
- A respirator inspection must include a check of the respirator's ability to work properly; the tightness of any connections; and the condition of the various parts, such as the face piece, head straps, valves, tubes, hoses, and any cartridges, canisters, or filters.
- Store respirator in sealed bag in a clean, dry, non-contaminated area.
- Replace respirator and/or cartridge or filter if it is damaged, distorted, a proper fit cannot be obtained, or breathing becomes difficult.
- If your respirator fails an inspection or is defective, your employer must remove it from service and either repair it or discard it.

RECOMMENDED RPE AGAINST ENMS

Half Mask Respirators (Filters: P3)

Full Face Masks (Filters: P3)

Perform a negative or positive seal check each time before entering a contaminated area.

Chemical Protective Gloves

TYPES

• Single-use chemical protective gloves
• Barrier materials: Nitrile / Latex / Butyl rubber / Neoprene / Norfoil gloves / Cotton

CERTIFICATION AND TESTING

• EN 420:2003+A1:2010, EN 420:2004+A1:2010, ERRATUM: 2011. Protective gloves - General requirements and test methods.
• EN 374-2:2004. Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration
• EN 16523-1:2015. Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact.

USE AND CARE OF PROTECTIVE GLOVES

• Don't wear chemical-resistant gloves that are damaged.
• Be sure the gloves you plan to wear are clean. Don't touch them if you're not sure
• Carefully inspect the gloves before you put them on. Look for cracks, tears, holes, swelling or other damage. Nanomaterials can pass through even the smallest pinhole.
• Never touch contaminated gloves with bare hands.
• Wash your hands with soap and water before you put on the gloves. Bandage any minor cuts or scrapes.

RECOMMENDED RPE AGAINST ENMs

• Don't wear leather or cotton gloves when handling chemicals
• Gloves worn with chemical-resistant sleeve guards are ideal for mixing and loading highly toxic NMs in dry form or dispersed in liquids (solvent / water)
• Nitrile gloves are recommended – Double glove for large exposure periods
• Latex gloves recommended only when handling ENMs in powder or in water suspensions
• Butyl rubber not recommended with ENMs in organic solvents.

Protective Clothing

TYPES

- Disposable Protective coveralls (Full Body Suit)
- Ventilated / pressurised protective suit
- Disposable laboratory coats
- Protective Oversleeves
- Aprons and protective overboots

CERTIFICATION AND TESTING

- EN ISO 13688:2013. Protective clothing - General requirements.
- EN 14605:2005+A1:2009. Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections.
- EN ISO 13982-1:2005, EN ISO 13982-1:2005/A1:2011. Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) (ISO 13982-1:2004).
- EN ISO 13982-2:2005. Protective clothing for use against solid particulates - Part 2: Test method of determination of inward leakage of aerosols of fine particles into suits (ISO 13982-2:2004).
- EN 13034:2005+A1:2009. Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6).

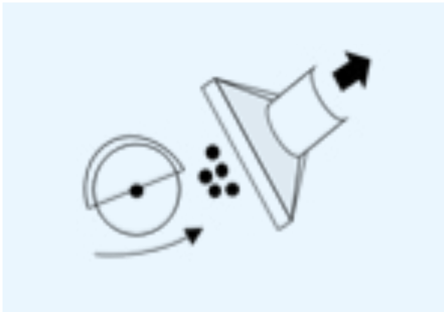
MAINTENANCE AND CLEANING

- The wearer must understand all aspects of protective clothing elements and their limitations.
- During protective clothing use, end users should be encouraged to report any perceived problems or difficulties to their supervisor, including: degradation of the protection ensemble, discomfort and restriction of movement.
- The anticipated duration of use should be established: factors such as suit ensemble permeation, degradation, and penetration by chemical contaminants, including expected leakage through suit, can limit the length of a mission.
- Ensure all closures and ensemble component interfaces are completely secured; and that no open pockets that could serve to collect contaminant are present.
- Protective clothing or equipment reuse depends on demonstrating that adequate decontamination has taken place: consider always a visual examination of protective clothing for signs of discoloration, corrosive effects, or any degradation of external materials.

RECOMMENDED RPE AGAINST ENMS

Full body protective coverall (EN type 4-6) made of PE laminated with built-in hood)
Full body protective coverall (EN type 4-6) made of polypropylene with or without built-in
Laboratory coats (Non-woven)

Local Exhaustive Ventilation (LEV)



TYPES

a) Enclosing Hoods
- Laboratory Glove Box (complete enclosure)
- Down-flow room (complete enclosure)
- Horizontal/downward laminar flow booth
- Laboratory Hood (partial enclosure)
- Walk-in booths
- Paint spray booth (partial enclosure)

b) Capturing Hoods
- Movable LEV systems (extendable arms)
- HEPA Filtered down flow booth
- Fixed Capturing Hoods
- On tool extraction

c) Receiving hoods

CERTIFICATION AND TESTING

- EN 14175-4:2005. Fume cupboards. Part 4. On-site test methods
- ASHRAE 52 2007. Method of testing general ventilation air-cleaning devices for removal efficiency by particle size.

MAINTENANCE AND CLEANING

- Maintenance Opening: The entire mechanical and electrical equipment of the ventilation system should be accessible via a secure and suitable opening.
- A fume cupboard function display should be installed to definitely indicate the correct functioning of the fume cupboard airflow.
- Routine checks on LEV systems must be undertaken by appropriately trained employees. The frequency of such checks will be determined by making reference to the manufacturer's recommendations, risk assessment findings, previous maintenance history, etc and should be recorded in the systems logbook.
- Before use: thorough visual examination to verify the LEV is in efficient working order, in good repair and in a clean condition.
- When installing LEV, use a reputable supplier, with experience of the type of control that is needed who can demonstrate that their system will adequately control potential contaminants.

RECOMMENDED RPE AGAINST ENMs

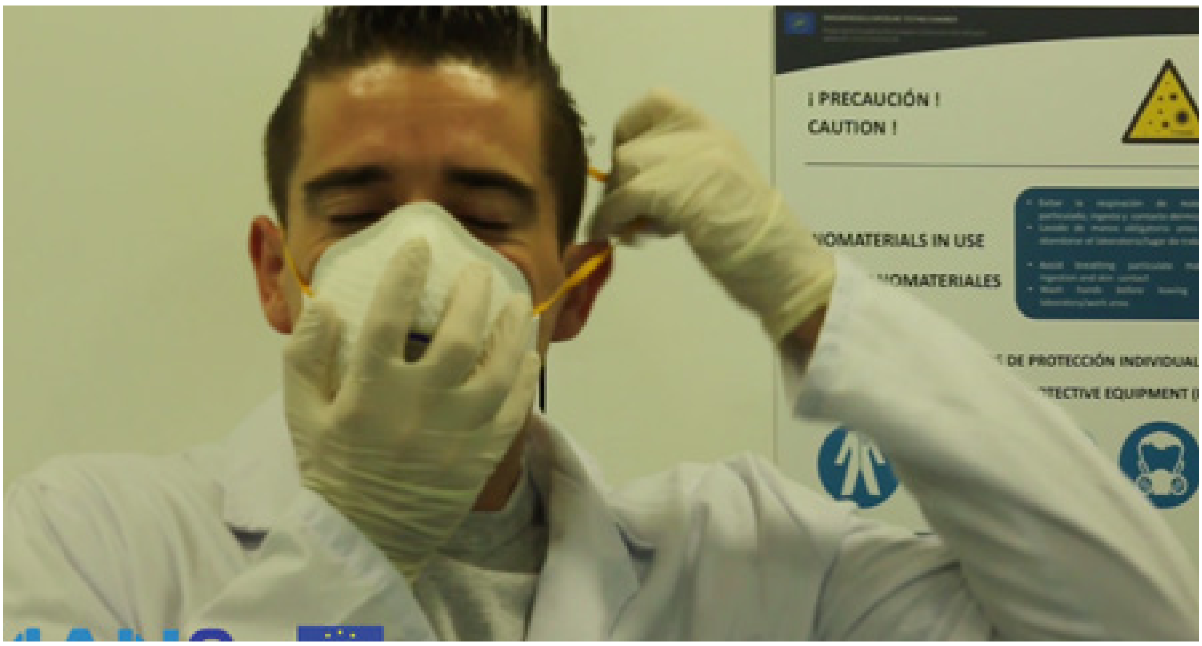
- Local exhaust enclosure (Glove Box)
- Ventilated Laboratory Hood (partial enclosure)
- HEPA filtered down flow booth
- Ventilated Laboratory Hood + built-in water wash down systems (sprays)
- Movable LEV systems (extendable arms)
- Receiving hood (hot process)

Sequence* for Donning PPE

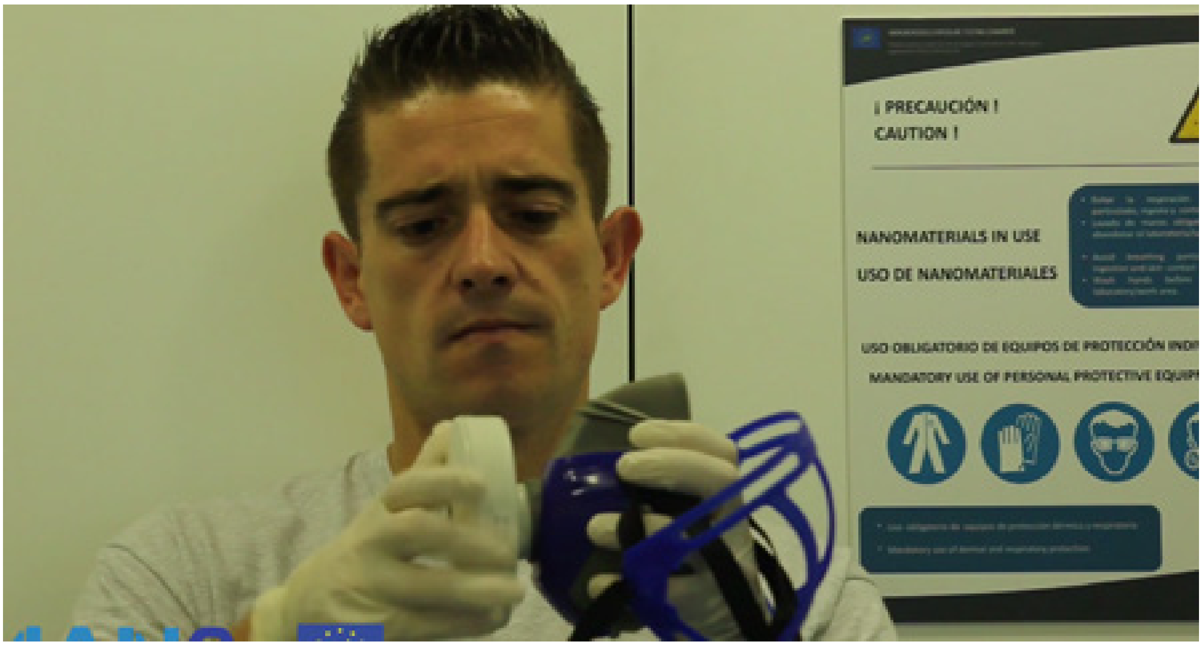
To reduce the risk of exposure to ENMs, PPE must be used appropriately. The following videos outline sequences and procedures for putting on and removing PPE. Please, watch with attention the set of videos developed under the framework of the project NanoRISK to support workers on the use of PPE.

1. Putting on and removing PPE- Video 1

2. Putting on and removing PPE - Video 2



3. Putting on and removing PPE - Video 3



2. Putting on and removing PPE - Video 4

Supplementary Information available on the web site

http://www.lifenanorisk.eu

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Annexes

FIGURES

TABLES

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