

NANOMATERIALS IN THE HEALTHCARE SECTOR: OCCUPATIONAL RISKS AND PREVENTION

The field of nanotechnology is advancing rapidly and the use of nanomaterials is becoming more common. As is the case with a broad range of industries, the healthcare sector is becoming increasingly influenced by nanotechnology, and this poses a greater risk for the exposure of workers to nanomaterials within their occupational settings. Nanotechnology and nanomaterials in healthcare applications can offer various benefits, for example miniaturisation techniques and approaches have converged with chemical synthesis and control of molecular assembly to produce exciting opportunities for the prevention, diagnosis and treatment of disease. However, despite ongoing research, the field of nanotechnology is developing faster than the generation of knowledge on the health and safety aspects of nanomaterials. There are still many unknowns, which raises questions concerning the evaluation of occupational safety and health (OSH) risks.

This e-fact explains how healthcare workers might come across nanomaterials in their workplaces when undertaking their everyday activities. It also provides information about steps that can be taken to prevent potential exposures.

1 Introduction

1.1 The healthcare sector

A large proportion of the EU workforce is employed in the healthcare sector. According to the Action Plan for the EU Health Workforce [1], job opportunities within this sector are increasing as a result of the ageing population and subsequent increases in healthcare demands.

The healthcare sector consists of enterprises and public services directly or indirectly providing different types of health services, such as diagnosis, treatment and preventative care. Locations of healthcare services may vary and can include hospitals, dental clinics, mobile emergency medical care and homes. This e-fact deals primarily with persons directly providing medical services (e.g. doctors, nurses or pharmacists), as well as workers closely linked to the healthcare sector, for example people working in laboratories or workers undertaking cleaning activities. Administrative workers or workers producing medical equipment do not fall under the scope of this e-fact and are therefore not covered.



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1.2 What are nanomaterials?

Nanomaterials are materials containing particles with one or more dimension between 1 and 100 nm ⁽¹⁾, a scale comparable to atoms and molecules. They may be natural, such as from volcano ashes, or an unintended consequence of human activities, such as those contained in diesel exhaust fumes. However, a large number of nanomaterials are intentionally manufactured and placed on the market, and it is these that this e-fact focuses on in the healthcare sector.

Even though nanomaterials can form agglomerates or aggregates that can be larger than 100 nm, these can decompose and release nanomaterials. Therefore, these agglomerates/aggregates should also be considered in any nanomaterial risk assessment [3, 4].

A large proportion of nanomaterials are manufactured and placed on the market because they exhibit specific properties and behaviours that are mainly a result of their small size, and therefore manifold larger surface areas, or of other characteristics, such as modified (coated) surfaces or a specific morphology (particle shape). This e-fact will focus only on manufactured nanomaterials found in the healthcare sector and will not include those that arise as unintended consequences of human activities, for example nanoparticles found in diesel exhaust fumes.

2 Nanomaterials in the healthcare sector

Once in the body, nanomaterials can circulate through the body by moving in and out of blood vessels, enter cells and interact with biomolecules both on the cell surface and inside cells in numerous areas of the human body [5]. As a result of this ability, nanomaterials in healthcare have the potential to detect diseases, deliver treatments and allow prevention in new ways.

The main therapeutic benefits of using nanomaterials are as follows: solubility (for otherwise insoluble drugs), carriers for hydrophobic entities, multifunctional capability, active and passive targeting, ligands (size exclusion) and reduced toxicity [6]. Furthermore, because of their specific properties, nanomaterials are also used in diagnostic tools, in imaging agents and methods and for implants and tissue-engineered constructs.

The properties and behaviours of nanomaterials therefore allow the diagnosis, monitoring, treatment and prevention of diseases, such as cardiovascular diseases, cancer, musculoskeletal and inflammatory conditions, neurodegenerative and psychiatric diseases, diabetes and infectious diseases [e.g. bacterial and viral infections, such as HIV (human immunodeficiency virus)] [7].

Table 1 details some of the nanomaterials already in use in the healthcare sector.

Table 1: Main types of nanomaterials in healthcare applications

Type of nanomaterial	Applications in healthcare
Metallic particles (e.g. iron (III) oxide, gold or silver)	<ul style="list-style-type: none"> ▪ Hyperthermia cancer treatment ▪ Selective magnetic bioseparations ▪ Coated with antibodies to cell-specific antigens, for separation from the surrounding matrix ▪ Membrane transport studies

⁽¹⁾ According to the European Commission's Recommendation [1]:

- A "nanomaterial" is "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 1 nm - 100 nm. The number size distribution is expressed as number of objects within a given size range divided by the number of objects in total."
- "In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%."
- "By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

Type of nanomaterial	Applications in healthcare
	<ul style="list-style-type: none"> ▪ Drug delivery ▪ Magnetic Resonance Imaging contrast agent
Silver nanoparticles	<ul style="list-style-type: none"> ▪ Anti-microbial agent ▪ Incorporated into a wide range of medical devices, including bone cement, surgical instruments, surgical masks
Gold shell nanoparticles	<ul style="list-style-type: none"> ▪ Improve solubility of drugs ▪ Permit further conjugation
Carbon nanomaterials [fullerenes and carbon nanotubes (CNTs)]	<ul style="list-style-type: none"> ▪ ‘Buckyballs’ (football-shaped structures made of 60 carbon atoms) are used in drug delivery systems to support the optimal transport and release of medicines to the right target inside the body [5] ▪ Coatings for prosthetics and surgical implants ▪ Functionalised CNTs: <ul style="list-style-type: none"> ○ for therapeutic delivery ○ for biomedical applications such as vascular stents and neuron growth and regeneration ○ gene therapy, as a strand of DNA can be bonded to a nanotube
Quantum dots	<ul style="list-style-type: none"> ▪ Tag multiple biomolecules to monitor complex cellular changes and events associated with diseases ▪ Optics technology [8] ▪ Disease diagnosis and screening technologies
Dendrimers	<ul style="list-style-type: none"> ▪ Polymerised macromolecules—highly branched structures with interior nanocavities or channels with properties different from those on the exterior ▪ Used as a carrier for a variety of drugs (e.g. anti-cancer, anti-viral, anti-bacterial, etc.) with capacity to improve solubility and bioavailability of poorly soluble drugs
Lipid-based nanoparticles	<ul style="list-style-type: none"> ▪ Can fuse with the cell membrane and deliver molecules inside the cells
Ceramic nanoparticles	<ul style="list-style-type: none"> ▪ Inorganic systems used as drug vehicles (if porous and biocompatible); used in cosmetic applications (zinc oxide, titanium dioxide)
Nanotubes, nanowires, magnetic nanoparticles	<ul style="list-style-type: none"> ▪ Disease diagnosis and screening technologies, including ‘lab on a chip’ [8]

Compiled by the authors from a range of sources [5, 6, 8–11].

The timescale from the invention of a medical device or drug to its release for clinical use is extremely long. However, at present certain nanotechnology applications are in development and will become available imminently. These will address, for example, enhanced medical imaging [5], the use of subcutaneous chips that can continuously monitor key parameters including pulse, temperature and blood glucose levels [5], and the minimisation of pathogen growth and transfer [8].

3 Risks from nanomaterials for healthcare workers

Although nanomaterials in the healthcare sector may offer a large number of benefits for patients, they may also expose healthcare workers to new risks.

There is still a knowledge gap in the information available regarding the toxicity of manufactured nanomaterials, which makes performing risk assessments difficult (see e-fact 72 available at: (<https://osha.europa.eu/en/publications/e-facts/e-fact-72-tools-for-the-management-of-nanomaterials-in-the-workplace-and-prevention-measures/view>) on risk management tools for nanomaterials). The main challenge is to understand the possible hazards healthcare workers may face when working with manufactured nanomaterials or nanodevices. Owing to the unique properties of these materials at the nanoscale - mainly linked to their small size but also particle shape, chemical nature, surface state (e.g. surface area, surface functionalisation, surface treatment) and state of aggregation/agglomeration [8, 12] - their interactions with the human body and consequently their health effects are expected to be different from those associated with the same materials of the same composition at the macro scale. Therefore, this raises concerns about the health effects that might result from occupational exposures to nanomaterials.

Under normal environmental conditions, nanomaterials may form agglomerates or aggregates larger than 100 nm, thereby changing (but not necessarily losing) their nano-specific properties. However, nanomaterials may be released again from weakly bound agglomerates and, under certain conditions, even possibly from more strongly bound aggregates. It is being investigated whether this could happen in lung fluid after inhalation of such agglomerates or aggregates [8, 12]. Agglomerates and aggregates containing nanomaterials should therefore also be taken into consideration in the workplace risk assessment.

The internal exposure mechanism, following the entry of nanomaterials into the body, could include further absorption, distribution and metabolism. Some nanomaterials have been found in, for example, the lungs, liver, kidneys, heart, reproductive organs, fetus, brain, spleen, skeleton and soft tissues [13]. There are open questions concerning the bioaccumulation of nanomaterials and elimination mechanisms from cells and organs. An additional issue is that, while a nanomaterial itself may not be toxic, it could act as a Trojan horse, meaning that a more toxic material may attach itself to the nanomaterial and gain entry to the body, organs or cells [14].

The most important effects of nanomaterials have been found in the lungs and include inflammation, tissue damage, oxidative stress, chronic toxicity, cytotoxicity, fibrosis and tumour generation. Some nanomaterials may also affect the cardiovascular system. The potentially hazardous properties of manufactured nanomaterials are a matter of ongoing research [8, 12].

There is a variety of pathways through which nanomaterials can enter the human body that may pose an occupational health hazard:

- **Inhalation** is the most common route of exposure to airborne nanoparticles in the workplace [15, 16]. Inhaled nanoparticles can deposit in the respiratory tract and the lungs depending on their shape and size. Following inhalation, they may cross the pulmonary epithelium, enter the bloodstream and reach further organs and tissues. Some inhaled nanomaterials have also been found to reach the brain via the olfactory nerve.
- **Ingestion** can occur from unintentional hand-to-mouth transfer from contaminated surfaces, or by ingestion of contaminated food or water. Ingestion may also occur as a consequence of inhalation of a nanomaterial, as inhaled particles that are cleared from the respiratory tract via the mucociliary escalator may be swallowed [15, 16]. Some ingested nanomaterials may cross the intestinal epithelium, enter the bloodstream and reach further organs and tissues.
- **Dermal** penetration is still being investigated [15, 16]. Intact skin seems to be a good barrier against the uptake of nanomaterials [17]. Damaged skin seems to be less effective, but the level of uptake is likely to be lower than that associated with inhalation. However, notwithstanding this, dermal contact should also be prevented and controlled.

Nanomaterials can also be introduced into the human body via the parenteral route ⁽²⁾; accidentally through needlestick injury, cuts and other damage to the skin [15].

Considering the activities that are undertaken within the healthcare sector, the workers who are most likely to be exposed to nanomaterials are those who prepare or administer nanodrugs or who work in areas where these drugs are used, as they can readily come into contact with these airborne agents (e.g. pharmacy and nursing personnel, physicians, environmental service workers, shipping and receiving personnel).

Other exposure situations to nanomaterials in the healthcare settings [15] may occur during:

- disposal of excreta from patients receiving nanodrugs;
- nanomaterial spills;
- handling of nanomaterial-contaminated items;
- consumption of food and beverages that have come into contact with nanodrugs; and
- cleaning and maintenance of areas where nanodrugs are handled.

Possible exposure situations can be found in dental and surgical procedures involving the milling, drilling, grinding and polishing of applied medical materials containing nanomaterials. An example of such an exposure situation is the treatment of tooth cavities in dental care, which is commonly done by applying fillings containing nanomaterials (e.g. nano-ceramic fillers) that are adjusted to the anatomical form by sanding the surface using high-speed tools. During this procedure there is a risk of nanoparticles becoming airborne and being inhaled by both the patient and healthcare personnel.

Some of the potential OSH risks resulting from nanomaterials in the healthcare sector are presented in Table 2.

Table 2: Examples of nanomaterials used in the healthcare sector and their potential health hazards and OSH risks

Example of nanomaterials	Potential health hazards and OSH risks
Carbon nanomaterials	When inhaled, there is evidence that some types of carbon nanomaterials can lead to lung disorders, including asbestos-like effects [9]
Dendrimers	In spite of extensive applicability in the pharmaceutical field, for example in delivery of anti-cancer drugs, the use of dendrimers in the human body is restricted because of their inherent toxicity [11]. There has been a case of erythema-multiforme-like contact dermatitis resulting from exposure to dendrimers [14].
Silver nanoparticles	According to ENRHES [18], the use of silver nanoparticles represents a potential hazard to human health; however, the study of its toxicity is still in its infancy. The EU's Scientific Committee on Emerging and Newly Identified Health Risks was asked for a scientific opinion on the safety, health and environmental effects and role in anti-microbial resistance of nanosilver [19]. Serious concerns arise because silver nanoparticles, at high doses, can cause adverse health effects, such as pulmonary oedemas and skin stains [3]. In fact, the most commonly reported response of humans to prolonged nanosilver exposure is argyria or argyrosis (i.e. grey or grey-blue discolouration or black pigmentation of the skin, nails, eyes, mucous membranes or internal organs by silver deposits) [20]. These conditions cannot be reversed and are incurable [20].

⁽²⁾ If a medication or other substance is introduced into the body parenterally, it is introduced via a route other than the gastro-intestinal tract (e.g. injection).

	<p>In the healthcare sector, nanosilver has been used as an anti-bacterial agent in wound dressings to protect patients with severe burns against infections. This results in one of the main exposure risks for healthcare workers. Furthermore, concerns were raised about indirect adverse effects of nanosilver on human health through an increasing resistance of micro-organisms to silver [19].</p> <p>In research carried out on rats, it was documented that silver nanoparticles can reach the brain through the upper respiratory tract [12]</p>
Titanium dioxide (TiO ₂)	<p>TiO₂ particles, when inhaled, have been classified by the International Agency for Research on Cancer (IARC) as Group 2B, 'possibly carcinogenic to humans' [21]. NIOSH (the National Institute for Occupational Safety and Health), in the USA, recommended a lower exposure limit for ultrafine particles of TiO₂: 0.3 mg/m³ for TiO₂ nanoparticles (<100 nm) versus 2.4 mg/m³ for fine particles (>100 nm) [22]</p>
Gold Nanoparticles	<p>The toxicity of gold nanoparticles, when inhaled by rats, has been studied, and an accumulation of gold in the lungs and kidneys was observed [23]</p>

Source: compiled by the authors.

In addition to health risks, the aerosolisation of nanodust or combustible nanoparticles can pose a risk of explosion or fire.

It is important to properly assess and manage the possible OSH risks of nanomaterials in the healthcare sector in order to protect workers' safety and health adequately.

4 Prevention

According to EU Directive 89/391/EEC [24], employers must conduct regular workplace risk assessments and put in place adequate prevention measures, and this also applies to the potential risks of nanomaterials in the workplace. In addition, Directive 98/24/EC on chemical agents at work [25] imposes more stringent provisions on the management of risks from substances at work, which also apply to nanomaterials as these fall within the definition of 'substances'.

Therefore, the mandatory workplace risk assessment and the hierarchy of control measures [elimination, substitution, technical measures at source, organisational measures and personal protective equipment (PPE) as a last resort] prescribed in these workers' protection directives also apply to workplaces in the healthcare sector and nanomaterials.

In addition, if a nanomaterial, or the macro-scale material of the same composition, is carcinogenic or mutagenic, Directive 2004/37/EC on carcinogens and mutagens at work [26] must be fulfilled. In any case, national legislation may have stricter provisions and should be consulted.

However, carrying out the workplace risk assessment of nanomaterials may, in general, be challenging because of the current limitations related to:

1. knowledge of the hazardous properties of nanomaterials;
2. methods and devices available to identify nanomaterials and the sources of emission and measure exposure levels; and
3. information on the presence of nanomaterials, in particular in mixtures or articles as well as down the user chain, when nanomaterials or products containing nanomaterials are used or processed.

Safety Data Sheets (SDSs), which are an important information tool for the prevention of risks from hazardous substances in workplaces, contain in general little or no information about the presence of nanomaterials and their characteristics, risks to workers and prevention [13, 27–29]. Organisations are therefore advised to contact suppliers to ask for additional information.

In addition, as nanomaterials are considered substances, the REACH (Registration, Evaluation and Authorisation of Chemicals) regulation [30] and the CLP (Classification, Labelling and Packaging of Substances and Mixtures) [41] regulations are equally relevant, and changes in REACH Annex II [31], the legal framework for the SDSs, as well as the guidance from European Chemicals Agency (ECHA) on the SDSs [32], which gives further advice on how to address characteristics of nanomaterials, are expected to improve the quality of the information contained in the SDSs. (E-fact 72: <https://osha.europa.eu/en/publications/e-facts/e-fact-72-tools-for-the-management-of-nanomaterials-in-the-workplace-and-prevention-measures>) introduces available guidance and tools to help manage the risks of nanomaterials in the context of current limitations and of the current state-of-the-art research. At present, there are no specific guidelines available for the prevention of OSH risks from nanomaterials in the healthcare sector. However, the measures recommended in other sectors (e.g. for research laboratories [33]) are partially applicable and the main principles and approaches can be transferred to the healthcare sector.

4.1 Elimination and substitution

As with all other dangerous substances, elimination and substitution should be given priority over other prevention measures (i.e. the aim is to prevent all workers from exposure to nanomaterials). However, in many cases, nanomaterial-containing chemical agents, drugs or devices are used in the healthcare sector for their specific properties and because they fulfil a specific function. Therefore, in these cases, if a nanomaterial poses a risk to healthcare workers, elimination or substitution by another less hazardous alternative might not be a feasible option, as the alternative might not readily exhibit the same desired properties and (positive) effects. However, the balance between the desired properties and effects, on the one hand, and health risks, on the other hand, should always be borne in mind and elimination and substitution given thorough consideration. In addition, it may be possible to:

- avoid the presence of nanomaterials that could become airborne (such as powders or dusts) by using a less hazardous form, e.g. by solubilising powder forms of nanomaterials into liquids, pastes, granulates or compounds or by binding them to solids; and
- reduce the hazardous behaviour by modifying the surface of the nanomaterial, for example by coating it in order to adjust the dustiness, solubility and other properties.

4.2 Engineering controls

Owing to the nature of the work in the healthcare sector, most workplaces, such as patients' rooms in hospitals or even patients' homes, may not have technical systems for reducing or preventing exposure to nanomaterials at source, for example closed systems that create a physical barrier between a person and the nanomaterial. However, engineering controls at source are feasible in other operations, such as the preparation of drugs containing nanomaterials, e.g. tablets or ointments in glove boxes.

Clean benches with high-efficiency particulate air (HEPA) filters are another effective risk prevention measure for activities such as the preparation of nanodrugs; of samples of patients' tissues, body fluids or excrements that could contain nanomaterials (if the patient is treated with nanodrugs); or for the preparation or analysis of samples using nanomaterial-containing analytical chemicals. Exposure to spills, dusts or vapours of nanomaterials from samples or sample preparation products should be controlled by the use of a high-throughput ventilation system in combination with PPE, particularly gloves and masks (see section 4.4).

Local exhaust ventilation systems are normally in place in laboratory workplaces, surgery rooms or areas with high safety standards (e.g. because of the risk of infection) and in storage areas. Such systems also capture nanomaterials. However, in the case of nanomaterials, the use of normal multistage filters, with high-efficiency particulate air filters (HEPA H14) or ultra-low penetration air filters, as the final filter before re-introduction of the extracted air is recommended. In any case, the suitability of the filtration systems in place should be evaluated.

4.3 Organisational measures

Risk prevention measures in workplaces in the healthcare sector in which hazardous nanomaterials are used include:

- specifically dedicated areas or workplaces for handling nanomaterials that are separated from other workplaces and clearly indicated with appropriate signs;
- minimising the number of workers being exposed to nanomaterials;
- minimising the duration of workers' exposure to nanomaterials;
- prohibiting access of unauthorised personnel;
 - regular cleaning (wet wiping) of work areas where nanomaterials are used or handled; and
 - monitoring of air concentration levels, e.g. in comparison with background levels when no handling of nanomaterials occurs.



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As there is currently no standardised approach for the use of safety signs or for the labelling of workplaces or containers with nanomaterials, it is recommended that a diligent approach is taken using existing risk and safety phrases from the EU Regulation on the classification, labelling and packaging of substances and mixtures (CLP) [41] and warning signs to provide adequate, relevant and specific information on any actual or potential health and safety risks from the use and handling of nanomaterials.

In addition, some general principles should also be followed, which apply regardless of the involvement of nanomaterials:

- Planning of the work should be based on risk assessment and include worker involvement. If work takes place at workplaces in which nanomaterials with unknown toxicity and behaviour are handled, these must be taken into account. Priorities in risk management should be given not only to known risks, but also to the assessment and management of nanomaterials at workplaces in which hazard and exposure information are missing, incomplete or uncertain.
- Time pressure should be avoided.
- Sufficient training should be provided to ensure that workers have the skills and knowledge to perform the work safely and to protect themselves from exposure to any nanomaterial releases.
- Instructions and information should always be provided to all workers, particularly when workers are contracted for only one task and/or are not familiar with chemical risks in general and risks from nanomaterials specifically (e.g. cleaning personnel, student assistants). This should include protection measures, for example how to safely handle pharmaceuticals or samples containing nanomaterials; grind or polish fillings and surfaces containing nanomaterials; and dispose of products. This information should also be documented in workplace instructions.
- Taking a precautionary approach to risk prevention for nanomaterials: all measures available should be implemented, in accordance with the hierarchy of prevention measures, to reduce the release of nanomaterials.

Workers handling, or otherwise exposed to, potentially hazardous nanomaterials should be included in health surveillance programmes with detailed documentation of the exposure situations.

4.4 Personal protective equipment (PPE)

PPE should be used as a last resort when exposure cannot be reduced effectively enough with the above-mentioned measures. If PPE is determined to be necessary in the risk assessment, a PPE programme should be designed. A good PPE programme will consist of the following elements: selection of appropriate PPE, fitting, training and maintenance of PPE. Workers in the healthcare

sector are likely to use PPE in their activities because of other health risks (e.g. biological agents) ⁽³⁾ [34]. However, the PPE used needs to be evaluated with regard to its suitability for nanomaterials.

The work rate and medical fitness of the PPE user needs to be assessed to make sure that the PPE provides the adequate level of protection and can be used appropriately. Trials carried out on the PPE should ensure that its users are able to carry out their work safely with the PPE on and that it still allows them to use other necessary equipment (e.g. spectacles) or tools simultaneously as required. It should be borne in mind that the level of protection provided by the PPE may become weaker during simultaneous use of several sets of PPE. Also, additional hazards, other than nanomaterials, may interfere and reduce the effectiveness of the PPE. Thus, all workplace hazards need to be taken into account when choosing the PPE. All PPE used should have a CE marking, and be used in accordance with the manufacturer's instructions without any modifications.

4.4.1 Respiratory protection

For activities involving airborne nanomaterials, for example grinding, sanding or milling of bridges or implants that contain nanomaterials, local exhaust ventilation systems may not be sufficient. In these cases, respiratory protection should also be used. HEPA filters, respiratory cartridges and masks with fibrous filtering materials are effective against airborne nanomaterials. Half- or full-face masks with P3/FFP3 or P2/FFP2 filters are considered effective for protection against such exposures. Filters of protection factor 3 provide better protection than those of factor 2 [35, 36]. Face masks should be sufficiently tight [36]—regular fit tests should be arranged for all users.

The choice of respiratory protection device (RPD) will depend on the:

- type, size and concentration of the airborne nanomaterial;
- assigned protective factor for the RPD (which integrates filtering effectiveness and face–seal fit); and
- working conditions.

In cases in which the respiratory devices do not cover the eyes, eye protection should also be used (tight-fitting safety goggles).

4.4.2 Gloves

Gloves are commonly used in the healthcare sector. Only gloves that fulfil the requirements of the standard series EN 374 ⁽⁴⁾ should be used against chemical hazards in general. In the case of nanomaterials, gloves from synthetic polymers, such as latex, nitrile or neoprene, have been found to be effective [36]. The effectiveness of gloves for a specific nanomaterial will depend on the form in which it occurs at the workplace (dusts, liquids, etc.), and this should be specifically checked with the glove suppliers. The thickness of the glove material is a major factor in determining the diffusion rate of the nanomaterial. Therefore, the use of two pairs of gloves at the same time is recommended [37].

4.4.3 Protective clothing

Non-woven textiles (air-tight materials), such as high-density polyethylene (low dust retention and low dust release), should be preferred over woven ones, and the use of protective clothing made with cotton fabrics should be avoided [36].

If re-usable protective clothing such as overalls is used, provision should be made for regular laundry and the prevention of secondary exposure. Provision must be made to allow clean overalls and

⁽³⁾ The European Directive 89/686/EEC regulates the design and use of PPE and ensures that it fulfills its intended function of protecting workers from specific risks.

⁽⁴⁾ EN 374-1:2003: Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements; EN 374-2:2003: Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration; and EN 374-3:2003: Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals.

protective clothing coats to be put on and dirty ones removed in a manner that does not contaminate the individuals or the general workplace.

4.5 Prevention of explosion and/or fire

As a result of their small size, nanomaterials in powder form may present risks of explosion that their respective coarse materials do not ⁽⁵⁾ [38]. Care should be taken when nanopowders are generated (e.g. grinding, sanding or polishing of implants and bridges containing nanomaterials) or handled (e.g. by mixing, cleaning or disposing of such powders).

The preventive measures for nanomaterials in powder form are essentially the same as those for any other explosive and flammable coarse material and explosive dust clouds, and should follow the requirements in Directive 99/92/EC on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres. These include:

- pharmacists should, for example, limit the handling of such materials to specific Ex-zones, and carry out the work in inert atmospheres, if possible;
- materials should be solubilised by wetting the workplace (prevention of dusts);
- low-spark equipment and other ignition sources, or conditions facilitating electrostatic charging, should be removed from the workplace; instead, intrinsically safe equipment (signal and control circuits operating with low currents and voltages) should be used, when possible;
- dust layers should be removed by wet mopping up; and
- storage of explosive or flammable materials at workplaces should be minimised. Anti-static bags may be used.

4.6 Checking the effectiveness of measures

The risk assessment should be regularly revised and the choice and implementation of risk management measures regularly controlled and checked with regards to their effectiveness. This means ensuring the proper functioning of all protective equipment, such as clean benches or laminar flow booths, and regular inspections of all ventilation equipment and their respective filtering systems. Furthermore, the suitability of PPE should be checked and updated, if necessary.

Additionally, the effectiveness of a risk reduction measure can be assessed by analysing the concentration of nanomaterials in the air before and after the prevention measure. The exposure levels measured when risk management measures are applied should not significantly differ from background concentrations, when there is no source of manufactured nanomaterials. Other indirect measurements for the effectiveness of technical preventative measures can also be applied, such as smoke tests and/or control velocity measurements.

Occupational exposure limit (OEL) values for nanomaterials ⁽⁶⁾ [39, 40] may be developed in the future; however, exposure minimisation should be the primary goal of workplace risk management, and therefore meeting OELs is not sufficient.

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⁽⁵⁾ The explosiveness of most organic and many metal dusts increases with decreasing particle size. 500 µm appears to be the upper particle size limit of an explosive dust cloud. At present, no size limit has been determined below which dust explosions can be excluded.

⁽⁶⁾ See, for example, the Social and Economic Council of the Netherlands (SER) (2012), *Provisional Nano Reference Values for Engineered Nanomaterials*, and Nanowerk (2012), *SAFENANO Team Complete BSI British Standards Guide to Safe Handling of Nanomaterials*.

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