

PUBLISHED DOCUMENT

Nanotechnologies –

Part 2: Guide to safe handling and disposal of manufactured nanomaterials

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 26, an inside back cover and a back cover.

Foreword

Publishing information

This Published Document is published by BSI and came into effect on 31 December 2007. BSI Committee NTI/1, *Nanotechnologies*, takes collective responsibility for its preparation. The Committee wishes to acknowledge the contribution of SAFENANO at the Institute of Occupational Medicine in preparing this Published Document. A list of organizations represented on the Committee can be obtained on request to its secretary.

This Published Document was commissioned by the UK Department for Innovation, Universities and Skills (DIUS) to provide guidance for manufacturers and users of nanoparticles on their proper handling and disposal in order to minimize the risk from known, and as yet unknown, health and environmental hazards associated with such materials.

Use of this document

As a guide, this Published Document takes the form of guidance and recommendations. It should not be quoted as if it were a specification and particular care should be taken to ensure that claims of compliance are not misleading.

It has been assumed in the preparation of this Published Document that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions in this Published Document are presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is “should”.

The word “may” is used in the text to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word “can” is used to express possibility, e.g. a consequence of an action or an event.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

This Published Document is not to be regarded as a British Standard.

1 Scope

This Published Document gives guidance on assessing risks and recognizing uncertainties in the development, manufacture and use of nanomaterials, and on developing and implementing an effective strategy to address and control the risks.

It is applicable to a wide range of nanomaterials and nanostructured materials as defined in PAS 136, including nanoparticles, nanofibres, nanopowders, nanotubes and nanowires, generically referred to as nano-objects, as well as aggregates and agglomerates of these materials. It also covers any material or preparation in which such nanomaterials comprise a significant proportion. This guide is not applicable to incidentally produced nanoparticles, such as diesel exhaust and welding fumes.

NOTE For the purposes of this guide the terms nanoparticle and nanomaterial are used interchangeably to refer to all of the nanomaterial types listed above.

This Published Document recognizes that there is considerable uncertainty about many aspects of effective risk assessment of nanomaterials, including the hazardous potential of many types of nanoparticles and the levels below which individuals might be exposed with minimal likelihood of adverse health effects. The guide therefore recommends a cautious strategy for handling and disposing of nanomaterials.

2 Manufactured nanomaterial types and characteristics

2.1 General

This clause describes some of the more common types of manufactured nanomaterials to which this guide may be applied. It is not intended to be a full and comprehensive guide to nanoparticle types.

2.2 Fullerenes

Fullerenes comprise one of four types of naturally occurring forms of carbon, first identified in the 1980s [1]. Their molecules are composed entirely of carbon and take the form of a hollow sphere or a tube.

Fullerenes are similar in structure to graphite which comprises a sheet of hexagonal carbon rings, but contain pentagonal or heptagonal rings which enable 3D structures to be formed. The best known fullerene is C₆₀, often referred to as a buckminsterfullerene or a buckyball.

Fullerenes are chemically stable materials and insoluble in aqueous solutions. Potential applications include drug delivery, coatings, lubrication and hydrogen storage (PAS 136).

2.3 Carbon nanotubes

Carbon nanotubes (CNTs) are a specific form of fullerenes, first reported by Iijima [2]. They are similar in structure to C₆₀ but are elongated to form tubular structures a few nm in diameter. They can be produced with very large aspect ratios and can be more than 1 mm in length. In their simplest form, CNTs comprise a single layer of carbon atoms arranged in a cylinder, known as single-wall carbon nanotubes (SWCNTs). They can also be formed as multiple concentric tubes (multi-wall carbon nanotubes, MWCNTs) with diameters up to 20 nm, and length greater than 1 mm. CNTs have great tensile strength and are considered to be 100 times stronger than steel, whilst being only one sixth of its weight. They also exhibit high conductivity, high surface area, unique electronic properties, and potentially high molecular adsorption capacity [3]. They are chemically stable materials and insoluble in aqueous solutions. Potential applications include coatings, composites, electronics, water purification and construction materials.

2.4 Nanowires

Nanowires are small conducting or semiconducting nanoparticles with a single crystal structure, a typical diameter of a few 10s of nm and a large aspect ratio. Various metals have been used to fabricate nanowires, including cobalt, gold and copper. Silicon nanowires have also been produced. Potential applications include inter-connectors in nano-electronic devices, photovoltaics and sensors.

2.5 Quantum dots

Quantum dots are small (2 nm to 10 nm) assemblies of semiconductor materials with novel electronic, optical, magnetic and catalytic properties. Typically containing 1 000 to 100 000 atoms, quantum dots are considered to be something between an extended solid structure and a single molecular entity. Semiconductor quantum dots exhibit distinct photo-electronic properties which relate directly to their size. For example, by altering the particle size the light emitted by the particle on excitation can be tuned to a specific desired wavelength. Applications include catalysis, medical imaging, optical devices and sensors.

2.6 Other nanoparticles

This category includes a wide range of spherical, aggregated or agglomerated forms of nanoparticles, including ultrafine carbon black and fumed silica, which are synthesized in bulk form through flame pyrolysis methods. Such nanoparticles can be formed from many materials, including metals, oxides, ceramics, semiconductors and organic materials. They can be composites having, for example, a metal core with an oxide shell, or alloys in which mixtures of metals are present. This group of nanoparticles is generally less well defined in terms of size and shape, and likely to be produced in larger bulk quantities than other forms of nanoparticles. Applications include coatings and pigments, catalysis, personal care products, cosmetics and composites.

3 Nanoparticle exposure and risk

3.1 General

It has been established for many years that exposure to particles, including nanoparticles, can cause ill health in individuals or exposed populations. There are many instances of this relating to exposure from industrial activity and environmental pollution. For example, in an occupational setting, exposure to coal dust is clearly linked to the onset of lung diseases, such as pneumoconiosis and chronic obstructive pulmonary disease (COPD), and exposure to asbestos is clearly linked with asbestosis, mesothelioma and lung cancer. In an environmental context, recent evidence has suggested that exposure to the particulate component of atmospheric pollution, might be associated with increased hospitalization rates and cardio-vascular disease.

However, many millions of the population are exposed to particles in environmental pollution on a daily basis without any apparent ill effects. For any material, the risk, or likelihood, of illness increases with increasing dose. Dose broadly refers to “how much” gets to an organ where disease occurs and “how long” it stays there. Toxicity, specifically for relatively insoluble particles, appears to relate to the total surface area of the particles.

3.2 Potential risks to health from inhalation of nanoparticles

More than 30 major reviews and position papers have discussed the potential risks to health and to the environment from exposure to nanoparticles [4]. The potential risks to health from inhalation of nanoparticles may be summarized as follows.

- a) Due to their small size, nanoparticles can reach parts of biological systems which are not normally accessible by larger particles. This includes the increased possibility of crossing cell boundaries or of passing directly from the lungs into the blood stream and so on to all of the organs in the body, or even through deposition in the nose, directly to the brain. This process is known as translocation and, in general, nanoparticles can translocate much more easily than other, larger particles.
- b) Due to their small size, nanoparticles have a much higher surface area than the same mass of larger particles. If surface area is a driver for toxicity this clearly implies potentially increased toxic effects.
- c) For some nanomaterials, reduction in size has been shown to relate to increased solubility. This effect might lead to increased bioavailability of materials which are considered to be insoluble at larger particle sizes.
- d) An important rationale for developing nanomaterials and nanoparticles is that they will have new and different properties to larger particles of the same material. Altered chemical and/or physical properties might be expected to be accompanied by altered biological properties, some of which could imply increased toxicity.

e) A specific issue relates to comparisons between high aspect ratio nanoparticles (e.g. some forms of carbon nanotubes or nanowires) and asbestos. Asbestos has a fibrous nature with high aspect ratio (the ratio of length to diameter). Some fibrous particles cause disease because they can be inhaled and enter the alveolar region of the lung and are not easily removed because (i) their physical dimensions mean they cannot be removed by lung clearance mechanisms and (ii) they are highly durable and do not dissolve in the lung lining fluids. Hence they remain in the lung for a long period of time, causing inflammation and ultimately disease. Some high aspect ratio nanoparticles can have similar morphology (shape) and durability and are therefore likely to persist in the lungs, if inhaled.

Along with increasing production volumes, lower costs and an increased general prevalence of these materials in industry and commerce, these issues indicate that more needs to be done to assess the potential risks associated with these nanomaterials and that a suitably cautious approach should be taken in their handling and disposal.

The likelihood (or risk) of disease occurring depends on the dose of the particles in the organ where disease can occur, and the toxicity of nanoparticles. Dose cannot be assessed directly, but can be inferred from the exposure to nanoparticles, which is a combination of the concentration of particles in the air which a person breathes in and the length of time the exposure lasts. If there is no exposure (i.e. no nanoparticles in the air), no dose will accumulate and, despite the potential toxicity of the particles, there will be no risk to health.

It therefore follows that an appropriate response to the risks from nanomaterials is to understand the potential exposures which could arise from the manufacture and use of nanomaterials and to put in place measures to mitigate, manage or reduce exposure. In this way the risks can be controlled.

3.3 Potential nanoparticle risks to health from dermal exposure or ingestion

Concerns have also been raised about the potential risks to health arising from dermal exposure to some types of nanoparticles, based on the possibility of these materials penetrating the skin and entering the bloodstream. To date, though, there have been very few studies of this effect [5], [6] and these have not demonstrated skin penetration by nanoparticles to any extent. However, the studies are preliminary and have not considered, for example, the effect of damaged skin. Other studies are currently under way but, until consensus emerges, a prudent approach would be to limit exposure to the skin.

Potential health effects due to ingestion have also been postulated based on the possibility of nanoparticle transfer across the gastro-intestinal wall. Again, however, there is presently no direct evidence that any occupational ill health is caused by this effect, but it would be prudent to minimize exposure by this route.

3.4 Nanoparticles as hazardous materials

Current guidance indicates that a hazardous material may be identified as follows [7].

- a) It may be listed in publications, such as the UK Health and Safety Executive's (HSE) EH40 workplace exposure limits [8], which lists substances which have been assigned workplace exposure limits (WELs).
- b) It may be identified as a carcinogen or mutagen in a safety data sheet.
- c) It may be classified as very toxic, toxic, harmful, sensitizing, corrosive, irritant or toxic to reproduction.
- d) It may be a cause of occupational asthma (in which case, the safety data sheet or package label ought to include R42 "May cause sensitization by inhalation" or R42/43 "May cause sensitization by inhalation and skin contact").

However, given the lack of current knowledge about the toxicity of nanomaterials and the concern that current safety data sheets do not adequately reflect the hazardous nature of nanomaterials, it is recommended that all nanomaterials are considered potentially hazardous unless sufficient information to the contrary is obtained.

3.5 Risk of fire and explosion from nanoparticles

Explosive dust clouds can be generated from most organic materials, many metals and even some non-metallic inorganic materials. The primary factor influencing the ignition sensitivity and explosive violence of a dust cloud is the particle size or specific surface area (i.e. the total surface area per unit volume or unit mass of the dust). As the particle size decreases the specific surface area increases. The general trend is for the violence of the dust explosion and the ease of ignition to increase as the particle size decreases, though for many dusts this trend begins to level out at particle sizes of the order of tens of micrometres (μm). However, no lower particle size limit has been established below which dust explosions cannot occur [7] and it has to be considered that many nanoparticle types have the potential to cause explosions. At the current time, however, there are almost no data relating to the fire and explosion hazards of nanoparticles.

4 General approach to managing risks from nanoparticles

In the UK, the law relating to the use of chemicals or other hazardous substances at work requires employers to control exposure to hazardous substances to prevent ill health to both employees and others who could be exposed. The Control of Substances Hazardous to Health Regulations (COSHH) 2002 [7], which are based on a risk assessment approach, provide a framework for assessing and managing the potential risks from nanomaterials. This framework comprises eight main steps:

- 1) identify the hazards and assess the risks;
- 2) decide what precautions are needed;
- 3) prevent or adequately control exposure;
- 4) ensure that control measures are used and maintained;
- 5) monitor the exposure;
- 6) carry out appropriate health surveillance;
- 7) prepare plans and procedures to deal with accidents, incidents and emergencies; and
- 8) ensure employees are properly informed, trained and supervised.

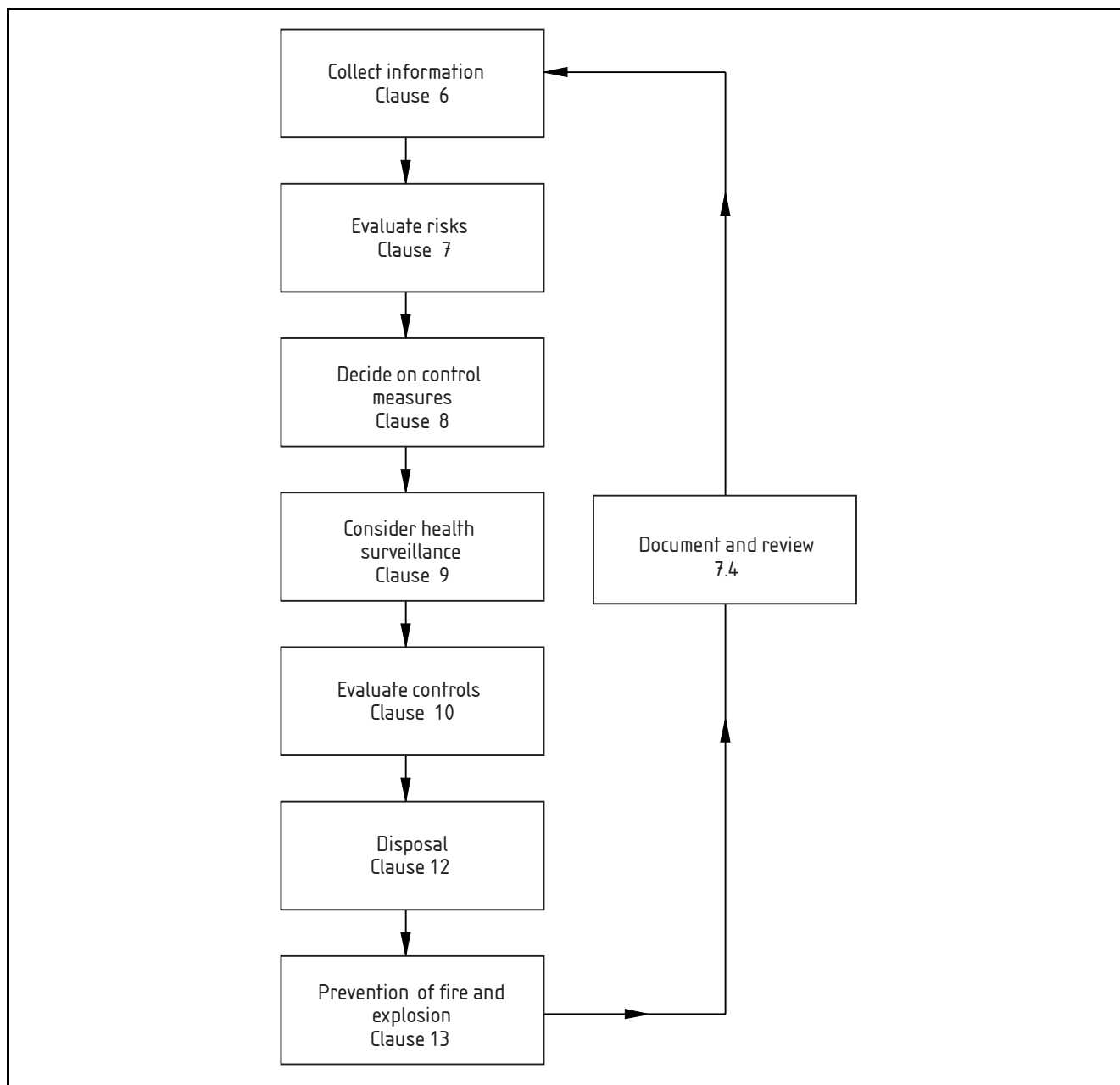
The approach proposed in this guide closely follows this framework.

COSHH relies on having good information about the hazardous nature of materials, the effectiveness of control approaches and convenient and accessible ways to monitor exposure. One of the difficulties in applying a COSHH approach to nanoparticles is that the information available might be incomplete or, worse, incorrect.

The knowledge gaps concerning the health hazards of new nanomaterials introduce significant uncertainty into any risk assessment. It is inappropriate in the absence of knowledge to assume that a nanoparticle form of a material has the same hazard potential as it has in a larger particulate form. In general, the greater the gaps in knowledge, the more cautious the control strategy should be.

The general approach adopted in this guide to managing risks from nanomaterials is illustrated in Figure 1, which is also a guide to the rest of this document. This figure provides a step-by-step approach to the assessment of risks, recognition of uncertainties and development and implementation of an effective strategy to control exposure and manage the risks.

Figure 1 Approach to managing risks from nanoparticles



5 Identification and competence of person conducting risk assessment

An initial decision relates to who will carry out the risk assessment. As in general chemical risk assessment processes, several people may be involved, such as those involved in the development or implementation of a process, managers, or professional occupational hygienists. The current state of knowledge concerning nanoparticles suggests that it will be difficult for an individual with no background knowledge of nanoparticle risk issues to make effective judgments about the appropriate steps to take. While this guide helps address this situation, it is strongly recommended that those involved in developing risk assessments for nanomaterials seek information more widely on these issues or undertake some external training.

6 Information collection

This is a key step in the risk assessment. If little is known about the material, it will be necessary to treat it as highly hazardous and apply tighter exposure controls.

It is therefore necessary to begin by collecting information about the material, the work and the working practices. It is important to consider both routine and non-routine practices, such as maintenance and cleaning.

This should focus on the collection of data that can inform the risk assessment.

- What are the commercial and technical names for the material?
- Is there an adequate material safety datasheet (MSDS)?
- What is the chemical composition?
- Is nanomaterial present? In what proportions?
- Are the particles long and thin?
- What is the particle size distribution?
- How dusty is the material?
- Does the material contain dust suppressants or is it bound into another material?
- Is the material water soluble?
- How hazardous or toxic is the material?

It is important to document both the information which is available and the information gaps. For commercial nanomaterials some of the information will be available on product safety data sheets. In using these sheets, however, it is necessary to evaluate the extent to which suppliers have taken account of the nanoscale nature of the substance.

It is also necessary to identify those who could be exposed. This could include production employees, ancillary or support-services employees, such as cleaners or maintenance workers, contractors on site, visitors, supervisors and managers, students, office workers and people outside.

7 Risk evaluation

7.1 Assessing the hazard

For most particulate materials that can become airborne and be inhaled, particularly those that are poorly soluble, the primary health concern is for effects on the lungs. This should be the first consideration for any nanoparticle that is being manufactured or used. However, consideration should also be given to other means of exposure, such as skin contact or ingestion, and other potential hazards, such as fire and explosion.

An assessment of hazard, coupled with an assessment of the likelihood of exposure, can be used to decide on a control strategy. Clearly, the more information available, the better this categorization will be. The information needs to be evaluated critically in terms of quantity and quality. A useful starting point in the assessment of hazard is to categorize the type of hazards which might be relevant to the material. The following four groups provide a basis for categorization of nanomaterials:

- Fibrous** a high aspect ratio insoluble nanomaterial;
- CMAR** any nanomaterial which is already classified in its larger particle form as carcinogenic, mutagenic, asthmagenic or a reproductive toxin;
- Insoluble** insoluble or poorly soluble nanomaterials not in the fibrous or CMAR category;
- Soluble** nanomaterials not in fibrous or CMAR category.

The assessment should consider the allocation into the above categories and what information is available within these categories to assess the comparative hazard (toxicity) of the nanomaterials with other larger forms of the material or other nanomaterials.

For all of the categories of nanomaterials identified it is a reasonable assumption that these materials have a hazardous potential which is greater than that of the larger, non-nanoscale forms of the material.

7.2 Assessing exposure

The key deliverable from this step is an exposure characterization; a summary and synthesis of the gathered exposure information. The exposure characterization should include:

- a) a statement of purpose, scope, level of detail, and the approach used in the assessment;
- b) estimates of exposure and dose by pathway, both for individuals and populations; and
- c) an evaluation of the overall quality of the assessment and the degree of confidence in the exposure estimates and conclusions drawn.

Risks are associated with the nature of material and the exposures that people have to that material. Information should be collected that helps assess what the exposures might be.

- What are the tasks where people can be exposed to nanoparticles (e.g. production, cleaning, maintenance, transport and storage)?
- Who can be exposed during each task? The individual undertaking the task, adjacent workers, visitors, contractors, managers and others might be exposed.
- What are the potential routes of human exposure (e.g. inhalation, ingestion and dermal penetration)?

- What is the chance of the exposure occurring? Consider routine work, accidental releases and maintenance (not just during normal activities).
- How often is exposure liable to occur (e.g. continuous over a working shift, intermittent, rarely)?
- What levels are people exposed to and for how long? This might require monitoring (see Clause 9).
- Can the nanomaterials be present in the ambient air or on the surfaces of the workplace, or other locations where people could be exposed?
- Which control measures can be applied for each task? These can include segregation of personnel from the source by enclosing them or the process, or by ventilation, training and PPE.

In addition, any relevant existing measurement data should be collected.

It is quite likely, given current knowledge about nanoparticles, that the information collected will be considered insufficient. As uncertainty about the levels of exposure increases, the need for caution in the assessment increases. It is therefore necessary to err on the side of caution and determine where significant doubt exists. Based on this assessment, a prioritized plan should be developed to collect additional information about exposure levels. This could include a programme of exposure measurements, methods for which are summarized in Clause 10.

7.3 Assessing the risk

At this stage, potential hazards should have been identified and an assessment made of the likely exposures. Consideration of hazard and exposure leads to an assessment of the risks. The next step is to decide what to do about them. If the risks are significant or could become so, then precautions are required.

Not all hazards can be addressed immediately and priorities for action will be required. Priorities are decided on the basis of assessments of:

- the most serious risks to health;
- the risks that are likely to occur soonest; and
- the risks that can be dealt with soonest.

The most important of these is the seriousness of the risks. If a risk is serious it should be dealt with immediately. Less serious risks should not assume greater priority merely because they can be dealt with more easily or might occur more quickly.

7.4 Document and review

The significant findings of the risk assessment should be recorded when the assessment is made or as soon as is practicable afterwards. In some circumstances not all the findings will occur at the same time. Some might be awaiting further information before they can be resolved so that it is not possible to record these until then, e.g. where there is a pilot operation which runs for a period before being assessed completely or where air monitoring results are awaited. In these circumstances, the record of the significant findings should be completed or updated as information becomes available.

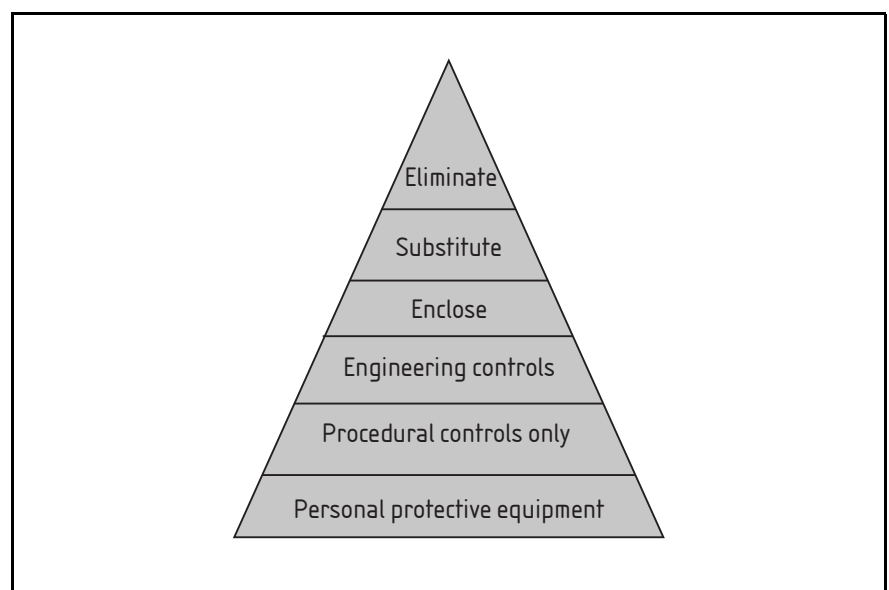
Given the emerging state of knowledge concerning the risk assessment of nanomaterials, it is probable that important new knowledge will become available at some time. It is critical therefore that the assessment is reviewed at least annually and that those involved in the process take steps to ensure that their knowledge is kept up-to-date

8 Control of exposure

8.1 Hierarchy of control

Exposure should be prevented, preferably by avoiding so far as is reasonably practicable the use of a hazardous substance by substituting a substance or process which eliminates or reduces the risks to health. If, however, this is not possible then exposure should be controlled by applying protection measures appropriate to the activity and consistent with the priority order given in Figure 2, which describes the hierarchy of control.

Figure 2 **Hierarchy of control**



8.2 Control of exposure

If exposure cannot be prevented, it should be adequately controlled. The hierarchy of control measures as applied to inhalation and dermal risks comprises the following.

- a) **Eliminate.** Avoid using the hazardous substance or the process which causes exposure. This is unlikely to be an option if the nanomaterial has been selected for its specific properties. However, consideration should be given as to whether the improved properties of the nanomaterial justify any enhanced risks associated with its use.
- b) **Substitute.** Change the nanomaterial or process to one which has less risk. Although it might not be possible to substitute that material, it might be possible to reduce the likelihood of exposure by, for example, binding powder nanomaterials in liquid or solid media. Dispersions, pastes or pelletized forms should be used instead of powder substances wherever this is technically feasible.
- c) **Enclose.** All operations in which there is deliberate release of nanomaterials into the air should be performed in contained installations, or where personnel are otherwise isolated from the process (e.g. in a cabin). This includes gas phase nanomaterial production and spray drying. All other processes involving the use of dry nanomaterials should be performed in enclosed installations where possible. More information about process enclosure is available [9].
- d) **Engineering control.** All processes where there is a likelihood of dust formation should be carried out with extract ventilation. A wide range of extract ventilation systems is available, including fume cabinets, fume hoods and dust extractors. Selection of appropriate controls will depend on the level of risk. More information about engineering control approaches is available [9].

Regular maintenance and performance testing of extraction facilities should be carried out. Extracted air should not be re-circulated without exhaust air purification.

Dermal exposure can be reduced by re-engineering the work process to avoid splashes or immersion.

- e) **Procedural control.** Procedural controls should accompany engineering controls, though the risk assessment might indicate that procedural controls alone are sufficient in some circumstances. Procedural controls include reducing the number of personnel exposed or the time spent by personnel on the process, and limiting the process to specified areas and denying unauthorized persons access to these areas. The personnel involved should be informed of the specific hazards of free nanoparticles, the need for special measures, and the potential health effects of exposure to dusts. Relevant information in the operating instructions might be included. Routine monitoring and health and medical surveillance should be carried out as needed.

Work wear should be cleaned by the employer and stored separately from private clothing. Planned cleaning of the workplace should be carried out regularly.

f) **Personal protective equipment (PPE).** Personal protection is a last option or a supplemental option to help support all of the other methods of exposure control.

i) **Protection from inhalation exposure.** In the UK information on the selection and use of respirators is given in the Health and Safety Executive's (HSE) HSG53 [10]. Depending on the outcome of the risk assessment process, appropriate types of respiratory protective equipment (RPE) include disposable filtering facepieces, half and full facemasks and a range of powered (air supplied) hoods, helmets, blouses and suits. High efficiency filters (P3 and FFP3 type) should always be used. All wearers of RPE should undergo face-piece fit testing to ensure correct fitting and proper wearing [11].

PPE, especially respiratory protection, needs a significant investment in training, supervision and maintenance if it is to provide the intended level of protection. Incorrect selection or fitting or insufficient use can render it ineffective.

ii) **Protection from dermal exposure.** The risk assessment might indicate a need for protective gloves, protection goggles with side protection and protective clothing.

Simply selecting gloves solely on the basis of glove manufacturers' published data is insufficient in ensuring adequate protection. There are four basic criteria for the selection of protective gloves: they should be appropriate for the risk(s) and conditions where they are to be used; they should be suitable for the ergonomic requirements and state of health of the intended wearer; they should fit the intended wearer correctly; and they should prevent exposure without increasing the overall risk. This, of course, assumes that the gloves are worn and maintained correctly.

The development of a glove management system, which emphasizes and reinforces the factors that need to be considered and addressed, how these interlink with each other and when they should be reviewed, should help ensure adequate protection. Packham [12] emphasizes several of the key elements to be considered in a glove management system, including an assessment of tasks/exposure scenario, glove material selection, ergonomics, training (both managers and workforce), monitoring the system and storage, maintenance and disposal.

8.3 Selection of controls

The purpose of applying controls is to ensure that exposure of the workforce is as low as reasonably practical. In general, it is advisable to adopt a control as high in the control hierarchy as is technically and economically feasible. However, this needs to be balanced against the level of control required to provide a safe working environment and the efficacy of the control measures. The risk assessment should help to decide the appropriate control, taking account of necessity, practicability and cost.

Currently, there is no dependable information about what is practically achievable. Nor is there dependable information about the relative hazard of many nanomaterials when compared to larger particulate forms.

To help guide this process, the following benchmark exposure levels have been suggested for the four nanoparticle hazard types identified in **7.1**. These are intended to provide reasonably cautious levels and are based in each case on the assumption that the hazard potential of the nanoparticle form is greater than the large particle form. This assumption will not be valid in all cases. Although these benchmark levels relate to current exposure limits, they have not been rigorously developed. Rather, they are intended as pragmatic guidance levels only and should not be assumed to be safe workplace exposure limits.

Fibrous nanomaterials. The most rigorous limit currently in place for fibres in air is 0.01 fibres/ml, used in the UK as the clearance limit in asbestos removal activities. A fibre is defined as a particle with aspect ratio greater than 3:1 and length greater than 5 000 nm. The counting method used is phase contrast optical microscopy. The proposed benchmark for fibrous nanomaterials is 0.01 fibres/ml, as assessed by scanning or transmission electron microscopy.

CMAR nanomaterials. The potentially increased solubility of CMAR materials in nanoparticle form could lead to increased bioavailability. To provide a margin of safety, a benchmark level of $0.1 \times$ material WEL is suggested. Typically, this would be expressed as a mass concentration.

Insoluble nanomaterials. For insoluble nanoparticles, work recently published by NIOSH [13] recommends exposure limits of 1.5 mg/m^3 for fine TiO_2 (particularly greater than $0.1 \mu\text{m}$ in diameter) and 0.1 mg/m^3 for ultrafine particles as time-weighted averages. In the absence of other published approaches, this seems to be a reasonable basis to judge other nanomaterials. On this basis, a benchmark level of $0.066 \times$ WEL is suggested. Typically, this would be expressed as a mass concentration.

An alternative would be to develop a benchmark based on particle number concentration. In the UK, current urban pollution is in the range 20 000 to 50 000 particles/ml. It is suggested that the lower end of this range 20 000 particles/ml discriminated from the ambient environmental particle concentration is an appropriate benchmark.

Soluble nanomaterials. For materials which are highly soluble in any case, nanoparticle forms are unlikely to lead to greater bioavailability. Nor are the types of effects associated with insoluble particles likely to occur. Therefore, for these materials, a benchmark of $0.5 \times$ WEL is suggested.

Minimum control approaches provided in Figure 3 are suggested for various common generic tasks which are intended to lead to exposure levels consistent with these benchmark levels. However, at present, there is almost no information with which to assess the effectiveness of these approaches. Use of all control measures should be supported by exposure measurements wherever possible.

Figure 3 Suggested control approaches for various generic tasks

Deliberate aerosolization, e.g. manufacturing, spray coating

| | |
|---------------------------------|---|
| Fibrous and CMAR nanomaterials | The process should be enclosed or otherwise separated from personnel. |
| Insoluble/soluble nanomaterials | The process should preferably be enclosed or otherwise separated from personnel, although ventilated engineering controls such as extraction booths or hoods might be sufficient. |

Transferring, mixing, filling, scooping of dry material

| | |
|---------------------------------|--|
| Fibrous and CMAR nanomaterials | The process should be enclosed or otherwise separated from personnel. |
| Insoluble/soluble nanomaterials | The process should preferably be enclosed or otherwise separated from personnel, although ventilated engineering controls such as extraction booths or hoods might be sufficient. If only small (e.g. mg) quantities are involved, procedural approaches such as segregation or RPE might be sufficient. |

Transferring, mixing, filling of suspensions

| | |
|---------------------------------|---|
| Fibrous and CMAR nanomaterials | The process should preferably be enclosed or otherwise separated from personnel. However, in most cases, ventilated engineering controls should be sufficient. If only small (e.g. mg) quantities are involved, procedural approaches such as segregation or RPE might be sufficient. |
| Insoluble/soluble nanomaterials | Ventilated engineering controls such as extraction booths or hoods should be sufficient. If only small (e.g. mg) quantities are involved, procedural approaches such as segregation or RPE might be sufficient. |

Maintenance and cleaning

| | |
|---------------------------------|---|
| Fibrous and CMAR nanomaterials | The extent to which this process can be enclosed should be maximized. In practice, however, use of appropriate RPE and skin protective equipment should be effective. Cleaning cannot involve any deliberate aerosolization |
| Insoluble/soluble nanomaterials | In most cases use of appropriate RPE and skin protective equipment should be effective. Cleaning cannot involve any deliberate aerosolization. |

8.4 Information, instruction and training

Arrangements should be put in place to ensure that all control measures are properly and fully applied. Clear allocation of managerial responsibilities and accountabilities is particularly important in this respect. The arrangements should include training/refresher training of those individuals who have to use the control measures and procedures for ensuring measures are working as they should.

Everyone who is involved or could be affected should be provided with the degree of training required to ensure their safety and the safety of others. It is necessary to inform and involve the employees in the risk assessment process. Without the informed and competent participation of employees, any measures identified as necessary in the risk assessment are unlikely to be fully effective. It is therefore necessary that the employees know at least:

- a) the names of the substances to which they are liable to be exposed and the risks to health created by exposure;
- b) any relevant workplace exposure limit (WEL) or similar self-imposed (in-house) exposure standard that applies to the substances;
- c) the information on any safety data sheet that relates to the substances;
- d) the significant findings of the risk assessment;
- e) the precautions they should take to protect themselves and their fellow employees;
- f) the results of any monitoring of exposure, especially if these exceed any WEL;
- g) the collective results of any health surveillance (see Clause 9).

9 Health surveillance

In the UK, the primary criterion for health surveillance is a reasonable likelihood that an identifiable disease or ill-health effect associated with exposure to a particular substance will occur in the workplace concerned. There are medically accepted techniques for detecting the disease or ill-health effect.

Currently, no specific measurable health effects have been uniquely associated with exposure to nanomaterials (other than those already associated with larger variants of the same materials). This would suggest that medical surveillance is not appropriate at this point in time.

However, a prudent approach in the current uncertainty is to collect at least some limited information about the materials being used and the duration of use. Such information will help to build up a profile of potential exposures which could be important if any health effects are observed at a later date.

10 Measurement methods for evaluating controls

10.1 Need for measurement

Particle sampling and measurement is extremely helpful in understanding exposure and risk in workplace scenarios. Measurement can be used to support various activities, including:

- 1) identification of sources of nanoparticle emissions;
- 2) assessment of the effectiveness of any control measure implemented;
- 3) ensuring compliance with any WEL or self-imposed (in-house) exposure standard;
- 4) identifying any failures or deterioration of the control measures which could result in a serious health effect.

Each of these tasks requires specific and often different types of instrumentation. A range of instrumentation is available (see **10.2**) and a strategy for their use is described in **10.3**. More information about particle measurement is provided in PD ISO/TR 27628.

10.2 Selection of instruments

A summary of currently available devices and methods for direct measurement of number, mass and surface area concentration is provided in Table 1, which is an updated version of that found in the PD/ISO TR 27628.

Several of the instruments and methods listed in Table 1 also enable information about particle size to be generated. Table 2 gives methods for deriving indirect estimates of number, mass and surface area concentration using the size information provided, based on assumptions about the interrelationships between these metrics.

Table 1 Devices for direct measurement of number, mass and surface area concentration (adapted from PD/ISO TR 27628)

| Metric | Devices | Remarks |
|-----------------------|--|--|
| Number directly | Condensation particle counter CPC | CPCs provide real-time number concentration measurements between their particle diameter detection limits. They operate by condensing vapour onto sampled particles and detecting/counting the droplets formed. Typically used with a 1 000 nm size selective inlet and able to detect down to around 10 nm. |
| | Differential mobility particle sizer DMPS | Real-time size-selective (mobility diameter) detection of number concentration, giving number-based size distribution. |
| | Electron microscopy: SEM, TEM | Off-line analysis of electron microscope samples can provide information on size-specific aerosol number concentration. |
| Mass directly | Size selective static sampler | Assessment of the mass of nanoparticles can be achieved using a size-selective personal sampler with a cut-off point of approximately 100 nm and the sample analysed by gravimetric weighing or by chemical analysis. Although there are no commercial devices of this type currently available, some cascade impactors (Bernier-type low pressure impactors or Microorifice impactors) have selection points around 100 nm and can be used in this way. |
| | Tapered element oscillating microbalance TEOM | Sensitive real-time monitors, such as the TEOM, can be used to measure nanoaerosol mass concentration on-line, with a suitable size-selective inlet. |
| Surface area directly | Diffusion charger | Real-time measurement of aerosol active surface area. Note that active surface area does not scale directly with geometric surface area above 100 nm. Not all commercially available diffusion chargers have a response that scales with particle active surface area below 100 nm. Diffusion chargers are only specific to nanoparticles if used with an appropriate inlet pre-separator. |
| | Electrostatic low pressure impactor ELPI | Real-time size-selective (aerodynamic diameter) detection of active surface area concentration. Note that active surface area does not scale directly with geometric surface-area above 100 nm. |
| | Electron microscopy: SEM, TEM | Off-line analysis of electron microscope samples can provide information on particle surface area with respect to size. TEM analysis provides direct information on the projected area of collected particles, which could be related to geometric area for some particle shapes. |

Table 2 Devices for indirect measurement of number, mass and surface area concentration (adapted from ISO 2007)

| Metric | Instruments | Remarks |
|-----------------------------|--------------------------------|---|
| Number by calculation | ELPI | Real-time size-selective (aerodynamic diameter) detection of active surface-area concentration, giving aerosol size distribution. Data may be interpreted in terms of number concentration. Size-selected samples may be further analysed off-line. |
| Mass by calculation | ELPI | Real-time size-selective (aerodynamic diameter) detection of active surface area concentration giving aerosol size distribution. Mass concentration of aerosols can be calculated only if particle charge and density are assumed or known. Size-selected samples may be further analysed off-line. |
| | DMPS | Real-time size-selective (mobility diameter) detection of number concentration, giving aerosol size distribution. Mass concentration of aerosols can be calculated only if particle shape and density are known or assumed. |
| Surface area by calculation | DMPS | Real-time size-selective (mobility diameter) detection of number concentration, giving aerosol size distribution. Mass concentration of aerosols can be calculated only if particle shape and density are known or assumed. |
| | DMPS and ELPI used in parallel | Differences in measured aerodynamic and mobility can be used to infer particle fractal dimension, which can be further used to estimate surface area. |

10.3 Sampling strategy

The National Institute for Occupational Safety and Health (NIOSH) provides the following advice on sampling strategy. [14]

“Currently, there is not one sampling method that can be used to characterize exposure to nanosized aerosols. Therefore, any attempt to characterize workplace exposure to nanoparticles must involve a multifaceted approach incorporating many of the sampling techniques mentioned above. Brouwer et al. [15] recommend that all relevant characteristics of nanoparticle exposure be measured, and a sampling strategy similar to theirs would provide a reasonable approach to characterizing workplace exposure.

The first step would involve identifying the source of nanoparticle emissions. A CPC provides acceptable capability for this purpose. It is critical to determine ambient or background particle counts before measuring particle counts during the manufacture or processing of the nanoparticles involved. If a specific nanoparticle is of interest (e.g. TiO₂), then area sampling with a filter suitable for analysis by electron microscopy should also be employed. Transmission electron microscopy (TEM) can identify specific particles and can estimate the size distribution of the particles.

Once the source of emissions is identified, aerosol surface area measurements should be conducted with a portable diffusion charger and aerosol size distributions should be determined with an SMPS or ELPI using static (area) monitoring. A small portable surface area instrument could be adapted to be worn by a worker, although depending on the nature of the work, this may be cumbersome. Further, losses of aerosol with the addition of a sampling tube would need to be calculated. The location of these instruments should be considered carefully. Ideally they should be placed close to the work areas of the workers, but other factors such as size of the instrumentation, power source, etc., will need to be considered.

Lastly, personal sampling using filters or grids suitable for analysis by electron microscopy or chemical identification should be employed, particularly if measuring exposures to specific nanoparticles is of interest. Electron microscopy can be used to identify the particles, and can provide an estimate of the size distribution of the particle of interest. The use of a personal cascade impactor or a respirable cyclone sampler with a filter, though limited, will help to remove larger particles that may be of limited interest and allow a more definitive determination of particle size. Analysis of these filters for air contaminants of interest can help identify the source of the respirable particles. Standard analytical chemical methodologies should be employed.

By using a combination of these techniques, an assessment of worker exposure to nanoparticles can be conducted. This approach will allow a determination of the presence and identification of nanoparticles and the characterization of the important aerosol metrics. However, since this approach relies primarily on static or area sampling some uncertainty will exist in estimating worker exposures.”

10.4 Limitations

Measuring particle number concentration in isolation can be quite misleading. In all particle number concentration measurements, the integration limits over which a particular instrument operates are critical in understanding the reported results. CPC instruments become increasingly insensitive to particles smaller than 10 nm to 20 nm. Concentrations measured with instruments with different sensitivities might therefore differ substantially, particularly if the particle count median diameter is close to or in this range. In this case instruments will significantly underestimate the nanoparticle aerosol number concentration.

A further complication relates to the ambient aerosol. Unless the workplace is operating under clean room conditions nanoaerosols from external sources will enter the workplace and result in overestimation of the levels of nanoparticles emitted from the process under investigation. One way to overcome this problem is to determine ambient or background particle counts prior to the commencement of manufacturing or processing of the nanoparticles. Another method is to carry out simultaneous measurement of background concentrations using a duplicate set of monitoring equipment to monitor outside the workplace, and to subtract the outdoor levels from those measured inside the workplace. However, this can be expensive and assumes that the ambient particles do not change during transport into the workplace [16].

A further approach is to utilize differences in composition between nanoparticles generated in the workplace and the ambient aerosol for discrimination purposes.

11 Spillages and accidental releases

Because of the potential for spillages and accidental releases of nanomaterials, it is essential that employers have documented policies and procedures in place which, as far as possible, cover both smaller and more significant events.

It is vital that suitable and sufficient risk assessments are completed to determine the exact course of action to be taken in the event of a nanomaterial spillage or accidental release. The methods used should be consistent with the level of hazard and the quantity of nanomaterial involved in the spill. All clean-ups should be carried out in such a way as to ensure that exposure to personnel is as low as reasonably practical. Personnel who might be required to deal with such events should receive adequate information, instruction and training on assessing the extent of any spill/accidental release, the clean-up measures to be taken, and the PPE which should be worn, as well as guidance on the safe disposal of any waste collected during the clean-up.

In the event of a spillage or accidental release, on-site personnel should determine the extent of the area potentially affected and demarcate the area to restrict access by non-essential personnel. Measures should also be put in place to reduce the likelihood of spreading nanomaterials from the affected area, for example the use of absorbent walk-off mats at the affected area's exit points.

In situations where on-site personnel might reasonably be expected to deal with a spillage or accidental release of nanomaterials, consideration may be given to the use of wet wiping cleaning methods, barriers to minimize air currents across an area affected by a spillage and tested and certified “HEPA” vacuum methods for dealing with dry materials or residues from dried liquid spill areas. Dry sweeping should be avoided. When using HEPA filters it is recommended that the effectiveness of these should be verified at a frequency consistent with manufacturers’ recommendation and, where possible, dedicated HEPA vacuums should be used for clean-up operations. It is also good practice to record the type of material collected and avoid mixing potentially incompatible materials in the vacuum or filters.

Employers need to consider and document which, if any, situations should trigger an evacuation of personnel from an affected area. Consideration should also be given to the severity of spillages and accidental releases which on-site personnel can be expected to deal with and when other agencies, such as the emergency services and environmental protection agencies, need to become involved.

All debris resulting from the clean-up of a spillage or accidental release (including any filters, wipes, absorbent mats and materials) should be considered as nanomaterial-bearing waste. Guidance on the disposal of collected debris and waste is provided in Clause 12.

12 Disposal procedures

12.1 Planning the storage and disposal of nanomaterials

The waste management guidance given in this clause is based on guidance developed and used by the US Department of Energy (DOE 2007) [17] and the UK Environment Agency (EA) Guidance for the disposal of hazardous materials (HWR01) [18], and applies to nanomaterial-bearing waste streams (solid and liquid waste), including:

- a) pure nanomaterials;
- b) items contaminated with nanomaterials, such as containers, wipes and disposable PPE;
- c) liquid suspensions containing nanomaterials; and
- d) solid matrices with nanomaterials that are friable or have a nanostructure loosely attached to the surface such that they can reasonably be expected to break free or leach out when in contact with air or water, or when subjected to reasonably foreseeable mechanical forces.

A plan for storage and disposal of nanomaterials or nanomaterials contaminated waste should be developed, taking account of the hazardous nature of the materials and the quantities involved. Any material that has come into contact with dispersible manufactured nanoparticles (that has not been decontaminated) should be considered as belonging to a nanomaterial-bearing waste stream. This includes PPE, wipes, blotters and other disposable laboratory materials used during research activities. Material from nanomaterial-bearing waste streams should not be put into the regular waste or down the drain. Surface contamination should be evaluated and removed. Equipment used to manufacture or handle nanoparticles should be decontaminated before it is disposed of or reused. Wastes (cleaning solutions, rinse waters, rags, disposable PPE) resulting from decontamination should be treated as nanomaterial-bearing waste.

12.2 Storage of nanomaterial waste prior to disposal

The following are appropriate approaches for collection and storage of nanomaterial waste prior to disposal.

- a) **Storage in waste containers.** Package nanomaterial-bearing wastes in compatible containers that are in good condition and afford adequate containment to prevent the escape of the nanomaterials. Label the waste container with a description of the waste and include available information characterizing known and suspected properties.
- b) **Storage in plastic bags.** Collect paper, wipes, PPE and other items with loose contamination in a plastic bag or other sealable container stored in the laboratory hood. When the bag is full, close it and carefully place it into a second plastic bag or other sealing container, avoiding outside contamination. Take it out of the hood and label the outer bag with an appropriate waste label.

12.3 Disposal of nanomaterial waste

In the UK, guidance provided by the Environment Agency provides a framework for assessing whether a waste material is hazardous and a process by which it can be disposed of [18]. It is a reasonable worst case assumption to consider all nanomaterial waste as potentially hazardous. It can therefore be disposed of as chemical waste.

The List of Waste Regulations 2005 (LOWR) [19] provides detailed information about how to handle and dispose of various types of waste. Two categories are particularly relevant: wastes from organic chemical process (Code 06) and wastes from inorganic chemical process (Code 07). Most nanomaterial waste can be categorized under these codes.

LOWR also provides a list of hazardous properties, including examples, such as H5 "Harmful substances and preparations which if they are inhaled or ingested or if they penetrate the skin may involve limited health risks" and H6 "Toxic substances and preparations which if they are inhaled or ingested or if they penetrated the skin may involve serious, acute or chronic health risks and even death".

H5 would be a reasonable worst case assumption for many insoluble and soluble nanoparticle types, as defined in 7.1. H6 would describe CMAR types and would be a reasonable worst case assumption for carbon nanotubes or other nanomaterials having a fibrous nature.

The regulations specify that the maximum concentration for substances classified as toxic is 3% by mass.

13 Prevention of fire and explosion

In the UK issues of fire and explosion are covered by the DSEAR regulations [20]. The effectiveness of methods for nanoparticle fire, explosion and catalysis prevention and control are yet to be evaluated. Some types of nanoparticle products can be raised from a layer into suspension more easily than coarser products, and can remain in suspension for a long time. Dense clouds of nanoparticle powder might be difficult to see, even though a suspension of the same product at the same concentration at a coarser grade is easily visible. The same principles applying to the management of fine powders, dusts or dusty materials should be considered for nanoparticles, with particular care taken in the case of easily oxidizable metallic dust. Explosion protection measures have been described for dust dispersions and for hazardous quantities of larger sized materials [17], and these can be applied to the handling of potentially explosive nanoparticles. For reactive or catalytically active nanoparticles, contact with incompatible substances should be prevented.

Fire prevention has to take into account existing regulations, especially electrical requirements. The design of electrical equipment protection should take account of the fine granulometry and very long settling time of nanoparticles, which necessitate dust protection. In addition, further precautions should be taken to avoid the risk of auto-ignition of nanoparticles [16].

The selection of an extinguishing agent should take account of the compatibility or incompatibility of the nanomaterial with water. Some metallic dusts react with water to form, among other things, hydrogen, which ignites very easily. Chemical powders are available to extinguish burning metallic dust powders, though this has the effect of putting the metallic dust in suspension, thereby increasing the risk of deflagration. To reduce the risks of fire and deflagration, it might prove necessary to use controlled-atmosphere production and storage processes, using carbon dioxide, nitrogen or another inert gas. This could introduce further hazards into the system, notably the risk of asphyxiation.

Anti-static shoes should be worn in areas where the materials are handled to reduce the build-up of static charge, which could potentially ignite the materials.

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PD ISO/TR 27628, *Workplace atmospheres – Ultrafine, nanoparticle and nano-structured aerosols – Inhalation exposure characterization and assessment*

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Sources of further information

Nanotechnology risks and good practice

UK Health and Safety Executive (HSE): Horizon scanning – Nanotechnology

<http://www.hse.gov.uk/horizons/nanotech.htm>

HSE Report R274: Nanoparticles, an occupational hygiene review

<http://www.hse.gov.uk/research/rrhtm/rr274.htm>

DuPont and Environmental Defence: Nano Risk Framework

<http://www.nanoriskframework.com/page.cfm?tagID=1095>

ICON – A Survey of Current Practices in the Nanotechnology Workplace: Condensed Report

<http://cohesion.rice.edu/CentersAndInst/ICON/emplibrary/ICONNanotechSurveyAbridgedReduced.pdf>

SAFENANO: The nanotechnology health and safety information site

www.safenano.org

General risk management approaches

HSE. Control of Substances Hazardous to Health – COSHH

<http://www.hse.gov.uk/coshh/index.htm>

HSE: COSHH Essentials, Easy steps to control risks from chemicals

<http://www.coshh-essentials.org.uk/>

Safe and Health Working: Working with hazardous substances

<http://www.sahw.co.uk/main-section/workplace-topics/hazardous-substances.cfm#6>

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