COMMISSION MANDATE M/409
ADDRESSED TO CEN, CENELEC AND ETSI
FOR THE ELABORATION OF A PROGRAMME OF STANDARDS TO TAKE INTO ACCOUNT THE SPECIFIC PROPERTIES OF NANOTECHNOLOGY AND NANOMATERIALS

Report from CEN/TC 352 Nanotechnologies

April 2008

Executive summary

The European Commission, in its mandate M/409, asked CEN, CENELEC and ETSI to provide a report on a possible programme of standards to take into account the specific properties of nanotechnology and nanomaterials.

The mandate broadly calls for information to be presented on:

- current standards relevant to nanotechnologies that may need to be revised;
- new standards needed;
- deliverables other than full European standards (ENs) that may be appropriate;
- the availability of stakeholders, and requirements for their engagement in the standardization process.

In order to fulfil the above tasks, an extensive consultation of CEN and CENELEC Technical Committees (TCs), European Technology Platforms (ETPs) and other organizations and associations with a possible interest in nanotechnologies and nanosciences (N&N) was undertaken. The responses obtained were variable. Some groups provided very comprehensive replies, indicating their high level of engagement with the subject. On the other hand, a number of those consulted either did not respond or declared little or no current interest or activity. Due to the dynamic nature of this subject area, there should be a further review in the future (see recommendation X below).

All relevant CEN/CENELEC TCs with responsibility for standards harmonized to New Approach Directives were consulted. Two standards harmonized to the medical devices Directives were identified as needing review. In view of the many TCs that either did not respond or indicated no current interest, it is possible that a complete picture has not been obtained.

The deliverables that are needed are primarily Technical Specifications (TSs) and Technical Reports (TRs), although full European standards (ENs) will be appropriate in some circumstances. There might also be a role for fast-track deliverables such as Publicly Available Specifications (PASs) and Workshop Agreements.

There is considerable untapped technical expertise in Europe that can contribute to standardization. The level of participation in standards activity in CEN/TC 352 'Nanotechnologies' is currently not fully representative of known stakeholders. Noticeably lacking are industry, consumer and national regulatory authority experts. There is a need for better communication about the existence and importance of standards activity as well as the role that standards can play in the regulatory context and in the commercialization of nanotechnologies. This view is supported by a recent Commission publication on the contribution of standards to innovation in Europe.[1]

[1] Towards an increased contribution from standardisation to innovation in Europe – European Commission, COM(2008)133

It is important to overcome existing hurdles to stakeholder engagement, such as lack of understanding about the use of standards in regulation, access to resources and lack of standards awareness.

Europe should play a leading role in ensuring the safe, responsible and successful development of nanotechnologies. European standards activity will be pivotal in:

- supporting the commercialization of nanotechnologies;
- assuring health, worker and environmental safety;
- achieving the Lisbon Agenda;
- furthering the societal agenda; and
- underpinning the European regulatory framework.

Indeed, the Commission communication referred to above (footnote 1) states:

"The success of the European standardisation system in removing technical barriers to trade has played a vital role in ensuring the free movement of goods between Member States. A strong role for Europe in international standardisation means European leadership in new markets and gaining first-mover advantages in global markets."

To achieve this, the European standards bodies recommend the following:

1. A programme of standardization should be initiated, by means of a standardization mandate, for the development of nanotechnology-specific standards in Europe and to encourage the participation of European stakeholders in the standardization process. The standards needs identified have been listed and prioritized in annex D;

2. The EC should provide clear and early guidance as to what nanotechnology standards projects are needed to support existing or planned legislation;

3. Support should be provided to enable the participation of all stakeholder groups in the nanotechnology standardization process;

4. A joint European Commission–European Standardization Organization (ESO) group should be established to identify nanotechnology standardization opportunities and needs arising from relevant Framework Programme projects, and facilitate their development;

5. Relevant ETPs should be requested to identify appropriate nanotechnology standardization opportunities and needs, and report to the above group.

6. In view of the rapid evolution of standardization and research in nanotechnology and nanosciences, it is recommended that a further programming mandate be given by the EC in 5 years.

1 Introduction

An extensive consultation of CEN and CENELEC Technical Committees (TCs), European Technology Platforms (ETPs) and organizations and associations with a possible interest in nanotechnologies and nanosciences (N&N) has been undertaken in order to determine the level of interest and/or activity by these groups in current or future standardization relating to N&N. Included in this consultation were specific questions about existing and future standards that relate to N&N or might need to be revised or prepared to take into account N&N. The outcomes have provided information that is discussed in sections 3 to 7, whilst detailed responses to the consultation are presented in annexes A to C.

Section 3 discusses existing harmonized and other standards, while section 4 provides a list of proposed new standards projects. These are presented under the three general categories of 1) health, worker and environmental safety, 2) the Lisbon Agenda, and 3) the societal agenda. This programme of proposed work is also set out in annex D, where a degree of prioritization is given, as well as additional information on the need or otherwise for pre-normative research. It also indicates where an individual item on the list would in fact require more than one standards publication. There has been no attempt to assign the proposed standards projects to any particular TC or standardization organization for development.

The standards deliverables that are likely to be needed are described in section 5, and discussed according to their relevance to the Mandate.

Stakeholder availability and engagement with the standardization process is considered in section 6, whilst section 7 expands on the wider context of European standards and section 8 discusses standards in the context of the regulatory process.

Section 9 contains recommendations for action, based on the information presented in this report and the experience to date with the standardization programme in Europe and elsewhere.

2 Sources of information

In order to complete this programming Report requested by Mandate M/409, CEN/TC 352 'Nanotechnologies' in cooperation with CENELEC/SR 113[2] consulted an extensive list of CEN and CENELEC TCs between November 2007 and March 2008 via a questionnaire. The TCs consulted and the results of the survey are shown in annex A. Similarly, questionnaires were sent to ETPs of particular relevance to N&N (ETPs and results are shown in annex B) as well as to European organizations and associations believed to have a

[2] CENELEC/SR 113 = CENELEC Reporting Secretariat for IEC/TC 113

possible interest in N&N (organizations/associations and results are shown in annex C).

In addition to the above consultations, and via liaison members of ISO/TC 229[3], IEC/TC 113[4], OECD and Nanostrand, the following additional sources were used:

- The FP6 Coordination Action "Nanostrand", completed in January 2008;
- The ISO/IEC/NIST/OECD sponsored Workshop on documentary standards for measurement and characterization for nanotechnologies held 26-28 February 2008;
- The ISO/TC 229 roadmap of standards needs, completed March 2008.

Annex E provides a list of published standards and current standards projects relevant to nanoscale measurement.

Information provided by Nanostrand and the ISO/IEC/NIST/OECD Workshop has been incorporated into section 4 of this report, whilst information on metrology roadmaps from Nanostrand is shown in Annex F.

Finally a number of nanotechnology roadmaps and similar have also been consulted, including those produced by the FP6 project Nanoroadmap[5] and the European Technology Platform MINAM[6] for micro and nano-manufacturing.

The review undertaken via the above sources provides a snapshot of the current and future needs of N&N standardization in Europe for the next 5-7 years.

3 Existing standards

3.1 Harmonized standards

All CEN/CENELEC TCs with responsibility for harmonized standards to all the New Approach Directives were included in the TC consultation results shown in annex A. The following standards were identified as possibly needing review to assess if revision is required to incorporate nanotechnological developments:

EN ISO 10993 series [Biological evaluation of medical devices]

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[3] ISO/TC 229 ' Nanotechnologies'

[4] IEC/TC 113 'Nanotechnology - Standardization for electrical and electronic products'

[5] Nanoroadmap: http://www.nanoroadmap.it/

[6] MINAM: http://www.minamwebportal.eu/index.php?m1=Public-Area

EN ISO 14155 Parts 1 and 2 [Clinical investigation of medical devices for human subjects]

These standards are harmonized under the Medical Device Directives 93/42/EEC, 90/385/EEC and 98/79/EC. In the case of EN ISO 14155, it was not the responsible CEN/TC (CEN/TC 258) that suggested the standard should be reviewed.

Other than the two standards given above, there is no positive information, that any harmonized standards need review or revision. In view of the many TCs that did not respond, however, it is possible that the picture presented, if accurate as far as it goes, is not complete.

3.2 Other standards

Annex E provides a list of other published standards and other current standards projects relevant to nanotechnologies and nano-materials. Some of these are developed specifically for the N&N domain. Others might need revision to be able to efficiently deal with N&N. Possibly, there exist more standards not currently relevant to nanotechnologies and nano-materials, which if revised, could be applicable in a "nano-context". Given the vast number of standards, it has not been possible to produce an exhaustive list.

At this time, CENELEC has not identified any European standards that need to be amended in order to incorporate requirements for nanotechnology. However, it can be noted that there is a close cooperation between CENELEC and IEC, which might identify nanotechnology standards needs at the IEC level that are relevant in Europe.

To date, ETSI has not identified any nanotechnology-specific standards needs in the area of telecommunications.

4 New standards needed relevant to nanotechnologies and nanomaterials

4.1 General

Sections 4.2 to 4.4 provide lists of new standards that are needed for nanotechnologies and nanomaterials. See also Annex A, Table A.4 for specific standards projects identified by CEN TCs, as well as the list of standards needs identified by the European Environmental Citizens' Organization for Standardization (ECOS), the European Food Safety Authority (EFSA) and the Nanotechnology Industries Association (NIA) in Annex C.

Annex D presents more detail on these standards needs.

The standardization needs identified here have been assembled from the following studies:

- the FP6 Coordination Action “Nanostrand”, completed in January 2008;
- the ISO/IEC/NIST/OECD sponsored Workshop on documentary standards for measurement and characterization for nanotechnologies, held on 26-28 February 2008;
- the ISO/TC 229 roadmap of standards needs, completed in March 2008;
- and a survey by CEN/TC 352 of relevant CEN TCs (completed March 2008) and ETPs and other European organizations (completed in January 2008).

These needs can be subdivided into the following three priority areas:

- Standards supporting health, worker and environmental safety
- Standards supporting the Lisbon agenda
- Standards supporting the societal agenda

Whilst it is recognized that standards in terminology and nomenclature are a fundamental requirement for other standards, it is acknowledged that this work must be done at the international level, with full input from European countries, therefore these have not been included in this report.

The standards topics listed in 4.2 to 4.4 have not been divided on the basis of where they should be developed. Most standards needed in Europe are also needed globally. Certainly many of these could be developed in either Europe or internationally, as long as there is good cooperation between the respective standards committees. CEN/TC 352 and ISO/TC 229 are already working very closely together, with a number of work items approved in CEN/TC 352 to be developed with an ISO lead, and with three work items already approved in ISO/TC 229 to be developed with a CEN lead. It should be noted that there is a preference among some stakeholders for standards work not to be done unless there is international cooperation.

Regarding the current work programme of the international standardization organizations, new standards on terminologies and basic measurement methods are being addressed by the Joint Working Groups (JWGs) 1 and 2 of ISO/TC229 and IEC/TC113. Standards addressing potential risks for human health and environment are being developed by ISO/TC 229 Working Group 3 (WG 3), and liaison with the OECD Working Party on Manufactured Nanomaterials (WPMN) ensures that this topic is well addressed. IEC/TC113 is also involved in the activities of ISO/TC229/WG3 as a liaison partner, although it is assumed that there are no special health and safety requirements relating to nanotechnology enabled electrotechnical products.

4.2 Standards supporting health, worker and environmental safety

Concerns about health, safety and environmental issues have to be addressed with the highest priority. It is recognized that any widespread doubt will have a negative impact on the future successful commercialization of nanotechnology. Based on the arguments outlined in this section, the development of the following standards or guidance documents (PAS, TS, TR, etc.) supporting HSE is proposed:

- Guidance on safe handling of manufactured nanoparticles and other nanoscale entities;
- Guidance on containment, trapping and destruction of nanoparticles and other nanoscale entities;
- Guidance on a common data-format for an integrated analysis for risk assessment;
- Guidance on integrated testing strategies (ITS) and integrated risk assessment;
- Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials;
- Guidance on detection and identification of nanoparticles and other nanoscale entities;
- Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.
- Guidance on nano-material characterization prior to, or in association with toxicity testing;
- Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;
- Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;
- Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;
- Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities;
- Fast track protocols for predicting the toxicity and ecotoxicity for classification of nanoparticles and other nanoscale entities, particularly for identifying and tracking the most dangerous ones in the framework of the REACH directive;
- Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage);
- Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities;
- Protocols for risk management that specifically refers to potential nanotechnology hazards;
- Protocols for whole life cycle assessment of nanoscale materials, devices and products.

Aspects of risk management are fundamental for the future commercial exploitation of nanotechnology and its acceptance by society. It is necessary to ensure a safe and responsible approach to risk assessment at all stages of the product life cycle. This requires an intense dialogue between the various stakeholders to understand their interests and concerns. At present, the discussion on risk in nanotechnology is focused on nanomaterials and their interaction with living cells. This is especially important if these materials are manufactured in large quantities and if they potentially will be released into the environment during normal use.

Standardization can support this dialogue by providing the proper terminology and reliable materials characterization and exposure measurement techniques. Therefore standards are needed on terminology and nomenclature as well as on basic measurements. Both are preconditions in order to make qualified statements and draw reliable conclusions as potential input for regulations.

For electrotechnical products, the risk for environmental and human health is significantly lower for two reasons:

- Electrotechnical products are typically manufactured under clean room conditions. Therefore the nanomaterials are well contained and the risk for human health in the workplace is reduced compared to large-scale nanomaterial production;
- In the final product the total amount of nanomaterial is typically very small and is encapsulated in the product. Therefore both manufacture and normal use are deemed to be low risk for humans and the environment.

Nevertheless aspects of risk for human health and the environment have to be addressed for electrotechnical products in case of accidents, accidental damage and risk during end of life handling and disposal.

4.3 Standards supporting the Lisbon agenda

4.3.1 General standards needs

The potential of nanotechnology to contribute to the future prosperity of the European economy and the targets formulated in the Lisbon Agenda require acceleration of the transformation of research results into marketable products. Therefore one focus of the R&D funding of the European Commission is the establishment of ETPs. A number of these especially address future manufacturing technologies that include aspects of nanotechnology. The work of the ETPs will both enable and require development of specific standards with relevance to achieving the Lisbon agenda. Based on the arguments outlined in this section, the following priority areas for standardization and guidance documents are proposed:

- Guide to performance measurement of nanoscale materials and devices;
- Guide to the evaluation of new functions specific to manufactured nano-particles and other nanoscale entities;
- Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance, etc., of materials and devices at the nanoscale;
- Specifications for different manufactured nanomaterials;
- Guide to methods and techniques for assessing the quality of nanoscale materials used in the preparation of devices;
- Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities;

- Guide to purity evaluation of manufactured nanoparticles and other nanoscale entities;
- Guide to modelling (measurement, simulation and visualization) at the nanoscale;
- Good practice guides for nano-fabrication and nano-engineering;
- Guides to existing national, regional and international regulations, codes of conduct, etc., relevant to nanotechnologies.

In addition to the need for standards development, a number of supporting measures providing technical underpinning of standards, including validation, are required:

- Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nanoscale entities;
- Co-normative research to evaluate repeatability, reproducibility and inter-comparability of test methods;
- Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.
- Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment;
- Development of in situ/on line non-destructive techniques and contact-less measurements relevant to nanotechnologies.

It can be noted that some of the above items occur also in section 4.2. This apparent duplication is a reflection of the information need naturally shared between performance and safety assessment.

Already, the lack of nanotechnology-specific standards is widely regarded as a negative indicator of the economic growth of nanotechnologies in Europe. The FP6 project Nanostrand conducted a survey of the nanotechnology industries in Europe, which revealed that, for over half of those replying, the absence of standards is affecting their business. Occupational health and safety standards, as well as nanomaterials specifications are particularly identified as key to further advancement of nanotechnology commercialization.

4.3.2 Specific considerations for CENELEC

IEC/TC 113 and its European reporting secretariat CENELEC/SR 113 intend to focus their work on product life cycle oriented standardization with principal activities in the areas of:

- Performance assessment – Pre-competitive research, Design, Manufacture and Use
- Reliability – Pre-competitive research, Design, Manufacture and Use
- Safety – Pre-competitive research, Design, Manufacture, Use and End-of-life (includes disposal, reuse and recycling)

Of these, standards relevant to performance assessment and reliability are identified above in this section, whilst standardization needs relevant to safety are identified in section 4.2.

4.3.3 Renewable energy generation and sustainability

According to a 2005 Commission document[7], the transition to a climate-friendly society offers economic opportunities for Europe, reinforcing its Lisbon agenda. 'The early development and commercialization of climate-friendly technologies would endow the EU with the "first-mover advantage" and allow it to capture new markets when global demand for such technologies grows'. The report calls for new climate-friendly technologies to be developed and mainstreamed rapidly. Nanotechnologies offer significant opportunities in the area of renewable, climate friendly, energy production and for reducing (conventional) energy consumption: new lighter, stronger, more robust materials for use in, e.g. wind-power equipment, and vehicle and aircraft construction; new, more efficient and lower cost solar cells for local electricity generation; new catalysts for gasification, for cleaner and more efficient combustion, and for removing atmospheric pollution; new, light weight and high efficiency fuel cells for use in vehicles and consumer electronics; heat-reflecting layers for windows; highly efficient thermal insulators for buildings and vehicles, and new thermal barriers and blade materials to increase the efficiency of gas turbines; highly efficient lighting; very low power-consumption consumer electronics; new lubricants and surface layers to reduce energy loss and increase component life; etc, etc.

Standardization in all of these areas would significantly assist commercial take-up and price reduction; if Europe takes a leading role in research, development and exploitation of these areas, it could make a substantial contribution both to achieving the Lisbon agenda and to reducing the causes of climate change. By being pro-active in the development, standardization and exploitation of nanotechnologies, particularly in the area of climate-friendly energy solutions, Europe can secure a successful and long term future as a knowledge-driven economy, and make significant progress towards achieving the Lisbon agenda.

4.4 Standards supporting the societal agenda

NOTE. The societal agenda can be considered to consist of a number of distinct, though related aspects, such as benefits derived from medical applications, sustainability, security and consumer interests.

4.4.1 Medical applications

As in many other areas, nanotechnology holds significant promise for maintaining and in many cases improving quality of life through the provision of new and improved medical imaging, non-invasive diagnostic techniques,

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[7] Winning the Battle Against Global Climate Change

COM (2005) 35 final

and new and enhanced pharmaceuticals, medical implants and devices. Many aspects will become increasingly important as European demographics shift towards an ageing population.

Development of standards in at least the following areas will contribute to this important field:

- Standard method for assessing stability of nanoparticles in vivo and in vitro;
- Standard method for in vitro evaluation of osseo-genetic behaviour of nanostructured surfaces;
- Design, construction and performance criteria for cantilever-arrays used in diagnosis;
- Design, construction and performance criteria for lab-on-a-chip devices;
- Standard method to measure release of active materials from nanoporous substrates.

Many other areas of medical application will require standards development as the technology develops.

<u>4.4.2 Sustainability</u>

With the rapidly growing world population placing increasing demands on limited resources, the need for sustainable production, consumption and living has never been greater – see for example OECD Environmental Outlook to 2030, OECD 2008.
Nanotechnology will impact efforts to achieve sustainability in a number of ways, including enabling the production of high efficiency photovoltaics and fuel cells for energy production, high efficiency, high energy density electricity storage, hydrogen storage systems, new and enhanced catalysts for e.g. clean combustion, supporting accessibility to potable water, replacing, recycling, and reducing the use of raw materials, increasing the use and application of polymer and printable electronics, enabling high efficiency lighting, enabling "electronic paper", improving thermal insulation of buildings, and enabling highly focused application of herbicides, pesticides and nutrients in agriculture, etc. Development of standards in the following areas will contribute to this important field:

- Guide to the design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water;
- Design and performance of nanoscale cantilever devices for detection and identification of pathogens in water and food;
- Material specifications for polymer and printable electronics;
- Design criteria for high spatial resolution monitors for environmental monitoring.

<u>4.4.3 Security</u>

There are many aspects to this area:

- Security of individuals and of their personal identity
- Cross border security

- Security of national infrastructure
- Security of transport
- Security of energy supplies
- Security of food supplies
- Security of water supplies
- Security of information
- Security of products through anti-counterfeiting measures
- Etc.

Through its interdisciplinary nature, nanotechnology will contribute to all of these areas, though great care will be required to ensure that the need for security does not lead to the erosion of personal liberty. Indeed, nanotechnology, could, in principle, support both of these areas in a complementary rather than contradictory manner. Development of standards in the following areas will contribute to this important field:

- RFID standards to complement ISO/IEC TR 18047-7:2005;
- Design and performance of cantilever devices for detection and identification of pathogens in water, food and the air;
- Design and performance of remotely addressable, anti-counterfeiting devices;
- Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water.

4.4.4 Consumer interests - Labelling and nanoMark

Groups representing consumers[8] have called for appropriate labelling of products containing nanomaterials in order that consumers can know if products contain nanoparticles and can make informed choices concerning whether to purchase a product or not. However, the issue of labelling such products is not straightforward. A labelling guidance document can only be voluntary, since no regulation exists that specifically requires labelling of products containing nanomaterials unless they are associated with identified risks. Therefore, not all such products will be labelled. It is possible that the labelling of (only) some nanoproducts could set up a wrong expectation, either that there are no nanoparticles in a product that is not labelled; or that a product that is so labelled is safe. In addition, some aspects of labelling are already covered through existing legislation. The General Product Safety Directive covers mis-labelling, such as false claims/advertising as well as failure to label hazardous substances. Food products, cosmetic products and medical devices already have their own labelling requirements. Nevertheless, it is possible that a guidance document on the specific labelling of nanoparticle content of products intentionally containing nanomaterials could prove useful to both manufacturers and consumers who wish to have guidance on the appropriate way to label their products. Such a document could be restricted to a particular type of product, and would have to be developed with close liaison of industry and consumers.

[8] For example, BfR Consumer conference on nanotechnology in foods, cosmetics and textiles, 24 Nov 2006.

Another aspect related to labelling is the possibility of a ‘nanoMark’ – a certified mark that guarantees the nanotechnology basis and benefits of a product and that could be affixed to the packaging of a product. It is possible that such a mark, if adopted in Europe, could have a positive impact on the market for nanotechnology by providing customers with independent verification that products contain, and benefit from, addition of nanoparticles. In this case, the standards deliverable would be a specification to be used in certifying the nanoparticle content and benefit derived from use of nanotechnology.

5 Appropriate standards deliverables

5.1 Description of possible deliverables

Procedures in CEN, CENELEC and ETSI allow for the preparation of different European standards deliverables, depending on the nature of the product or process, the expectations of the industry and the maturity of the technology concerned. Details of deliverables can be found by reference, for example, to standard CEN guidance[9], and may be summarised as follows.

European standards (ENs)

ENs are normative documents issued in at least the three official languages of CEN/CENELEC. National members of CEN/CENELEC must transpose the final text ENs, as ratified by vote, into national standards – translating them if desired – without deviation or alteration, and retain the prefix EN in the national designation: e.g. BS EN 1234, NF EN 1234, DIN EN 1234. Thus the number and technical content of the standard are exactly the same throughout Europe.

ENs may also be ISO and/or IEC standards (see also reference to the Vienna and Dresden Agreements in 7.2 below).

Other principal products

- Technical Specification (CEN/TS or CLC/TS) – normative document presented where the state-of-the-art is not yet stable enough for preparation of an EN
- Technical Report (CEN/TR or CLC/TR) – for information and transfer of information
- CEN or CENELEC Workshop Agreement (CWA) – for consensual agreements in open workshops

[9] http://www.cen.eu/boss/supporting/guidance+documents/gd059+-+cen+deliverables/gd+-+cen+deliverables.asp#background

5.2 Relevance of the different deliverables for the mandate

Only full ENs can be used as harmonized standards in support of New Approach Directives (see also 7.2). ENs of ISO/IEC origin may also be used in this context. However, since "standards should be based on the consolidated results of science, technology and experience"[10], in the new yet fast developing field of nanotechnologies, it is currently premature to embark on writing EN's or 'full' standards. Hence, deliverables other than ENs will have to be considered. Where ENs already exist, however, it is possible that they can be amended in the future to make them applicable to products containing nanomaterials and processes using nanotechnology. At present, the medical device sector is the only one regulated by New Approach Directives, in which harmonized standards have been identified for possible amendment to take into account nanotechnology.

For the greater part of the nanotechnologies subject matter, Technical Specifications and Technical Reports are expected to be appropriate, at this stage. Since these deliverables can be developed more quickly they can be used to track the rapid development of technology. This is not without policy relevance since TS and TR publications can provide best available options for example to industries requested to demonstrate product compliance with regulation.

Deliverables that can be developed quickly to track the rapid development of technology also have a potential use in this field. These include CWAs and the ISO/IEC PAS (Publicly Available Specification) and equivalent national documents.

However the work is developed, there should be close cooperation between CEN/CENELEC and ISO/IEC, and there is scope for Vienna and Dresden Agreements deliverables with both ISO/IEC and CEN/CENELEC leads. Indeed, the standardization programme is potentially so large that all available standardization resources should be utilized.

6 Availability of stakeholders

6.1 General

There already exists a substantial network of nanotechnology expertise, including from industry, which has developed in the context of the Framework Programmes of the European Community. There are also industrial and other stakeholders within ETPs[11] that can be expected to have a strong interest in building a European position on standardization. Despite this, these stakeholders (with the exception of metrology institutes and a few universities)

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[10] ISO/TMB Policy and Orinciples Statement

[11] European Technology Platforms: http://cordis.europa.eu/technology-platforms/home_en.html

have yet to involve themselves to a significant extent in the CEN/TC 352-CENELEC/SR 113 standards activity established so far. Especially lacking is the involvement of industrial stakeholders and representatives of smaller countries, although there are signs that interest will increase, and that these stakeholders will begin to participate more.

The reluctance of industry to become more involved at this stage might be for one or more reasons: a lack of knowledge of the standards process; difficulties in establishing mechanisms for input; lack of time or other resource necessary for input itself; belief that it is too early for standards for these products and processes; a desire to use their own in-house standards; and unwillingness to participate in European standardization (preferring to participate only at the ISO/IEC level). In addition, many of the organizations involved in nanotechnologies are SMEs, and it is well recognized that this sector of industry, and other stakeholders, such as users/consumers and researchers, are inhibited from participation in standardization by a number of barriers.[1] It is also likely that some standards bodies are not communicating sufficiently well with stakeholders at the national level, and therefore there is a lack of information concerning the standards activity.

For some stakeholders, the motivation for participation in standardization activities depends on the existence or expectation of regulatory requirements. To many stakeholders the role standardization activities play in the discussion of necessary or emerging novel regulation is not clear; under these circumstances, stakeholders avoid participation in the standardization process.

6.2 CEN/TCs, ETPs, European Organizations/Associations

Many CEN TCs, ETPs and other European bodies were consulted in the course of preparing this report. It should be noted that, of those consulted, a number did not reply or indicated no interest in nanotechnology. See annexes A-C.

ETPs of particular interest in relation to the work of CEN/TC 352 and CENELEC/SR 113 are:

- Artemis[12] – Embedded computing systems
- ECTP[13] – European Construction Technology Platform
- ENIAC[14] – European Nanoelectronics Initiative Advisory Council
- EPoSS[15] – European Technology Platform on Smart Systems Integration
- ETPIS[16] – Industrial Safety European technology Platform

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[12] Artemis: http://www.artemis-office.org/DotNetNuke/Home/tabid/36/Default.aspx

[13] ECTP: http://www.ectp.org/

[14] ENIAC: http://www.eniac.eu/

[15] EPoSS: http://www.smart-systems-integration.org/public)

[16] ETPIS: http://www.industrialsafety-tp.org/

- EuMaT[17] – Advanced Engineering Materials and Technologies
- Euratex[18] – Future textiles and clothing
- Food for Life[19] – Food
- HFP[20] – Hydrogen and Fuel Cell Platform
- Innovative Medicines Initiative[21]
- ManuFuture[22] – Future Manufacturing Technologies
- MINAM[23] – Micro- and Nano-manufacturing
- Nanomedicine[24] – Nanotechnologies for Medical Applications
- Photonics21[25] – Photonics
- Photovoltaics[26] – Photovoltaics
- SusChem[27] – Sustainable Chemistry

The need to establish and/or build upon existing appropriate links for the execution of the mandate with the relevant ETPs (and Joint Technology Initiatives) is clearly indicated. In this respect, we strongly believe that the European Commission has an important role to play in encouraging the identification and translation of knowledge obtained in ETPs into appropriate standards deliverables.

7 European standards - the wider context

7.1 General

The free movement of goods, persons, services and capital is steadily becoming a reality in today's European Single Market, to which the New Approach and the European standards organizations have contributed significantly. It is CEN's mission as well as that of its sister European standards organizations CENELEC (specializing in electrotechnical standardization) and ETSI (specializing in telecommunication standardization) to develop European standards (ENs). Barriers to trade are being eliminated through the development of these ENs. Standardization diminishes trade barriers, promotes safety, allows interoperability of products, systems and services, and promotes common technical understanding.

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[17] EuMat: http://www.eumat.org/

[18] Euratex: http://www.euratex.org/

[19] Food for life: http://etp.ciaa.be/asp/home/welcome.asp

[20] HFP: http://ec.europa.eu/research/energy/nn/nn_rt/nn_rt_hlg/article_1261_en.htm

[21] Innovative Medicines Initiative: imi.europa.eu/index_en.html

[22] Manufuture: http://www.manufuture.org/

[23] MINAM: http://www.minamwebportal.eu/index.php?m1=Public-Area

[24] Nanomedicine: http://cordis.europa.eu/nanotechnology/nanomedicine.htm

[25] Photonics21: http://www.photonics21.org/

[26] Photovoltaics: http://www.eupvplatform.org/

[27] SusChem: http://www.suschem.org/

Once ratified, a European standard (EN) has to be implemented by CEN members as an identical national standard and any conflicting national standards must be withdrawn. A European standard, therefore, potentially substitutes 30 different national standards.

As standardization is expensive and time-consuming, wherever possible the European standards organizations work together and with international bodies in order to minimize overlaps and inefficiencies. In this respect, CEN, CENELEC and ETSI have concluded agreements with their international partners in order to ensure cooperation between the European and international levels:

CEN & ISO: Vienna Agreement (VA)
CENELEC & IEC: Dresden Agreement (DA)
ETSI & ITU-T: MoU Telecommunication sector
ETSI & ITU-R: Agreement on radio-communication sector

CEN promotes close cooperation with ISO, as its international partner organization, with a view to avoiding duplication of work, making the best use of limited resources, and establishing a coherent set of standards. Essentially, the VA recognizes the primacy of international standards. But the agreement also recognizes that particular needs (of the Single European Market for example) might require the development of standards for which a need has not been recognized at the international level. The prioritization of ISO work is also such that in some instances CEN needs to undertake work which is urgent in the European context, but less so in the international one. In particular, CEN/TC 352 works closely with international committee ISO/TC 229 Nanotechnologies. For topics of mutual interest to ISO and CEN, the VA is implemented with an ISO or CEN lead.

CENELEC has worked closely with the IEC for several decades, and will adopt for nanotechnologies what is developed at the international level.

7.2 Need for a European standardization programme

Based on recent discussions at European standardization meetings it is becoming ever clearer that it makes sense to build a European position in nanotechnologies standardization. This is true both for CEN and for CENELEC. Although it has been suggested that, for resource reasons, nanotechnologies standardization should be carried out only at the international (ISO or IEC) level, there are some reasons why this will not always be appropriate.

Firstly, the status of ENs (European standards) in Europe is different from that of ISO or IEC standards (international standards) in other countries. Since European countries must adopt ENs as national standards when they become available, it is essential that, if an international standard is to be adopted as an EN in Europe following use of the Vienna or Dresden Agreement, a true consensus opinion is developed in Europe. It is also important that ENs are developed to avoid the gradual appearance of conflicting national standards or other deliverables, which then become a burden to industry. In addition, CEN has an ongoing duty to elaborate specific European standards in response to needs that clearly differ from other regions of the world, e.g., when societal perspectives differ in Europe from elsewhere, or in response to the regulatory framework in Europe. In this context, the possibility exists that specific standards or recommendations may be needed to support European legislation, e.g. for REACH, or where New Approach Directives exist and harmonized standards are needed to support them. For these reasons, it is appropriate to have a viable and active European standardization structure such as CEN/TC 352.

Additionally, it should be noted that at the ISO level, a number of European countries are not actively participating. The industry members are few and represent large corporate interests. Some European countries only participate at the national or CEN level, and some SMEs and staff of research establishments in Europe are only able to attend meetings that are held in Europe. If some topics are not yet on the programme in ISO, a European TC provides an opportunity for all European interests to be addressed.

The above arguments are equally true for CENELEC, the European mirror to IEC/TC 113, which currently is represented in CEN/TC 352. This partnership between CEN and CENELEC can be further strengthened in the future, providing a stronger structure for CLC/SR 113.

7.3 OECD Working Party for Manufactured Nanomaterials (WPMN)

In 2006 the OECD established a Programme on the Safety of Manufactured Nanomaterials with the objective of promoting international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MN), in order to assist in the development of rigorous safety evaluation of nanomaterials.

The programme concentrates on human health and environmental safety implications of manufactured nanomaterials (limited mainly to the chemicals sector), and will ensure that the approach to hazard, exposure and risk assessment is of a high, science-based, and internationally harmonized standard.

The programme of work consists of eight projects:

1. Development of an OECD (Nanosafety) Database on Human Health and Environmental Safety (EHS) research
2. EHS Research Strategies on Manufactured Nanomaterials
3. Safety Testing of a Representative Set of Manufactured Nanomaterials
4. Manufactured Nanomaterials and Test Guidelines
5. Co-operation on Voluntary Schemes and Regulatory Programmes
6. Co-operation on Risk Assessments and Exposure Measurements
7. The Role of Alternative Methods in Nano-Toxicology
8. Exposure Measurement and Exposure Mitigation

The projects of particular relevance to the field of standardization are:

Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials, for which the objective is to agree and test a representative set of manufactured nanomaterials using appropriate test methods;

Project 4: Manufactured Nanomaterials and Test Guidelines, with the objectives of reviewing existing OECD Test Guidelines for adequacy in addressing manufactured nanomaterials, and identifying the need for development of new or revision of existing test guidelines; and

Project 8: Exposure Measurement and Exposure Mitigation, where the intention will be to identify and compile guidance information for exposure measurement and exposure mitigation related to manufactured nanomaterials in occupational settings (note that this project was approved at the meeting held in November 2007 and has not yet started work).

Steering Group 4 has completed its first review of the existing Test Guidelines for determining physical and chemical properties and preliminarily concluded that although most might be applicable or potentially applicable to the evaluation of manufactured nanomaterials, few are appropriate for determining the properties deemed to be relevant to toxicological and eco-toxicological properties as well as environmental fate.

In the absence of suitable (OECD) guidelines, alternative, validated methods will contribute to the determination these properties. The steering group is currently reviewing available standardized testing methods, including ISO, CEN, ASTM and various national standards for their applicability to manufactured nanomaterials but it is clear from a preliminary assessment that some new test methods will be required to support this work. Whether these should be developed in CEN or ISO will be a matter for discussion, though it is clear that the efforts of multiple TCs will be required to ensure the timely delivery of the necessary documents. However, the issue of resources will feature high on any standardization agenda.

In the case of the newly approved project 8, Exposure Measurement and Exposure Mitigation, standardization will almost certainly provide the most viable route to ensuring safety in occupational settings. Again coordination of standards development amongst a number of committees will be required to ensure the timely delivery of relevant documents.

7.4 Integration of research and standardization

The development of normative and informative standards documents frequently requires pre- or co-normative research (PNR/CNR). In addition, existing research can be used as a basis for standards documents.

7.4.1 Standardization needs and opportunities within the EC Framework Programmes and the wider research arena

Prior to the commencement of FP6, the SMT (Standards Measurement and Testing) instrument within the Framework RTD programmes provided a valuable mechanism supporting pre- and co-normative research. However, since the introduction of FP6, opportunities for research in support of standardization have been subsumed into pre-competitive RTD projects. Although this should, in principle, ensure the development of standards focused at industrial needs, the reality is that, not being a primary deliverable of projects, PNR and CNR will be amongst the first things to be deleted from a project's work programme if and when there is a need for revision. In addition, because standards are not awarded the same status as academic publications (even though they might have a much greater impact on commerce and society), there is little incentive to invest time and effort in their preparation. Also few projects will have partners with direct experience of, or contact with, the standardization process, hence there is little incentive to focus attention on possible standardization deliverables, even if it is necessary to pay lip service to them at the proposal stage. Finally, the primary focus of all projects being the development of new IPR puts them in direct conflict with a guiding principle of standardization that standards should be based on generic technology wherever possible. This then acts as a further disincentive to invest effort in PNR and CNR.

We therefore have the situation that, despite the requirement for projects to identify standardization needs and opportunities, and, where appropriate, undertake supporting research, there is little, if any, incentive to treat such activity as a priority and no imperative to exploit opportunities to support standardization. It is widely recognised that one failing of the Framework programmes has been their lower than anticipated impact on innovation and economic growth, despite the fact that this should be their principal outcome. By showing that standardization makes a significant contribution to GDP through its impact on innovation, the outcome of two studies[28] suggests that one cause of lower than anticipated economic impact of Framework projects might, in fact, be the absence of parallel developments in standardization.

All of this suggests that alternative mechanisms are required to support standardization and the PNR and CNR that underpin it. One option might be to establish a group to focus on the opportunities and needs for standardization that can arise within, e.g. ETPs and Framework Programme (FP) projects. Membership of such a group should be representative of relevant stakeholders, including TCs and other structures within CEN and CENELEC. This could also enable coordination of standards development within the innovative fields covered, and provide a link to relevant

28 The Empirical Economics of Standards, DTI Economics Paper No.12, United Kingdom, 2005.
Economic benefits of standardization, Beuth Verlag, Germany, 2000.

standardization committees. Such a group would also strongly support element 4 of the Commission's nine key elements for focusing EU standardization policy on innovation[1].

The FP6 project 'COPRAS' can be cited as an example of a successful mechanism for gathering information at the research-standards interface. COPRAS, the Cooperation Platform for Research and Standards, was set up to assist in identifying standards needs in information and communications technology. Further information on this project can be found at the project homepage (http://www.w3.org/2004/copras/), but it can be noted here that one of the deliverables of the project was a set of guidelines to other FP supported ICT projects, for their use in identifying standards deliverables that could arise from their work. It might be that a similar set of guidelines should be developed for FP supported nanotechnology projects.

7.4.2 EURAMET – The European Association of National Metrology Institutes

EURAMET is the Regional Metrology Organization for Europe. It coordinates the cooperation of National Metrology Institutes (NMI) of Europe in fields such as research in metrology, traceability of measurements to SI units, international recognition of national measurement standards and of the calibration and measurement capabilities of its members. EURAMET is responsible for the development and execution of the European Metrology Research Programme (EMRP).

Both in the EMRP and the current activities of NMIs, much research is being done on measurement at the nanoscale, which has direct relevance to standardization in nanotechnologies. It is important to ensure that work in EURAMET, including the planned Article 169 on metrology, is properly utilized in future European standardization work.

7.4.3 VAMAS: CNR/PNR for nanotechnology standards

VAMAS – the Versailles project on Advanced Materials and Standards, was established in 1982 as one of 18 cooperative projects aimed at stimulating trade in new technologies using advanced materials, through pre-standardization research. Work is undertaken in Technical Working Areas (TWA's), two of which – TWA 29: Nanomechanics Applied to SPM, and TWA 33: Polymer Nanocomposites, are directly relevant to nanotechnologies. These will shortly be complemented by the establishment of three new TWAs, in Airborne Nano-particles, Multiwall Carbon Nanotubes, and Nano-EHS. VAMAS provides a platform for PNR and CNR and has been very successful in supporting the delivery of high quality consensus standards and complementary deliverables to the international community. Whilst originally populated by a rather small number of highly developed countries, VAMAS membership is about to become more widely accessible, with the founding members – Canada, France, Germany, Italy, Japan, UK, USA and European Commission – shortly to be joined by Korea, with a number of other countries showing a keen interest in joining as well. Organizations in non-member countries are already encouraged to participate in relevant research projects.

Although VAMAS has been highly successful in a number of areas associated with advanced materials, it should not be viewed as supporting PNR and CNR in all areas of standardization of relevance to nanotechnologies. However, the membership typically comprises representative of the national measurement institutes, hence all work is set in the frame of metrological excellence.

8 The regulatory process

8.1 General

At present, it is not clear if the current regulatory frameworks are sufficient to ensure the safe development of nanotechnologies and their many applications. On the other hand, a lack of guidance on how the existing regulatory framework should be applied, has been acknowledged, e.g. by SCENIHR.[29] Standardization can support the regulatory process by providing clear terminologies, the necessary measurement procedures and appropriate guides and specifications for products and processes.

8.2 Legal status of European standards

As already indicated (sections 5 and 7), the national members of CEN and CENELEC must adopt available European standards and withdraw or amend conflicting national standards. Given that the European standards bodies expect to adopt many of the corresponding international (ISO and IEC) documents, it will be important for the Vienna and Dresden Agreements to be applied in some areas of the work. This will be especially so if it is anticipated that some or all of the European publications will be used to support European Directives, e.g. of the New Approach type (in which case the standards would become 'harmonized', permitting a 'presumption of conformity' with the essential requirements of the relevant New Approach Directive.)

8.3 Consideration of REACH

In Europe, Regulation (EC) 1906 REACH[30] generally applies to all substances, but it is unclear whether REACH is sufficient for nanomaterials. An analysis by the Commission services of the regulatory situation in the EU27[31] reads:

"To determine specific hazards associated with the nanoform, current test guidelines may need to be modified. (…) Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or

[29] SCENIHR – Scientific Committee on Emerging and Newly Identified Health Risks

[30] REACH is the Regulation on Registration, Evaluation, Authorization and Restriction on Chemicals

[31] EU27 is the Eurozone of 27 countries

authorization procedures in REACH, or that information needs to be passed on to other authorities responsible for relevant legislation."

SCENIHR states in its report SCENIHR/002/05, referring to nanomaterials: "At present, there is insufficient data available to identify any generic rules governing the likely toxicology or eco-toxicology". At present, although much information is generated, the practical value is often limited beyond the respective research projects.

The following problems have been identified:

- materials might not be representative or well characterized, or are of unknown stability;

- test systems and procedures are not standardized;

- the few datasets on defined materials, which were gained under defined conditions, are mostly incomplete;

- a common data-format for an integrated analysis and development of appropriate integrated testing strategies (ITS) and integrated risk assessment is lacking;

- data are often not complemented by mechanistic information to support reliability assessment and method validation.

REACH takes into account the international advancements in the field and progress on standardization, such as by OECD. Nevertheless, there are a number of issues on nanotechnology and nanomaterials, which need to be addressed at the European level due to the existing (REACH) legislation.

These comprise components of:

1. Physico-chemical properties: Measurement systems.
2. Biophysical properties: Measurement systems.
3. Hazard identification for human health: definition of specific endpoints and their role in decision making
4. Hazard identification for environment: definition of specific endpoints and their role in decision making
5. Hazard identification for human health and ecotoxicology: Definition and application of integrated testing strategies for hazard prediction and decision making
6. Environmental fate analysis: Measurement systems for decision making
7. Exposure assessment and scenarios: Definitions, Measurement systems, and application for decision making and waiving of testing.
8. Risk assessment for human health and ecotoxicology: Definition and application of integrated methodology for decision making.
9. Determination of uncertainty and safety factors in toxicological and ecotoxicological risk assessment

10. Derivation of thresholds of concern in toxicological and ecotoxicological risk assessment
11. Alternative methods following REACH Annex XI paragraph 1: Measurement systems for reduction of animal tests. Possible use of 3R[32] methods including non test methods and integrated weight of evidence approach.

The following are still needed in order to be able to apply REACH to nanomaterials:

- Specific measurement procedures or reference materials/reference substances;
- Some definitions
- Guides for application of integrated approaches

Contribution to standardization in these areas will assist European policy implementation, risk assessment and risk management. It is of utmost importance for the use of nanotechnology and its acceptance by society.

8.4 Need for voluntary standards in the absence of regulation

It is expected that the establishment of an appropriate regulatory process will take some time. During this period, voluntary standards, codes, specifications and guides should be developed and adopted by industry, in order to enable the nanotechnology industries to advance nanotechnologies in a safe and responsible manner. In addition, such voluntary initiatives serve to reassure stakeholders (i.e. the general public, customers, employees, governments, business partners, investors and insurance companies), that companies commercialising nanotechnologies are adopting a responsible approach.

Some stakeholders, however, regard the adoption of ‘soft regulation’, such as voluntary standards, codes, specifications and guides, as means to delay or entirely avoid the development and implication of ‘hard regulation’. It is therefore important to ensure that no voluntary standard, code, specification or guide supplants, displaces or otherwise subverts the evolving regulatory processes, and that these voluntary agreements are adopted to support the responsible development of nanotechnologies during the transitional period whilst the appropriate national and international regulatory frameworks are being evaluated and, if necessary, developed, and to complement any existing and future regulation. If future scientific assessments identify the need for amendments in regulation, voluntary initiatives and their development processes might represent a constructive contribution.

[32] Russel and Burch 1959

9 Recommendations

To fulfil the needs expressed above, the European standards bodies recommend the following:

1. A programme of standardization should be initiated, by means of a standardization mandate, for the development of nanotechnology-specific standards in Europe and to encourage the participation of European stakeholders in the standardization process.

   The standards needs identified have been listed and prioritized in annex D;

2. The EC should provide clear and early guidance as to what standards projects are needed to support existing or planned legislation;

3. Support should be provided to enable the participation of all stakeholder groups in the nanotechnology standardization process, e.g. through the provision of straightforward means of funding participation in standards committee meetings;

4. A joint European Commission–European Standardization Organization (ESO) group should be established to identify nanotechnology standardization opportunities and needs arising from relevant Framework Programme projects, and facilitate their development;

5. Relevant ETPs should be requested to identify appropriate nanotechnology standardization opportunities and needs, and report to the above group.

6. In view of the rapid evolution of standardization and research in nanotechnology and nanosciences, it is recommended that a further programming mandate be given by the EC in 5 years.

ANNEX A CEN Technical Committees - Consultation

Approximately 60 other CEN Technical Committees and 8 CENELEC Technical Committees were consulted during the period November 2007-March 2008, to ascertain their level of interest and specific needs relating to nanotechnology. They were informed of Mandate M/409 and asked to return a consultation response sheet as shown below.

Table A.0 indicates the overall level of response from committees, while tables A.1 to A.4 give the comments received. From these, it can be seen that the perceived importance of nanotechnology varies widely with committee. For some there is no envisaged application of nanotechnology, while for others, standards either already exist or are under consideration, that will be affected by nanotechnological developments. It can be expected that this diversity will be reflected in the future involvement of other committees in the work, mandated or otherwise, of CEN/TC 352 and CENELEC/SR 113.

<u>M/409 Consultation Response sheet</u>

From Committee:

Q 1. Does your Committee have any current published standards or other deliverable in its portfolio which relate to nanotechnology? Please list any.
Q 2. Does your Committee expect to revise any of its existing standards in order to take into account of nanotechnological developments? If so, when? Please list any.
Q 3. Does your Committee have any other items in its current or future work programme that relate to nanotechnology? Please list any.
Q.4. Are there any standards projects relating to nanotechnology in your sector that you believe are needed in the future (not necessarily within the current Scope of your TC)?

Table A.0 Overall level of response from CEN/CENELEC committees

CEN/CLC Technical Commitee	Answer to Q.1	Answer to Q.2	Answer to Q.3	Answer to Q.4
CEN/CLC/TC 3 Quality management and corresponding general aspects for medical devices	Comment received	Comment received	Comment received	Comment received
CEN/TC 19 Petroleum products, lubricants and related products	No/None	No/None	Comment received	Comment received
CEN/TC 51 Cement and building lime	No/None	No/None	Comment received	Comment received
CEN/TC 52 Safety of toys	No/None	No/None	No/None	No/None
CEN/TC 79 Respiratory protective devices	No/None	No/None	No/None	Comment received
CEN/TC 88 Thermal insulating materials and products	No/None	No/None	No/None	No/None
CEN/TC 102 Sterilizers for medical purposes	No/None	No/None	No/None	No/None
CEN/TC 104 Concrete and related products	No/None	No/None	No/None	No/None
CEN/TC 122 Welding	Nil response	Nil response	Nil response	Nil response
CEN/TC 123 Lasers and photonics	No/None	No/None	No/None	No/None
CEN/TC 137 Assessment of workplace exposure	No/None	No/None	Comment received	Comment received
CEN/TC 138 Non-destructive testing	Comment received	No/None	No/None	No/None
CEN/TC 139 Paints and varnishes	No/None	No/None	Comment received	No/None
CEN/TC 140 In vitro diagnostic medical devices	No/None	Comment received	No/None	No/None
CEN/TC 153	Comment	Nil	Nil	Comment

Machinery intended for use with foodstuffs and feed	received	response	response	received
CEN/TC 156 Ventilation for buildings	Nil response	Nil response	Nil response	Nil response
CEN/TC 162 Protective clothing including hand and arm protection and lifejackets	Comment received	Comment received	Comment received	Comment received
CEN/TC 164 Water supply	No/None	No/None	No/None	No/None
CEN/TC 165 Waste water engineering	No/None	No/None	No/None	Comment received
CEN/TC 183 Waste management	Nil response	Nil response	Nil response	Nil response
CEN/TC 184 Advanced technical ceramics	Comment received	Comment received	Comment received	Comment received
CEN/TC 187 Refractory products and materials	No/None	Comment received	No/None	Comment received
CEN/TC 193 Adhesives	Nil response	Nil response	Nil response	Nil response
CEN/TC 194 Utensils in contact with food	Nil response	Nil response	Nil response	Nil response
CEN/TC 195 Air filters for general air cleaning	Comment received	Comment received	Comment received	Comment received
CEN/TC 206 Biological of medical and dental materials and devices	Comment received	Comment received	Comment received	Comment received
CEN/TC 209 Zinc and zinc alloys	Nil response	Nil response	Nil response	Nil response
CEN/TC 216 Chemical disinfectants and antiseptics	Comment received	Comment received	No/None	Comment received
CEN/TC 223 Soil improvers and growing media	No/None	No/None	No/None	No/None
CEN/TC 230 Water analysis	No/None	No/None	Comment received	No/None

CEN/TC 233 Biotechnology	Comment received	Comment received	No/None	Comment received
CEN/TC 240 Thermal spraying	Comment received	No/None	No/None	No/None
CEN/TC 241 Gypsum and gypsum based products	No/None	No/None	No/None	No/None
CEN/TC 243 Cleanroom technology	Comment received	Comment received	Comment received	Comment received
CEN/TC 248 Textiles and textile products	Comment received	Comment received	Comment received	Comment received
CEN/TC 249 Plastics	No/None	No/None	No/None	No/None
CEN/TC 260 Fertilizers and liming materials	No/None	No/None	No/None	No/None
CEN/TC 261 Packaging	No/None	No/None	No/None	No/None
CEN/TC 262 Metallic and other inorganic coatings	No/None	No/None	No/None	No/None
CEN/TC 264 Air quality	No/None	No/None	No/None	Comment received
CEN/TC 275 Food analysis - Horizontal methods	No/None	No/None	Comment received	Comment received
CEN/TC 276 Surface active agents	No/None	No/None	No/None	No/None
CEN/TC 285 Non-active surgical implants	Comment received	Comment received	Comment received	Comment received
CEN/TC 290 Dimensional and geometrical product specifications	Comment received	Nil response	Comment received	Nil response
CEN/TC 292 Characterization of waste	No/None	No/None	No/None	No/None
CEN/TC 296 Tanks for transport of dangerous goods	Nil response	Nil response	Nil response	Nil response
CEN/TC 298	Nil response	Nil response	Nil response	Nil response

Pigments and extenders				
CEN/TC 302 Milk and milk products - Methods of sampling and analysis	No/None	No/None	No/None	No/None
CEN/TC 305 Potentially explosive atmospheres – Explosion prevention and protection	Comment received	Comment received	Comment received	Comment received
CEN/TC 306 Lead and lead alloys	Comment received	Comment received	No/None	No/None
CEN/TC 308 Characterization of sludges	Nil response	Nil response	Nil response	Nil response
CEN/TC 310 Advanced Manufacturing Technologies	No/None	Comment received	Comment received	Comment received
CEN/TC 312 Thermal solar systems and components	No/None	No/None	No/None	No/None
CEN/TC 317 Derivatives from coal pyrolysis	No/None	No/None	No/None	No/None
CEN/TC 321 Explosives for civil uses	No/None	No/None	No/None	No/None
CEN/TC 327 Animal feeding stuffs - Methods of sampling and analysis	No/None	No/None	No/None	No/None
CEN/TC 328 Standard measuring system for cleaning performance	Nil response	Nil response	Nil response	Nil response
CEN/TC 332 Laboratory equipment	Nil response	Nil response	Nil response	Nil response
CEN/TC 338 Cereal and cereal products	Nil response	Nil response	Nil response	Nil response
CEN/TC 347 Methods for analysis of allergens	No/None	No/None	No/None	No/None
CLC/TC 21X Secondary cells and batteries	Nil response	Nil response	Nil response	Nil response
CLC/TC 34Z Luminaires and associated	No/None	No/None	No/None	No/None

equipment				
CLC/TC 40XA Capacitors and EMI suppression components	No/None	No/None	No/None	Comment received
CLC/TC 40XB Resistors	Nil response	Nil response	Nil response	Nil response
CLC/TC 76 Optical radiation safety and laser equipment	No/None	No/None	No/None	Comment received
CLC/TC 82 Solar photovoltaic energy systems	Nil response	Nil response	Nil response	Nil response
CLC/TC 86A Optical fibres and fibre cables	Nil response	Nil response	Nil response	Nil response
CLC/TC 206 Consumer equipment for entertainment and information and related subsystems	Nil response	Nil response	Nil response	Nil response

Table A.1 CEN Technical Committees – Answers to Q.1

CEN/TC No.	CEN/TC Title	Answer to Question 1 'Does your Committee have any current published standards or other deliverables in its portfolio which relate to nanotechnology? Please list any.'
CEN/CLC/ TC 3	Quality management and corresponding general aspects for medical devices	CEN/CLC JTC 3 has no published standards or other deliverable in its portfolio which relate specifically to nanotechnology. However, the horizontal standards EN ISO 13485 on Quality Management Systems and especially EN ISO 14971 on Risk Management provide important general concepts which are very valuable for nanotechnology products.
138	Non-destructive testing	No. At the present time, there is no standard published in CEN TC138 directly related to nanotechnologies. The scope of the standards related to non destructive testing does not concern nanotechnology. Nevertheless, some of techniques could be used in the field of nanotechnology in the future.
153	Machinery intended for use with foodstuffs and feed	Up to now there are no activities related to nanotechnology in TC 153.
162	Protective clothing including hand and arm protection and lifejackets	For the time being, our TC has no published standards or other deliverables which relate directly to nanotechnology.
184	Advanced technical ceramics	There are numerous CEN/TC 184 standards that could be considered relevant to nanotechnology. These include:* CEN/TR 13233 *Notations and symbols* EN 1007 *Ceramic composites – Methods of test for reinforcement* Part 3: *Determination of filament diameter and cross-section area* Part 4: *Determination of tensile properties of filaments at ambient temperature*

		Part 5: *Determination of distribution of tensile strength and of tensile strain to failure of filaments within a multifilament tow at ambient temperature* Part 6: *Determination of tensile properties of filaments at high temperature* EN 623 *Monolithic ceramics – General and textural properties* Part 3: *Determination of grain size and size distribution (characterized by the Linear Intercept Method)* EN 725 *Methods of test for ceramic powders* Part 5: *Determination of particle size distribution* EN ISO 18757 *Determination of specific surface area of ceramic powders by gas adsorption using the BET method* ENV 14232 *Terms, definitions and abbreviations* EN 1071 *Methods of test for ceramic coatings* Part 4: *Determination of chemical composition by electron probe microanalysis (EPMA)* * All CEN/TC 184 standards have the generic title *Advanced technical ceramics* or similar.
195	Air filters for general air cleaning	EN 1822 is also related to nanotechnology because this standard describes the laboratory testing of air filters to be used for contamination controlled environments where nanodevices are manufactured.
206	Biological of medical and dental materials and devices	The development in the field of nanotechnology will not yet be an item on the work program of CEN/TC206.
216	Chemical disinfectants and antiseptics	The standards developed by CEN/TC 216 are test methods for the evaluation of antiseptics and chemical disinfectants. The methodology used does not require the use of nanotechnology as defined in PAS 71:2005.
233	Biotechnology	No But some aims are similarly related to confinement and release of products
240	Thermal spraying	EN 1274:2004 (the powder is related to nanotechnology)

243	Cleanroom technology	Several Parts of EN ISO 14644 *Cleanrooms and associated controlled environments* will be of relevance to procedures nanotechnological in nature which are being carried out in a cleanroom environment. The published Parts of EN ISO 14644 are as follows: Part 1: *Classification of air cleanliness* Part 2: *Specifications for testing and monitoring to prove continued compliance with ISO 14644-1* Part 3: *Test methods* Part 4: *Design, construction and start-up* Part 5: *Operations* Part 6: *Vocabulary* Part 7: *Separative devices (clean air hoods, gloveboxes, isolators and minienvironments)* Part 8: *Classification of airborne molecular contamination*
248	Textiles and textile products	None of the standards published by CEN/TC248 have a direct relation with nanotechnology. On the other hand, most of the test methods published in the standards can be applied to fabrics that include chemical finishes based on nanoparticles.
290	Dimensional and geometrical product specifications	EN ISO 11562:1997 Geometrical product specifications (GPS) - Surface texture: Profile method - Metrological characteristics of phase correct filters EN ISO 12085:1997 Geometrical product specification (GPS) - Surface texture: Profile method - Motif parameters EN ISO 12179:2000 Geometrical Product Specifications (GPS) - Surface texture: Profile method - Calibration of contact (stylus) instruments EN ISO 3274:1997 Geometrical product specifications (GPS) - Surface texture: Profile method - Nominal characteristics of contact (stylus) instruments EN ISO 4287:1998 Geometrical Product Specifications (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters - Amendment 1: Peak count parameter EN ISO 4288:1997 Geometrical product specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture

		EN ISO 5436-2:2001 Geometrical Product Specifications (GPS) - Surface texture: Profile method; Measurement standards - Part 2: Software measurement standards CEN ISO/TS 17450-1:2007 Geometrical product specifications (GPS) - General concepts –Part 1: Model for geometrical specification and verification (ISO/TS 17450-1:2005) EN ISO 1302:2002 Geometrical product specifications (GPS) - Indication of surface texture in technical product documentation (ISO 1302:2002) EN ISO 14253-1:1998 Geometrical Product Specifications (GPS) - Inspection by measurement of workpieces and measuring equipment - Part 1: Decision rules for proving conformance or non-conformance with specifications (ISO 14253-1:1998) EN ISO 1101:2005 Geometrical Product Specifications (GPS) – Geometrical tolerancing - Tolerances of form, orientation, location and run-out (ISO 1101:2004) and its AMD1, not already published as CEN document. and ISO 8015:1985 Technical drawings -- Fundamental tolerancing principle
305	Potentially explosive atmospheres – Explosion prevention and protection	For the time being, our TC has no published standards or other deliverables which relate directly to nanotechnology.
306	Lead and lead alloys	No (due to lack of financing the TC can be considered as dormant)

Table A.2 CEN Technical Committees – Answers to Q. 2

CEN/TC No.	CEN/TC Title	Answer to Question 2 'Does your Committee expect to revise any of its existing standards in order to take into account nanotechnological developments? If so, when? Please list any.'
CEN/CLC/ TC 3	Quality management and corresponding general aspects for medical devices	CEN/CLC JTC 3 expect no revisions of its existing standards in order to take into account of nanotechnological developments. Concepts in the standards are sufficiently general to be applicable to the nanotechnological developments.
140	In vitro diagnostic medical devices	No CEN/TC 140 'In vitro diagnostic medical devices' has reviewed the new Mandate M/409 and came to the conclusion that the Mandate is not applicable to its scope. In fact, nanotechnology affects IVDs only in few cases. But in these cases vertical standards would be concerned, whilst so far the standardization in the IVD area involves horizontal standards only.
162	Protective clothing including hand and arm protection and lifejackets	At present, our committee does not envisage to revise any standards in order to take into account nanotechnological developments. However, this may change in the future.
184	Advanced technical ceramics	CEN/TC 184's work is such that many of its standards, both published and in preparation, can be considered relevant to nanotechnology. TC 184's revisions currently under way include the following:* EN 1007-5 *Ceramic composites – Methods of test for reinforcement* Part 5: *Determination of distribution of tensile strength and of tensile strain to failure of filaments within a multifilament tow at ambient temperature* EN 14232 *Terms, definitions and abbreviations*

		* All CEN/TC 184 standards have the generic title *Advanced technical ceramics* or similar.
187	Refractory products and materials	In principle EN 1402, very small overlapping
195	Air filters for general air cleaning	In the revision of EN 1822 we plan to include a method to evaluate the efficiency of air filters for particles around 70 nm (below 100 nm which is the present size limit).
206	Biological of medical and dental materials and devices	Because CEN/TC 206 follows the work of ISO/TC 194, the development and possible subjects on nanotechnology within ISO/TC 194 will be followed by CEN/TC 206 and if necessary added to the program. Possible revision of standards related to biological evaluation of medical devices containing or consisting of free nanoparticles and medical devices with surface nano features related to e.g. coatings or topography which may come into contact with human organs, cells or tissues.
216	Chemical disinfectants and antiseptics	The revision of the standards has already been launched and the agreed new format does not require the use of nanotechnology.
233	Biotechnology	TC 233 is dormant No re-activation foreseen
243	Cleanroom technology	Nanotechnological developments have not yet been specifically considered. However, at a recent meeting of ISO/TC 209, with which CEN/TC 243 works closely, it was agreed to set up an ad hoc group to review the possible needs of the cleanrooms community for cleanrooms standards or similar taking special account of nanotechnology needs. This group will report in 2008.
248	Textiles and textile products	For the moment we have not identified any standard that needs to be revised in order to take into account nanotechnological developments.
285	Non-active surgical implants	We do not expect CEN/TC 285 to take into account nanotechnological developments in the near future. Nevertheless, some surface aspects of surgical implants as well as ceramic materials, e.g. starting material for hydroxyapatite applications (in the nano size range) could become an issue.

305	Potentially explosive atmospheres – Explosion prevention and protection	At present, our committee does not envisage to revise any standards in order to take into account nanotechnological developments. However, this might change in the future.
306	Lead and lead alloys	No (the present work program consists of material standards for lead and the chemical analysis of elements present in alloys of lead)
310	Advanced Manufacturing Technologies	None planned currently (though see Q4)

Table A.3 CEN Technical Committees – Answers to Q. 3

CEN/TC No.	CEN/TC Title	Answer to Q. 3 'Does your Committee have any other items in its current or future work programme that relate to nanotechnology? Please list any.'
CEN/CLC/ TC 3	Quality management and corresponding general aspects for medical devices	At the moment, CEN/CLC JTC 3 has no other items planned in its current or future work programme that relate to nanotechnology.
19	Petroleum products, lubricants and related products	No. See also Q.4.
51	Cement and building lime	To be checked in the field of concrete with eventual influence for one of its constituents: cement.
137	Assessment of workplace exposure	**YES** PWI 00137034 Workplace atmospheres – Characterization of ultrafine aerosols/nanoaerosols – Determining the size distribution and number concentration using differential electrical mobility analysing systems (corresponds to ISO/CD 28439 of ISO/TC 146/SC 2)
139	Paints and varnishes	No (or not yet known respectively)
162	Protective clothing including hand and arm protection and lifejackets	There are two ways in which standardization of protective clothing may be related to nanotechnology. In very broad terms: In TC 162, we have testing standards and performance standards describing the product performance. The performance requirements specified in the standards may also be achieved where nanotechnology or nanomaterials play a role in the production process of the materials of the protective clothing.

		Secondly, protective clothing could be required where nanomaterials bear a risk to health of people working with these materials. So far, we have no such standards projects. Again, this may change in the future if there is an identified need for such protective clothing standards.
184	Advanced technical ceramics	TC 184 has the following items on in its programme which may be relevant in a nanotechnological context.* Further such items may be added to the programme in due course. *Ceramic composites – Determination of the fibre/matrix interfacial frictional shear stress at room temperature by the single fibre push-out method* *Ceramic composites – Determination of the fibre/matrix interfacial frictional shear stress at room temperature by tensile tests on mini-composites* *Ceramic composites – Determination of the thermal diffusivity of ceramic fibres* *Ceramic composites – Determination of the degree of misalignment in uniaxial mechanical test* * All CEN/TC 184 standards have the generic title *Advanced technical ceramics* or similar.
195	Air filters for general air cleaning	Please see answer to Q.4.
206	Biological of medical and dental materials and devices	Attached is document ISO/TC 194/WG 15/N 70 *Nanotechnology Reference and discussion*[33] provided on 2007-08-20 by Dr. J Lang. This reference list will be updated after every ISO/TC 229 meeting.
230	Water analysis	We have had so far a preliminary discussion regarding effects of nanotechnological products on water quality, e. g. TiO_2 coatings released into the environment. We are very certain that these kinds of problems will need more awareness in the coming years.
243	Cleanroom technology	Of note in the current work programme is a further Part of EN ISO 14644, which is the following:

[33] Document ISO/TC 194/WG 15 N 70 has not been included in this report.

		Part 9: *Classification of surface particle cleanliness* It should also be noted that Parts 1 and 2 of the 14644 series are currently subject to revision.
248	Textiles and textile products	At the meeting of CEN/TC248 in 2006 the following resolution has been adopted: "CEN TC 248 agrees to amend the scope of its Business Plan to include development of new technologies related to textiles, e.g. nanotechnologies, cosmetotextiles and smart textiles". For the moment, there is no concrete item in the work programme of CEN/TC248 that relates to nanotechnologies.
275	Food analysis - Horizontal methods	No. Perhaps a link with Novel Foods?
285	Non-active surgical implants	Abrasion particles of surgical implants can be in the size range of nano particles. It may become necessary to quantify not only the size but also the shape of distribution of nano size particulates in the medium term. As mentioned above, there are currently no CEN/TC 285 standards which address this issue.
290	Dimensional and geometrical product specifications	prEN ISO 22432 Geometrical product specifications (GPS) - Features utilized in specification and verification ISO 25378 Spécification géométrique des produits -- Spécifications -- Caractéristiques et conditions (at DIS stage).
305	Potentially explosive atmospheres – Explosion prevention and protection	There is a way in which standardization of explosion prevention and protection may be related to nanotechnology. In very broad terms: CEN/TC 305 WG 1 (Test methods for determining the flammability characteristics of substances) prepares standards describing explosion characteristics of dust clouds as well as explosion characteristics of gases and vapours. Also, the group deals with spontaneous ignition of dust accumulations and determination of max. explosion pressure. The tests specified in the standards may also play a role for potentially hazardous nanotechnological materials or in the production process of the nano-materials. We will discuss the need for such additional standards at the next plenary meeting of CEN/TC 305 in September.

310	Advanced Manufacturing Technologies	None currently (though see Q4)

Table A.4 CEN Technical Committees – Answers to Q. 4

CEN/TC No.	CEN/TC Title	Answer to Q.4 'Are there any standards projects relating to nanotechnology in your sector that you believe are needed in the future (not necessarily within the current Scope of your TC)?'
CEN/CLC/ TC 3	Quality management and corresponding general aspects for medical devices	- Revision of standards related to biological evaluation of medical devices containing or consisting of free nanoparticles and medical devices with surface nano features related to e.g. coatings or topography which may come into contact with human organs, cells or tissues. - Revision of standards related to clinical evaluation of medical devices containing or consisting of free nanoparticles and medical devices with surface nano features related to e.g. coatings or topography which may come into contact with human organs, cells or tissues. (Probably relatively small revision including warnings related to specific properties of nanomedical devices).
19	Petroleum products, lubricants and related products	Three items may come forward in the long term: 1- nano-suspensions (water in diesel, colouring or stanching agents in fuels, biomass-derivates in fuels) for optimization of fuel and ignition quality are being developed. But for the moment only the final fuel quality is of interest and we would prefer the general health, safety and environmental issues to be judged upon by a general standard (from CEN/TC 352 for instance). 2- additives that use nano-components, but these fuel components are in general not standardized by CEN/TC 19. 3- nano-scale contaminants resulting from nano-products that become a fuel contamination and need to be detected. Supposing we will build on general nano-detection standards by CEN/TC 352, we do not foresee short- or mid-term work for our test method development working groups at this stage.

51	Cement and building lime	To be checked in the field of concrete with eventual influence for one of its constituents: cement.
79	Respiratory protective devices	No. We currently do not have any relation to nano particles. Could be, that in the future we might have requirements for nano particle filtration, but at the moment not.
137	Assessment of workplace exposure	Yes There is an ongoing discussion about the development of a standard regarding the dustiness of nanoscaled materials. This would be in close connection to the existing EN 15051.
153	Machinery intended for use with foodstuffs and feed	It could be interesting to see if there are any possibilities to use nanotechnology in the food processing area, but right now, this is not taken under consideration.
162	Protective clothing including hand and arm protection and lifejackets	There are two ways in which standardization of protective clothing may be related to nanotechnology. In very broad terms: In TC 162, we have testing standards and performance standards describing the product performance. The performance requirements specified in the standards may also be achieved where nanotechnology or nanomaterials play a role in the production process of the materials of the protective clothing. Secondly, protective clothing could be required where nanomaterials bear a risk to health of people working with these materials. So far, we have no such standards projects. Again, this may change in the future if there is an identified need for such protective clothing standards.
165	Waste water engineering	TC 165 is linked with this subject with the definitions and the wastewater treatment. Perhaps is it possible to consider other applications in pipes (for example liners manufactured with nanomaterials installed on the surface of pipes to increase the speed of the wastewater) or in pumping stations but if this field is interesting it is not a priority in the business of nanotechnologies. It is conceivable that special coatings may be developed for pumps, screens, etc. to

		prevent the build-up of fats, but this is probably some years away.
184	Advanced technical ceramics	We note the consideration of particle sizing at the nano-scale in CEN/TC 352 and ISO/TC 229. This will be of relevance to CEN/TC 184 and ISO/TC 206. Some of the other nanotechnology standards work may prove to be of importance in the ceramics industry, but we have not identified any 'ceramics-specific' nanotechnology documents requiring urgent preparation.
187	Refractory products and materials	No. due to very high costs of nanopowder, the refractory industry does not deal with them. In principle nanos have also a high potential for RI, especially for the unshaped products (EN 1402). If I understood well, the newly build TC deal with nanos itself. Therefore no overlapping of interests can be expected.
195	Air filters for general air cleaning	EN 1822 could be revised in such a way to be able to establish the efficiency of air filters for particles of any size. This would require probably a higher cost for test equipment so it should be discussed inside our technical committee before starting an official work item.
206	Biological of medical and dental materials and devices	During the last meeting on 2007-10-04 ISO/TC 194/WG 14 Material characterization discussed the developments in nanotechnology, but no NWIP resulted from this discussion. Revision of standards related to clinical evaluation of medical devices containing or consisting of free nanoparticles and medical devices with surface nano features related to e.g. coatings or topography which may come into contact with human organs, cells or tissues. (Probably relatively small revision including warnings related to specific properties of nanomedical devices).
216	Chemical disinfectants and antiseptics	I do not know if there is a project but there are some surfaces with antimicrobial activities that, according to the chair of CEN/TC 216, might use nanotechnology.
233	Biotechnology	Abstention
243	Cleanroom technology	See the answer to Q. 2. It is likely that the ISO/TC 209 ad hoc group will identify standards needs to be pursued jointly by ISO/TC 209 and CEN/TC 243.

248	Textiles and textile products	At the meeting of CEN/TC248 held on 1st November 2007 the following resolution has been adopted: "CEN/TC 248 agrees that CEN/TC 352 be requested to prioritise the preparation of a standard related to the release of nano-particles from textiles, which can be transferred to the human skin or be inhaled."
264	Air quality	There may be a future project "Particle counting" in CEN/TC 264. Here and in connection with the running projects on the determination of PM 10 (EN 12341) and PM 2.5 (EN 14907) there may be in the future the highest possibility that also nanoparticles are included in the discussions.
275	Food analysis - Horizontal methods	Definition or maximum particle size to be categorized as nanotechnology, is the particle bigger, then it is not longer classified as nano.
285	Non-active surgical implants	There is currently research done on carbon-nano-tubes enforced plastic materials. As soon as these products are developed and tested for the use in medical products, they might be interesting for the use in surgical implants. Surface treatment could be important for silicone based soft part implants. Please do note that we do not believe that the mentioned issues will be discussed in CEN/TC 285 in the near future.
305	Potentially explosive atmospheres – Explosion prevention and protection	There is a way in which standardization of explosion prevention and protection may be related to nanotechnology. In very broad terms: CEN/TC 305 WG 1 (Test methods for determining the flammability characteristics of substances) prepares standards describing explosion characteristics of dust clouds as well as explosion characteristics of gases and vapours. Also, the group deals with spontaneous ignition of dust accumulations and determination of max. explosion pressure. The tests specified in the standards may also play a role for potentially hazardous nanotechnological materials or in the production process of the nano-materials. We will discuss the need for such additional standards at the next plenary meeting of CEN/TC 305 in September.
310	Advanced Manufacturing	CEN TC310 will probably have interests in aspects related to product definition information for nanotechnology products, including the definitions of material content for through life

	Technologies	product management. Please note that we would anticipate that any necessary work would be done in the first instance at international rather than European level, in common with much of the TC310 work programme.
CLC/TC 40XA	Capacitors and EMI suppression components	CLC TC 40XA is following closely the future development within IEC TC 40 and IEC TC 113.
CLC/TC 76	Optical radiation safety and laser equipment	New laser sources: The area of laser technology is influenced to an increasingly important extent by nanotechnology, since development of new laser sources often builds upon nanotechnology. Examples of this include quantum well, quantum dot, and quantum cascade lasers. New uses of lasers: Much of the equipment used in nanotechnology involves the use of lasers. Examples include lasers for ablation in thin film fabrication, lasers for lithography in patterning nanometer scale components, lasers for process monitoring, test and measurement of nanoscale devices. Nanoparticle monitoring: The spread of nanoparticles causes concern, and lasers are well suited for measuring particle concentration and size distribution, for example in the laboratory or clean-room environment. Bionanophotonics: More and more used of lasers in combination with resonant nanoparticles are finding their way into biology and medicine. For example, new cancer treatment methods are being studied based on laser excitation of plasmon resonances in nanoparticles injected into a tumor.

		Clean-room laser safety: Safety education is provided on a regular basis for all clean-room users at universities and research institutes, but mainly concentrated on chemical hazards. Laser safety for personnel using laser equipment needs to be included in such courses as well.

ANNEX B European Technology Platforms (ETPs) - Consultation

Thirteen of the currently existing ETPs were selected, on the basis of perceived importance of nanotechnology to their sectors, for consultation during November-December 2007 on Mandate M/409. They were asked to return a consultation response sheet, indicating their expected needs for nanotechnology-related standards, as well as describing any current or past research projects that should lead to associated standards publications.

Table B.1 gives the responses received to this consultation, which indicates a low level of interest at present. The paucity of information may reflect a gap in the knowledge of the industrial research community and a general lack of understanding of the role standards can play in facilitating the development of high technology industry.

M/409 Consultation Response sheet

From (European Technical Platform and Contact):

Q 1: Are there any standards projects relating to nanotechnology/nanosciences in your sector that you believe are needed, now or in the future? If so, please list any, including what they are needed for (e.g. for regulatory purposes, R & D, or health & safety), and when they are needed (e.g. as soon as possible, in 3-5 years, in 5-10 years, or in the longer term).
Q 2: Are you aware of any projects that have produced, or could result in the generation of methods, guides or other data that would be appropriate to form the basis of nanotechnology standards, such as test methods, best practice guides or recommended procedures?

Table B.1 ETPs – Answers to Q. 1 and Q. 2

ETP	ETP Full Title	Answer to Question 1 ' Are there any standards projects relating to nanotechnology/nanosciences in your sector that you believe are needed, now or in the future? If so, please list any, including what they are needed for (e.g. for regulatory purposes, R & D, or health & safety), and when they are needed (e.g. as soon as possible, in 3-5 years, in 5-10 years, or in the longer term).' Answer to Question 2 ' Are you aware of any projects that have produced, or could result in the generation of methods, guides or other data that would be appropriate to form the basis of nanotechnology standards, such as test methods, best practice guides or recommended procedures?'
Artemis	Embedded computing systems	Nil response
ENIAC	European Nanoelectronics Initiative Advisory Council	Nil response
EPoSS	European Technology Platform on Smart Systems Integration	Nil response
ETPIS	Industrial Safety European Technology Platform	I confirm the receipt of this message. ETPIS will organise a consultation, in particular with the Focus Group NANOSAFETY, and we will send the input by the end of the year.

EuMaT	Advanced Engineering Materials and Technologies	Nil response
Euratex	Future Textiles and Clothing	Nil response
HFP	Hydrogen and Fuel Cell Platform	Nil response
ManuFuture	Future Manufacturing Technologies	Nil response
MINAM	Micro- and Nano-manufacturing	Metrology related projects like: **"PRONANO"**, coordinated by: Thomas Sulzbach Head of R&D NanoWorld Services GmbH Schottkystraße 10 91058 Erlangen Germany e-mail: sulzbach@nanoworld.com "**NanoCMM",** coordinated by: Dr Oscar Lázaro Managing Director Innovalia Association Rodriguez Arias, 6, Dept. 605

		48008 Bilbao Tel1.: +34 94 480 51 64 Tel2.: +34 94 479 51 90 Fax: +34 94 480 41 30 E-mail: olazaro@innovalia.org Also the Network of Excellence **"4M"** may have useful information to provide from their **metrology cluster**, lead by: Ph.D. Lars Mattsson Professor in Industrial metrology and optics Department head Production Engineering KTH - School of Industrial Technology and Management Brinellv. 68 SE-100 44 Stockholm Sweden tel: +46-8-7909175 fax +46-8-7906899 e-mail Larsm@iip.kth.se
Nanomedicine	Nanotechnologies for Medical Applications	Nil response
Photonics21	Photonics	Nil response
Photovoltaics	Photovoltaics	For the moment, the Photovoltaic industry and the Photovoltaic sector in general has not special requirements for the development of any standard in PV Nanotechnologies since it is still a very new and emerging technology in the photovoltaic field.
SusChem	Sustainable Chemistry	Thank you for considering SusChem in this consultation process. SusChem is a stakeholder grouping and we have thus consulted with the SusChem stakeholders on this issue. Doing this we found that some of our stakeholders (notably

		VCI, the German Chemical Industry association) have already participated in CEN/TC 352 and commented on Mandate M/409. Beyond these stakeholder comments which you have already received[34] we are not aware of any other needs or projects in this area.

[34] VCI comments did not identify any standards projects, either present or future.

ANNEX C European Associations and Organizations - Consultation

Eighteen European bodies were selected, on the basis of perceived importance of nanotechnology to their sectors, for consultation during November-December 2007 on Mandate M/409. They were asked to return a consultation response sheet, indicating their current or future needs for nanotechnology-related standards.

Table C.1 gives the responses received to this consultation. As in the case of CEN and CENELEC TCs, there was a wide variation in the level of interest displayed. Some responses indicated that little consultation among members had taken place. On the other hand, the response from ECOS provides a valuable overview of the environmental concerns surrounding nanomaterials. As with CEN and CENELEC TCs, it can be expected that the involvement of European associations and organizations in the future activity of CEN/TC 352 and CENELEC/SR 113 will vary considerably.

M/409 Consultation Response sheet

From Association/Organization (please include contact name):

Question: Are there any standards projects relating to nanotechnology/nanosciences in your sector that you believe are needed, now or in the future? **If so, please list any, including what they are needed for (e.g. for regulatory purposes, R & D, or health & safety), and when they are needed (e.g. as soon as possible, in 3-5 years, in 5-10 years, or in the longer term).**

Table C.1 European Associations and Organizations – Answers to Consultation

European Association/ Organization	Full Name of Association/Organization	Answer to Question ' Are there any standards projects relating to nanotechnology/nanosciences in your sector that you believe are needed, now or in the future? If so, please list any, including what they are needed for (e.g. for regulatory purposes, R & D, or health & safety), and when they are needed (e.g. as soon as possible, in 3-5 years, in 5-10 years, or in the longer term).'
ANEC	European Association for the Coordination of Consumer Representation in Standardization	[ANEC submitted comments during the BT consultation.] Thank you once again for inviting ANEC to submit comments for TC 352. After consultation with our members, we have decided we need to revise and further develop ANEC's position on nanotechnologies. This will be done in the coming months, probably in parallel to your work. Thus, at this stage, we do not have anything more to contribute to our previous comments[35] made during the BT consultation period.
Business Europe	The Confederation of European Business	Nil response
CEFIC	European Chemical Industry Council	After consultation with our members, please be informed that for the moment Cefic is not aware of any need or knowledge about these standards projects.
COLIPA	European Cosmetic and Toilet Perfumery	Nil response

[35] The content of ANEC's comments submitted to the BT (CEN Technical Board) have not been included in this report.

	Association	
ECMA International	European Association for Standardizing Information and Communication Systems	Nil response
ECOS	European Environmental Citizens' Organization for Standardization	In Europe, some Member States are reluctant to push standardization at EU level mainly with the argument to avoid double work of ISO and CEN. Additionally, certain industry representatives mentioned that some industry hesitates to engage in the nanotechnologies` standardization process because the proposals aim to standardize substances instead of products, which is normally not the focus of standards. The needs and specifications for substances are so far dealt with and assured by negotiations between the trading partners. **Approaches on how to govern nanotechnologies** The regulatory framework so far does not adequately address the specific properties of nanomaterials and nanoparticles. This should be a clear priority of the EC to establish a mandatory risk assessment at national and EU level. The compliance of mandatory risk assessment can be demonstrated by standards as the European Commission states; however, the risk assessment should be as detailed as possible and should leave as few topics to standards as possible (see the proposals below). Risk assessment should foresee involvement of the public which should have access to vital environmental safety and human health data. Testing methods and test guidelines to assess (eco-) toxicology of nanomaterials and nanoparticles should be rather elaborated and published by the OECD because this is traditionally its responsibility. ISO/TC 229/WG 3 on 'Health, Safety & Environmental Aspects of Nanotechnologies' is currently working on different documents. Though ISO/TC 229 and the OECD are exchanging experts and ISO/TC 229 established a 'Memorandum of Understanding' with the OECD, this situation bears possibly inconsistent developments. Besides, the expected technical report of ISO/TC 229/WG 3 on 'Health, Safety & Environmental Aspects of Nanotechnologies' on 'Health and Safety Practices in

		Occupational Settings Relevant to Nanotechnologies', as well as the draft standard on 'Endotoxin test on nanomaterial samples for in vitro systems' should undergo a wide and open scientific discussion that should not be restricted to standardization bodies. As far as labelling is concerned, it is questionable whether this should be dealt with by standards. The proposed CEN-work item 'Format for reporting the engineered nanomaterials content of products' can turn out to be relevant for consumers, if the reporting also concerns the final product. The reporting within the production chain is very useful, undoubtedly, so that every company has relevant information, e.g. on how to properly bag, transport and dispose of the product. However, a format for labelling in order to give informed choice to the consumer should be developed in an open process involving a broad range of stakeholders and possibly the public. Maybe, labelling turns out to be desirable only for special product groups such as personal care products and cosmetics and food and has to be legally regulated. **In any case labelling should in no way be seen as a substitute to higher-level regulatory tools, e.g. legislation.** **Ideas and demands of the environmental community on standards for nanotech** There are however topics in the area of nanotechnologies that may and can only be addressed by standards. **ECOS strongly supports an ambitious and quick standardization programme** which provides real progress in terms of risk assessment and measurement of nanomaterials, especially manufactured ones. Quick does not mean that fast-track deliverables with limited consensus and public enquiry requirements should be privileged. However, ECOS sees a clear urgency for standards in this field. - Terminology and definitions of nanoparticles and nanomaterials should be carefully worked out taking into account the requirements for toxicological assessment. Generally terminology and definitions should be worked out in cooperation with toxicologists and material scientists. **Especially the definition of the particle size might show the need to be expanded because of toxicological concerns.** When defining specific production processes, the particle size of a substance should be defined in a narrow range if the toxicological

		profile of a nanoparticle in different sizes shows differences. Toxicologically relevant parameters for different exposure routes should be defined within the general terminology and definitions, such as e.g. particle concentration and particle size distribution. - Terminology and definitions should provide taxonomy of all different kinds of nanoparticles and nanotechnologies as a basis for specific standards on how to test the impact of the different types of nanoparticles arising in different applications and production processes. - Terminology and definitions should clarify the naturally occurring and diffuse exposure by nanoparticles in order to define acute exposure by specific applications. - The development of measurement methods is necessary and urgent in order to better assess the exposure and thus possible risks of nanomaterials and nanoparticles. The measurement methods should be validated and at the best addressing any measurement uncertainty as well as the limitations of the methods. Reporting schemes on the measurement results should be standardized as well. This could be covered in a general document or by an extra paragraph in each measurement standard. - The development of standardized laboratory procedures, biomarkers, and analytical methods for the detection of nanoparticles in biological samples should be enforced to be able to assess risks for health and the environment. - If there are different approaches for the measurement of a specific nanoparticle and thus different standards for measuring its e.g. concentration are available, a scheme for comparability should be provided. - A focus should be on measurement methods and defined requirements to assess the exposure. Requirements and definitions are needed to be able to compare exposure scenarios.

		- Sampling schemes are an important issue that should be addressed as well by the measurement standards or as a separate standard. - At best, measurement of a given nanoparticle in different environments is provided in order to make environmental monitoring possible. - Standards on the production or processing of nanomaterials and nanoparticles should address a contained use or minimized environmental release unless the safety of the nanoparticle or nanomaterial is proven. - If standards will cover single substances as nanoparticles, the range of size should be defined as narrow as possible. Besides, packaging, transport and proper disposal should be addressed therein as well. - In terms of priority products to be targeted, ECOS gives priority to food, food packaging and personal care products. - Another focus should be on products that are used by lay people in their private households such as varnishes, colours, household cleaning agents etc. because of the possibility of uncontrolled release into the environment. As long as the regulatory frame for a specific risk assessment as well as the above-mentioned standards on definitions and testing methods are not available, ECOS members call for a precautious approach and to restrict the uncontrolled release of nanoparticles. Products containing nanoparticles already on the market (e.g. cosmetics) should be clearly marked.
EDMA	European Diagnostic Manufacturers Association	Nil response

EFPIA	European Federation of Pharmaceutical Industries and Associations	Nil response
EFSA	European Food Safety Authority	CEN Standards dealing with areas related to food and food safety are already existing, e.g. in the field of food contact materials (CEN/TC 194 - Utensils in contact with food)[36]. For these standards it would need to be stated more precisely whether they are suitable or not to cover the nanoparticulate aspect. This would be equally applicable to standards of microbial quality testing and the like. It can be anticipated that chemical substances, e.g. food or feed additives, might be added in the future in nanoparticulate form to food and feed. In the case of legal restriction it might become necessary for compliance testing to have analytical methods in place which are capable a) to measure the concentration in complex matrices and b) at the same time ensure that they are suitable to distinguish between the bulk and the nano-form of such substance. Any standards should be developed in discussion with development of possible guidelines for risk assessment to avoid inconsistencies and to facilitate harmonization and implementation.
ENTA	European Nanotechnology Trade Alliance	Nil response
ESF	European Safety Federation	At this moment, there is not enough knowledge about the possible health/safety risks involved in nanotechnology and thus it is too early to prepare any standards for Personal Protective Equipment related to these risks. However, ESF and its members do acknowledge the need for research in this field and

[36] CEN/TC 194 provided 'Nil response' to the questionnaire.

		supports any standardization work that will help to better understand and describe the possible risks.
ETUI-REHS	European Trade Union Institute for Research, Education and Health and Safety	Nil response
Eucomed	European Confederation of Medical Device Associations	Thank you for your message. Unfortunately, in the absence of a replacement for our former Scientific Director, Richard Moore, and of any feedback from our members, Eucomed is not able to provide this information at the moment.
FESI	Federation of the European Sporting Goods Industry	Nil response
FoEE	Friends of the Earth Europe	Many thanks for your email. I would like to draw your attention to the fact that Friends of the Earth Europe is a member of ECOS and therefore ECOS' contribution to this consultation will equally reflect the views of FoEE.
IoN	Institute of Nanotechnology	Nil response
NIA	Nanotechnology Industries Association	- Occupational health and safety standards (e.g. filter material specification, personal protective clothing specification, venting requirements, transport, etc.); needed for occupational guidance and between-company trade agreements (as soon as possible) - Materials specifications (e.g. aspect ratio, morphology, size distribution, what characterization equipment was used to measure physical data, etc.); needed for user and health official information (3-5 years)

		- Characterization equipment specification; needed to support materials specification (3-5 years)
NORMAPME	European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardization	Nil response

ANNEX D Standards Needs in Nanotechnology and Nanomaterials

The standards needs identified in section 4 of the main text are presented in table D.1, in which the subdivision into needs relating to Health, Safety and the Environment (HS&E), the Lisbon agenda and the societal agenda are maintained, and the HS&E needs are further broken down under 'Occupational handling and exposure', 'Toxicology testing and screening' and 'Risk assessment/Risk management'.

Table D.1 Standards needs in nanotechnology and nanomaterials

1	**HS&E**	Need for Pre-Normative Research (PNR)?	Multiple standards required?	In current ISO Work programme?	Priority: High (H) Medium (M) Low (L)	Notes
2	***Occupational handling and exposure***					
3	Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities *(including selection of Personal Protective Equipment).*			yes	H	
4	Guidance on containment, trapping and destruction of nanoparticles and other manufactured nanoscale entities.	yes			H	
5	Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials.	yes			H	
6	Methodology to Determine effectiveness of Filtration Media against Nanomaterials				M/H	
7	Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products				M	
8	Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage).	yes			M	
9	Guidance on detection and identification of nanoparticles and other nanoscale entities *(in all media types, including waste streams from manufacturing and manufacturing discharges)*	yes	yes		H	Items 9 and 10 are related
10	Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.		yes		H	Items 9 and 10 are related
11	***Toxicology testing and screening***					
12	Guidance on nano-material characterization prior to, or in association with toxicity testing			yes	H	
13	Guidance on sample preparation *(including dispersion)* for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other manufactured nanoscale entities.	yes	yes	partial	H	Relevant Test methods are also required

14	Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other manufactured nanoscale entities.	yes	yes		H	
15	Guidance on dosimetry for in vitro studies on nanoparticles and other nanoscale entities	yes			H	
16	Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities.	yes			H	Requires input form item 15
17	Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities *(includes occupational and consumer products, e.g. cosmetic and sunscreen, exposure)*	yes	yes		H	Input needed from item 13
18	Fast track protocols for predicting the toxicity and ecotoxicity for classification of nanoparticles and other nanoscale entities, particularly for identifying and tracking the most dangerous ones in the framework of the REACH directive.	yes	yes		M	
19	***Risk assessment/risk management***					
20	Guidance on a common data-format for an integrated analysis for risk assessment				H	
21	Guidance on integrated testing strategies (ITS) and integrated risk assessment	yes			H	
22	Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities.	yes			H	22 and 23 are related - see also 20 and 21.
23	Protocols for risk management that specifically refers to potential nanotechnology hazards	yes				22 and 23 are related - see also 20 and 21
24	Protocols for whole life cycle assessment of nanoscale materials, devices and products.	yes	yes		H	
25	Standard Method to Assess Product Degradation and Release of Nanomaterials from Consumer Products				M	
26	Product Safety Standards for Consumer Products Containing Nanomaterials		yes		M/H	

27	Nanocomposites - guidance on ageing / particle release				M	
28						
29	**Lisbon - General**					
30						
31	Guide to performance measurement of nanoscale materials and devices.	yes	yes		M	Product dependent - for dev elopment in sectorial TC?
32	Guide to the evaluation of new functions specific to manufactured nano-particles and other nanoscale entities	yes	yes		M	Material or function dependent
33	Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance, etc, of materials and devices at the nanoscale.				H	
34	Product specifications for different manufactured nanomaterials.	yes	yes	started	depends on materials and applications	Possible meterial classes: metallic nano-particles; metal oxides; other compound particles; functionalized particles; quantum dots
35	Guide to methods and techniques for assessing the quality of nanoscale materials used in the preparation of devices.		yes		M	Device dependent?
36	Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities.				H	General guide

37	Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities		yes	started for Carbon Nano Tubes	M/H depending on materials and applications	Material specific
38	Guide to modelling (measurement, simulation and visualization) at the nanoscale.	yes			M/L	
39	Good practice guides for nano-fabrication and nano-engineering		yes		M/H depending on applications	feeds 55 and 56
40	Guides to existing national, regional and international regulations, codes of conduct, etc., relevant to nanotechnologies.	CNR required			H	
41	Nanocomposites - guidance on dispersion of nanoscale component				M	
42						
43	***In addition to the need for standards development, a number of supporting measures to provide technical underpinning of standards, including validation, are required:***					
44						
45	Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nanoscale entities				H	
46	Co-normative research to evaluate repeatability, reproducibility and inter-comparability of test methods.	yes			H	
47	Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.	yes			H	
48	Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment.	yes			H depending on specific need	
49	Development of In situ/on line non-destructive techniques and contact-less measurements relevant to nanotechnologies.	yes			M/H depending on application	

50	**Societal agenda**					
51	***Medical applications***					
52						
53	Standard methods for assessing stability of nanoparticles in vivo and in vitro	yes			M/H	application dependent
54	Standard method for in vitro evaluation of osseo-genic behaviour of nanostructured surfaces.	yes			M	
55	Design, construction and performance criteria for cantilever-arrays used in diagnosis				H	see 39
56	Design, construction and performance criteria for lab-on-a-chip devices				H	see 39
57	Standard method to measure release of active materials from nanoporous substrates	yes			M/H	
58						
59	***Sustainability***					
60						
61	Guide to the design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water;	yes			M	
62	Design and performance of nanoscale cantilever devices for detection and identification of pathogens in water and food;	yes	yes		M/H	
63	Material specifications for polymer and printable electronics	yes	yes		M/L	
64	Design criteria for high spatial resolution monitors for environmental monitoring	yes			M/L	
65						
66	***Security***					
67						
68	RFID standards to complement ISO/IEC TR 18047-7:2005				M	
69	Design and performance of cantilever devices for detection and identification of pathogens in water, food and the air	yes	yes		M/H	see 39
70	Design and performance of remotely addressable, anti -counterfeiting devices	yes	yes		M/H	see 39
71	Guide to the design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water;	yes			M	

ANNEX E Published standards and current standards projects relevant to nanoscale measurement or observation

Reference/No.	Title	Responsible committee
AES and XPS		
E1078-02	Standard Guide for Specimen Preparation and Mounting in Surface Analysis	ASTM E42
E827-02	Standard Practice for Identifying Elements by the Peaks in Auger Electron Spectroscopy	ASTM E42
E902-05	Standard Practice for Checking the Operating Characteristics of X-Ray Photoelectron Spectrometers	ASTM E42
E983-05	Standard Guide for Minimizing Unwanted Electron Beam Effects in Auger Electron Spectroscopy	ASTM E42
E995-04	Standard Guide for Background Subtraction Techniques in Auger Electron Spectroscopy and X-ray Photoelectron Spectroscopy	ASTM E42
ISO 14237:2000	Surface chemical analysis -- Secondary-ion mass spectrometry -- Determination of boron atomic concentration in silicon using uniformly doped materials	ISO/TC 201
ISO 15470:2004	Surface chemical analysis -- X-ray photoelectron spectroscopy -- Description of selected instrumental performance parameters	ISO/TC 201
ISO 15471:2004	Surface chemical analysis -- Auger electron spectroscopy -- Description of selected instrumental performance parameters	ISO/TC 201
ISO 15472:2001	Surface chemical analysis -- X-ray photoelectron spectrometers -- Calibration of energy scales	ISO/TC 201
ISO 17560:2002	Surface chemical analysis -- Secondary-ion mass spectrometry -- Method for depth profiling of boron in silicon	ISO/TC 201
ISO 17973:2002	Surface chemical analysis -- Medium-resolution Auger electron spectrometers -- Calibration of energy scales for elemental analysis	ISO/TC 201
ISO 17974:2002	Surface chemical analysis -- High-resolution Auger electron spectrometers -- Calibration of energy scales for elemental and chemical-state analysis	ISO/TC 201
ISO 18114:2003	Surface chemical analysis -- Secondary-ion mass spectrometry -- Determination of relative sensitivity factors from ion-implanted reference materials	ISO/TC 201
ISO 18118:2004	Surface chemical analysis -- Auger electron spectroscopy and X-ray photoelectron spectroscopy -- Guide to the use of experimentally determined relative sensitivity factors for the quantitative analysis of homogeneous materials	ISO/TC 201
ISO 18516:2006	Surface chemical analysis -- Auger electron spectroscopy and X-ray photoelectron spectroscopy -- Determination of lateral resolution	ISO/TC 201
ISO 19318:2004	Surface chemical analysis -- X-ray photoelectron spectroscopy -- Reporting of methods used for charge control and charge correction	ISO/TC 201

ISO 20341:2003	Surface chemical analysis -- Secondary-ion mass spectrometry -- Method for estimating depth resolution parameters with multiple delta-layer reference materials	ISO/TC 201
ISO 20903:2006	Surface chemical analysis -- Auger electron spectroscopy and X-ray photoelectron spectroscopy -- Methods used to determine peak intensities and information required when reporting results	ISO/TC 201
ISO 21270:2004	Surface chemical analysis -- X-ray photoelectron and Auger electron spectrometers -- Linearity of intensity scale	ISO/TC 201
ISO 24236:2005	Surface chemical analysis -- Auger electron spectroscopy -- Repeatability and constancy of intensity scale	ISO/TC 201
ISO 24237:2005	Surface chemical analysis -- X-ray photoelectron spectroscopy -- Repeatability and constancy of intensity scale	ISO/TC 201
ISO 5472:2001/CD Amd 1	Surface chemical analysis -- X-ray photoelectron spectrometers -- Calibration of energy scales/CD Amd 1	ISO/TC 201
ISO/AWI 29081	Surface chemical analysis -- Auger electron spectroscopy -- Reporting of methods used for charge control and charge correction	ISO/TC 201
ISO/DIS 23812	Surface chemical analysis -- Secondary-ion mass spectrometry -- Method for depth calibration for silicon using multiple delta-layer reference materials	ISO/TC 201
ISO/DIS 23830	Surface chemical analysis -- Secondary-ion mass spectrometry -- Repeatability and constancy of the relative-intensity scale in static secondary-ion mass spectrometry	ISO/TC 201
ISO/TR 18392:2005	Surface chemical analysis -- X-ray photoelectron spectroscopy -- Procedures for determining backgrounds	ISO/TC 201
ISO/TR 18394:2006	Surface chemical analysis -- Auger electron spectroscopy -- Derivation of chemical information	ISO/TC 201
ISO/TR 19319:2003	Surface chemical analysis -- Auger electron spectroscopy and X-ray photoelectron spectroscopy -- Determination of lateral resolution, analysis area, and sample area viewed by the analyser	ISO/TC 201
ISO/WD 10810	Surface chemical analysis -- X-ray photoelectron spectroscopy -- Guide to analysis	ISO/TC 201
STM/AFM		
E1813-96(2007)	Standard Practice for Measuring and Reporting Probe Tip Shape in Scanning Probe Microscopy	ASTM E42
E2382-04	Guide to Scanner and Tip Related Artifacts in Scanning Tunneling Microscopy and Atomic Force Microscopy	ASTM E42
E2530-06	Standard Practice for Calibrating the Z-Magnification of an Atomic Force Microscope at Subnanometer Displacement Levels Using Si(111) Monatomic	ASTM E42
ISO/NP 11039	Standards on the definition and measurement methods of drift rates of SPMs	ISO/TC 201
ISO/WD 27911	Surface chemical analysis - Scanning Probe Microscopy- Definition and calibration of lateral resolution of a Near-field optical microscope	ISO/TC 201

ISO 14887	Sample preparation -- Dispersing procedures for powders in liquids	ISO/TC 24/SC4
Characterization		
E56 WK10417	Standard Practice for the Preparation of Nanomaterial Samples for Characterization	ASTM E56
ISO/TS 10993-19:2006	Part 19: Physico-chemical, Morphological and Topographical Characterization of Materials	ISO/TC 194
ISO WD 30011	Workplace air – Determination of metals and metalloids in airborne particulate matter by inductively coupled plasma mass spectrometry	ISO/TC 146
ISO/AWI TR 11808	Nanotechnologies -- Guide to nanoparticle measurement methods and their limitations	ISO/TC 229//CEN/TC 352
ISO/AWI TR 11811	Nanotechnologies -- Guide to methods for nanotribology measurements	ISO/TC 229//CEN/TC 352
ISO/AWI TS 10797	Nanotubes -- Use of transmission electron microscopy (TEM) in walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/AWI TS 10798	Nanotubes -- Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the characterization of single walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/AWI TS 10929	Measurement methods for the characterization of multi-walled carbon nanotubes (MWCNTs)	ISO/TC 229
ISO/AWI TS 11251	Nanotechnologies -- Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/AWI TS 11308	Nanotechnologies -- Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes (SWCNT)	ISO/TC 229
ISO/FDIS 14488	Particulate materials -- Sampling and sample splitting for the determination of particulate properties	ISO/TC 24/SC4
ISO/NP TS 10812	Nanotechnologies -- Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/NP TS 10867	Nanotubes -- Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/NP TS 10868	Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	ISO/TC 229
ISO/NP TS 11888	Determination of mesoscopic shape factors of multiwalled carbon nanotubes (MWCNTs)	ISO/TC 229
ISO/PWI 20998-2	Measurement and characterization of particles by acoustic methods -- Part 2: Guidelines for linear theory	ISO/TC 24/SC4
ISO/PWI 20998-3	Measurement and characterization of particles by acoustic methods -- Part 3: Guidelines for non-linear theory	ISO/TC 24/SC4
Particle size/size distribution		
CEN/ISO CD 28439	Workplace atmospheres – Characterization of ultrafine aerosols/nanoaerosols – Determining the size distribution and number concentration using differential electrical mobility analyzing systems	ISO/TC 146//CEN/TC 137
E2578-07	Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions	ASTM E56

E56 WK8705	Standard guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (PCS)	ASTM E56
ISO 13318-1	Determination of particle size distribution by centrifugal liquid sedimentation methods -- Part 1: General principles and guidelines	ISO/TC 24/SC4
ISO 13318-2	Determination of particle size distribution by centrifugal liquid sedimentation methods-- Part 2: Photocentrifuge method	ISO/TC 24/SC4
ISO 13318-3	Determination of particle size distribution by centrifugal liquid sedimentation methods -- Part 3: Centrifugal X-ray method	ISO/TC 24/SC4
ISO 13320-1	Particle size analysis -- Laser diffraction methods -- Part 1: General principles	ISO/TC 24/SC4
ISO 13321	Particle size analysis -- Photon correlation spectroscopy	ISO/TC 24/SC4
ISO 13322-1	Particle size analysis -- Image analysis methods -- Part 1: Static image analysis methods	ISO/TC 24/SC4
ISO 13322-2	Particle size analysis -- Image analysis methods -- Part 2: Dynamic image analysis methods	ISO/TC 24/SC4
ISO 13323-1	Determination of particle size distribution -- Single-particle light interaction methods -- Part 1: Light interaction considerations	ISO/TC 24/SC4
ISO 20998-1	Measurement and characterization of particles by acoustic methods – Part 1: Concepts and procedures in ultrasonic attenuation spectroscopy	ISO/TC 24/SC4
ISO/CD 21501-1	Determination of particle size distribution -- Single particle light interaction methods -- Part 1: Light scattering aerosol spectrometer	ISO/TC 24/SC4
ISO 21501-2	Determination of particle size distribution -- Single particle light interaction methods -- Part 2: Light scattering liquid-borne particle counter	ISO/TC 24/SC4
ISO 21501-3	Determination of particle size distribution -- Single particle light interaction methods -- Part 3: Light extinction liquid-borne particle counter	ISO/TC 24/SC4
ISO 21501-4	Determination of particle size distribution -- Single particle light interaction methods -- Part 4: Light scattering airborne particle	ISO/TC 24/SC4
ISO 9276-1	Representation of results of particle size analysis – Part 1: Graphical representation, ISO 9276-1:1998/Cor 1:2004	ISO/TC 24/SC4
ISO 9276-2	Representation of results of particle size analysis - Part 2: Calculation of average particle sizes/diameters and moments from particle size distributions	ISO/TC 24/SC4
ISO 9276-4	Representation of results of particle size analysis - Part 4: Characterization of a classification process	ISO/TC 24/SC4
ISO 9276-5	Representation of results of particle size analysis - Part 5: Methods of calculation relating to particle size analyses using logarithmic normal probability distribution	ISO/TC 24/SC4
ISO 9277	Determination of the specific surface area of solids by gas adsorption using the BET method	ISO/TC 24/SC4
ISO DIS 15767	Workplace atmospheres – Controlling and characterizing errors in weighing collected aerosols	ISO/TC 146
ISO/DIS 15900	Determination of particle size distribution -- Differential electrical mobility analysis for aerosol particles	ISO/TC 24/SC4
ISO/DIS 9276-3	Representation of results of particle size analysis --	ISO/TC 24/SC4

	Part 3: Adjustment of an experimental curve to a reference model	
ISO/DIS 9276-6	Representation of results of particle size analysis -- Part 6: Descriptive and quantitative representation of particle shape and morphology	ISO/TC 24/SC4
ISO/DIS13320	Particle size analysis -- Laser diffraction methods 40.20 2009	ISO/TC 24/SC4
ISO/FDIS 22412	Particle size analysis -- Dynamic light scattering (DLS)	ISO/TC 24/SC4
ISO/TS 13762	Particle size analysis -- Small angle X-ray scattering method	ISO/TC 24/SC4
ISO/PWI 27891	Validation and calibration of aerosol particle number counters	ISO/TC 24/SC4
PWI	'Dispersed Stability Characterization in Liquids	ISO/TC 24/SC4
EN 12341:1999	Air quality. Determination of the PM10 fraction of suspended particulate matter. Reference method and field test procedure to demonstrate reference equivalence of measurement methods	CEN/TC 264
EN 14907:2005	Ambient air quality. Standard gravimetric measurement method for the determination of the PM2,5 mass fraction of suspended particulate matter	CEN/TC 264
Pore size		
ISO 15901-1	Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption -- Part 1: Mercury porosimetry	ISO/TC 24/SC4
ISO 15901-2	Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption -- Part 2: Analysis of mesopores and macropores by gas adsorption	ISO/TC 24/SC4
ISO 15901-3	Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption -- Part 3: Analysis of micropores by gas adsorption	ISO/TC 24/SC4
Nanomaterial specifications		
ISO/AWI TS 11803	Nanotechnologies -- Format for reporting the engineered nanomaterials content of products	ISO/TC 229//CEN/TC 352
ISO/NP 11931	Nanotechnologies -- Nano-calcium carbonate	ISO/TC 229
ISO/NP 11937	Nanotechnologies -- Nano-titanium dioxide	ISO/TC 229
ISO/NP 12025	Nanomaterials -- General framework for determining nanoparticle content in nanomaterials by generation of aerosols	ISO/TC 229
Electrical characterization		
1650™-2005	Standard Test Methods for Measurement of Electrical Properties of Carbon Nanotubes	IEEE
P1620.2™	Standard Methods for the Characterization of Printed and Organic Diode Bridges Structures for RF Devices	IEEE
P1690™	Standard Methods for the Characterization of Carbon Nanotubes Used as Additives in Bulk Materials	IEEE
Cleanrooms/ Filtration		
EN ISO 14644-1:1999	Cleanrooms and associated controlled environments -- Part 1: Classification of air	ISO/TC 209//CEN/TC 243

	cleanliness	
EN ISO 14644-2:2000	Cleanrooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	ISO/TC 209//CEN/TC 243
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments -- Part 3: Test methods	ISO/TC 209//CEN/TC 243
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments -- Part 4: Design, construction and start-up	ISO/TC 209//CEN/TC 243
EN ISO 14644-5:2004	Cleanrooms and associated controlled environments -- Part 5: Operations	ISO/TC 209//CEN/TC 243
EN ISO 14644-6:2007	Cleanrooms and associated controlled environments -- Part 6: Vocabulary	ISO/TC 209//CEN/TC 243
EN ISO 14644-7:2004	Cleanrooms and associated controlled environments -- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	ISO/TC 209//CEN/TC 243
EN ISO 14644-8:2006	Cleanrooms and associated controlled environments -- Part 8: Classification of airborne molecular contamination	ISO/TC 209//CEN/TC 243
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods	ISO/TC 209//CEN/TC 243
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data	ISO/TC 209//CEN/TC 243
EN ISO 14698-2:2003/Cor 1:2004	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data/Cor 1	ISO/TC 209//CEN/TC 243
ISO/CD 14644-9	Cleanrooms and associated controlled environments -- Part 9: Classification of surface particle cleanliness	ISO/TC 209//CEN/TC 243
EN 1822 (5 Parts)	High efficiency air filters (HEPA and ULPA).	CEN/TC 195
Health and medical		
E2524-08	Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles	ASTM E56
E2525-08	Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies	ASTM E56
E2526-08	Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells	ASTM E56
EN ISO 10993-1:2003	Biological evaluation of medical devices – Part 1: Evaluation and Testing	ISO/TC 194//CEN/TC 206
EN ISO 10993-2:2006	Part 2: Animal Welfare Requirements	ISO/TC 194//CEN/TC 206
EN ISO 10993-3:2003	Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	ISO/TC 194//CEN/TC 206
EN ISO 10993-4:2002	Part 4: Selection of Tests for Interactions with Blood	ISO/TC 194//CEN/TC 206
EN ISO 10993-5:1999	Part 5: Tests for Cytotoxicity: In-Vitro Methods	ISO/TC 194//CEN/TC 206
EN ISO 10993-6: 2007	Part 6: Tests for Local Effects After Implantation	ISO/TC 194//CEN/TC 206
EN ISO 10993-	Part 9: Framework for the Identification and	ISO/TC

9:1999	Quantification of Potential Degradation Products	194//CEN/TC 206
EN ISO 10993-10:2002	Part 10: Tests for Irritation and delayed-type hypersensitivity	ISO/TC 194//CEN/TC 206
EN ISO 10993-11:2006	Part 11: Tests for Systemic Toxicity (2006, NWIP)	ISO/TC 194//CEN/TC 206
EN ISO 10993-12:2007	Part 12: Sample Preparation & Reference Materials	ISO/TC 194//CEN/TC 206
EN ISO 10993-13:1999	Part 13: Identification and Quantification of Degradation Products from Polymeric Medical Devices	ISO/TC 194//CEN/TC 206
EN ISO 10993-14:2001	Part 14: Identification and Quantification of Degradation Products from Ceramics	ISO/TC 194//CEN/TC 206
EN ISO 10993-15:2001	Part 15: Identification and Quantification of Degradation Products From Metals and Alloys	ISO/TC 194//CEN/TC 206
EN ISO 10993-16:1997	Part 16: Toxicokinetic Study Design for Degradation Products and Leachables	ISO/TC 194//CEN/TC 206
EN ISO 10993-17:2002	Part 17: Establishment of allowable limits for leachable substances	ISO/TC 194//CEN/TC 206
EN ISO 10993-18:2005	Part 18: Chemical Characterization of Materials	ISO/TC 194//CEN/TC 206
EN ISO 10993-20:2006	Part 20: Principles and Methods for Immunotoxicology Testing of Medical Devices	ISO/TC 194//CEN/TC 206
ISO/AWI 10801	Nanotechnologies -- Generation of silver nanoparticles for inhalation toxicity testing	ISO/TC 229
ISO/AWI 10808	Nanotechnologies -- Monitoring silver nanoparticles in inhalation exposure chambers for inhalation toxicity testing	ISO/TC 229
ISO/NP 29701	Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems	ISO/TC 229
EN ISO 14155 (2 Parts)	Clinical investigation of medical devices for human subjects	ISO/TC 194//CEN/TC 258
EN ISO 13485:2003	Medical devices. Quality management systems. Requirements for regulatory purposes	ISO/TC 210//CEN/CLC/WG QS
Occupational health		
E2535-07	Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings	ASTM E56
ISO 7708	Air quality – Particle size fraction definitions for health-related sampling (1995)	ISO/TC 146
ISO TR 27628	Workplace atmospheres – Ultrafine, nanoparticle and nano-structured aerosols – Inhalation exposure characterization and assessment (2006).	ISO/TC 146
Risk		
ISO/TS 20993:2006	Biological evaluation of medical devices -- Guidance on a risk-management processhttp://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E983.htm?L+mystore+axhd3469+1192075174	ISO/TC 194
EN ISO 14971:2007	Medical devices. Application of risk management to medical devices	ISO/TC 210//CEN/SS S99
Terminology		
E2456-06	Standard Terminology Relating to Nanotechnology	ASTM E56
ISO 18115:2001	Surface chemical analysis -- Vocabulary	ISO/TC 201
ISO 18115:2001 /Amd 1:2006	Surface chemical analysis – Vocabulary Amd 1	ISO/TC 201
ISO 18115:2001	Surface chemical analysis – Vocabulary Amd 2	ISO/TC 201

/Amd 2:2007		
ISO/AWI TR 11360	Nanotechnologies -- Outline of nanomaterials classification (Nano tree)	ISO/TC 229
ISO/AWI TS 11751	Terminology and definitions for carbon nanomaterials	ISO/TC 229
ISO/NP 26824	Particle characterization of particulate systems -- Vocabulary	ISO/TC 24/SC4
ISO/PRF TS 27687	Nanotechnologies - Terminology and definitions for nanoparticles	ISO/TC 229
Ceramic/Refractory/ Powder Technology		
EN 623-3:2001	Advanced technical ceramics. Monolithic ceramics. General and textural properties. Determination of grain size and size distribution (characterized by the linear intercept method)	CEN/TC 184
EN 725-5:2007	Advanced technical ceramics. Methods of test for ceramic powders. Determination of particle size distribution	CEN/TC 184
EN ISO 18757:2005	Fine ceramics (advanced ceramics, advanced technical ceramics). Determination of specific surface area of ceramic powders by gas adsorption using the BET method	CEN/TC 184//ISO/TC 206
EN 1071-4:2006	Advanced technical ceramics. Methods of test for ceramic coatings. Determination of chemical composition by electron probe microanalysis (EPMA)	CEN/TC 184
ENV 14232:2003	Advanced technical ceramics. Terms, definitions and abbreviations	CEN/TC 184
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ANNEX F FP6 Project 'Nanostrand'

F.1 Introduction

Nanostrand, a European nanometrology and standards foresighting project, was supported under FP6 and completed in January 2008. Its goal was to identify new measurement tools, technologies and standards required to support nanotechnology development and exploitation.

Key deliverables of the project were two sets of roadmaps – one defining nanometrology research priorities and one focusing on nanotechnology standardization priorities. The directions given by the Nanostrand roadmaps for standardization have been integrated in the main body of this document (section 4), together with the outcome of the ISO/TC 229 standardization roadmapping exercise. This annex deals with the metrology roadmaps developed in Nanostrand.

F.2 Metrology and standardization

Metrology is the field of knowledge concerned with measurement. Because many standards are related to, or have aspects of, measurement, there is a strong link between metrology and standardization: standardization can help in the development of new metrological understanding, by making measurement results easier to compare, thus allowing combination of know-how established in different parts of the world; on the other hand, metrology can help in the development of better standards, by identifying the essential parts in a measurement procedure for a standard to address when method performance must be improved.

In certain cases a full, metrological understanding of a particular measurement process can render standardization or a particular standard obsolete. This is the case when SI-traceable results for a particular measurand can be achieved with different measurement methods and instruments. However, many measurement methods assess a method-defined property, i.e. a property for which comparable values can only be achieved if the same measurement method is followed. In this case, standardization of the measurement method is the only route to achieve globally comparable measurement results. For the majority of the measurement methods at the nanoscale, even the 'simple' measurement of the size of a nanoparticle, the measurement results are method-defined. This is why, also from the metrological point of view, standardization is so important for nanotechnology.

F.3 Metrology and nanotechnology

Although several definitions for 'nanotechnology' have been proposed, they all agree on one essential element: it is all about things that happen at the 'nano'-scale. 'Nano' then is the prefix corresponding to a factor 10^{-9} and the scale is that of size, with the meter as the SI-unit. It follows that whether something is nanotechnology or not, can be judged based on some measurement of size. Nanotechnology therefore is intrinsically linked to metrology.

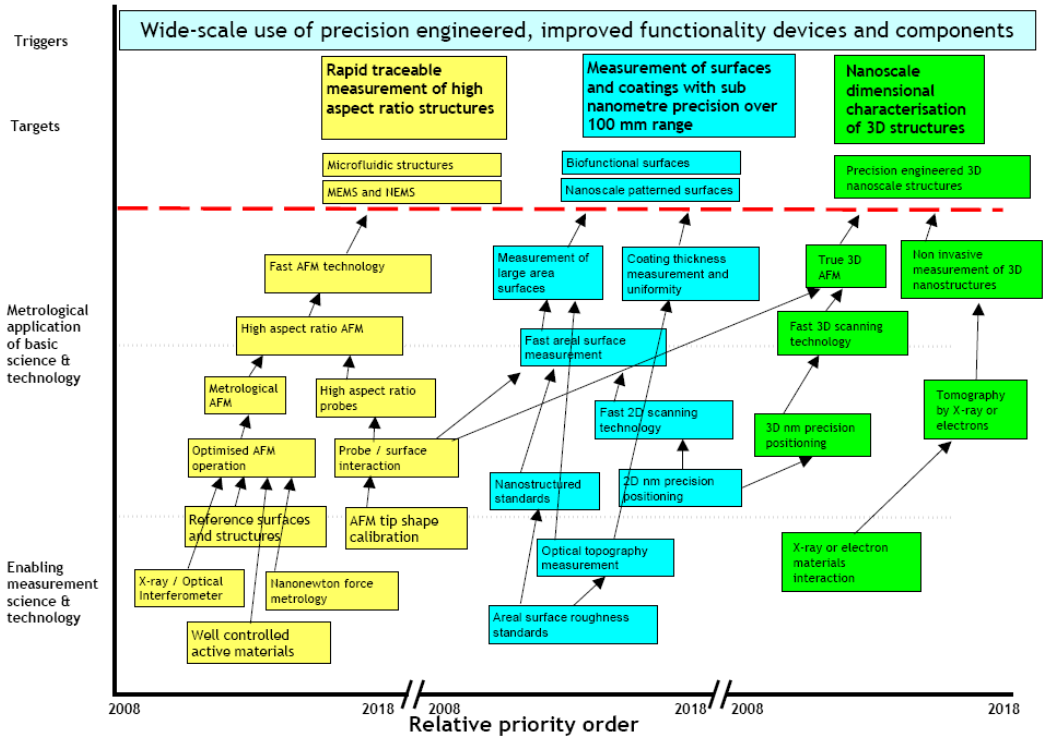
While physical size does matter, the phenomena occurring at the nanoscale are not dominated by size necessarily. Nanotechnology brings together physics, chemistry and biology creating a highly multidisciplinary field. Existing measurement techniques suitable for chemical, physical or biological measurements at the macro-scale, for bulky samples, suddenly become much more complicated, when they need to be applied at or adapted for application, at the nanoscale. Otherwise validated and trustworthy measurement methods reveal their limits in terms of spatial resolution, or the measurand they are assessing becomes less-well defined. A large number, if not most, existing, standard methods need be submitted to dedicated validation studies to justify an extension of their range of applicability to the nanoscale.

Metrology can contribute to the development of suitable nanotechnology standards in two ways. Firstly, the development of metrologically sound new instruments and techniques will enable the development of new, to be standardized measurement procedures. Secondly, the metrological concepts and defined terminology provide the framework for an efficient and intelligent validation and application of new or adapted methods.

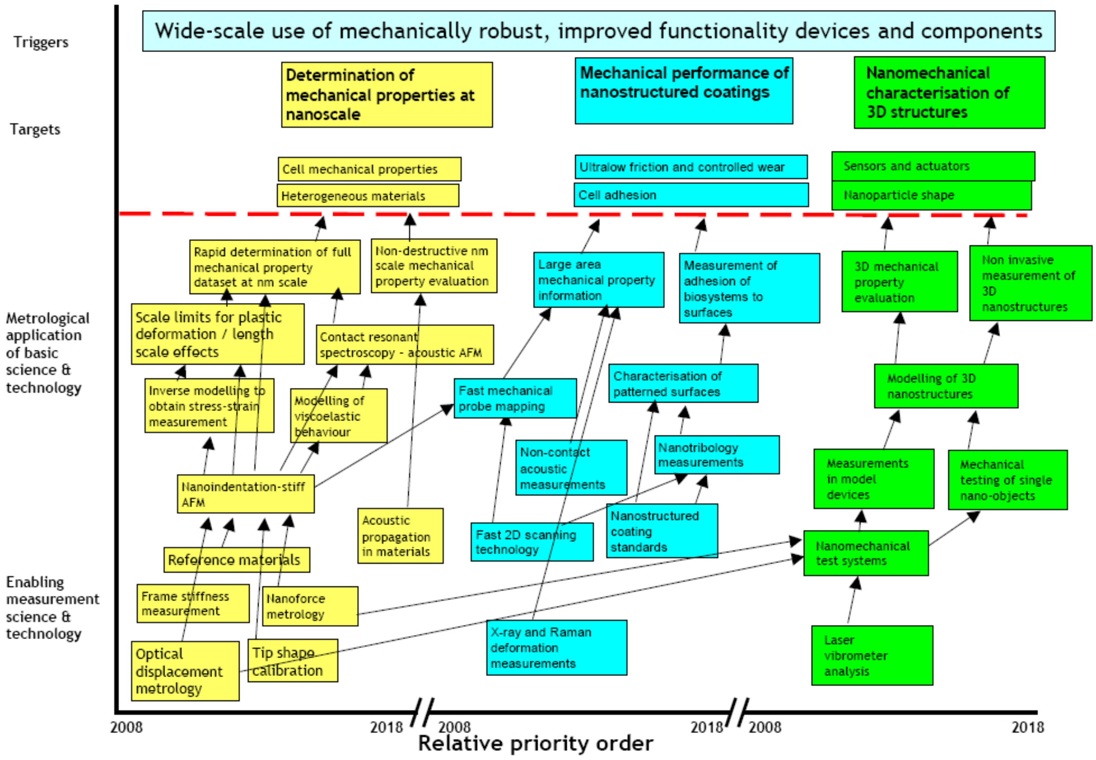
F.4 Nanostrand roadmaps for metrology

Nanostrand has chosen to approach metrology along 5 different axes (dimensional, mechanical, chemical, structural and biological/healthcare). The resulting roadmaps are shown below. They indicate which are the enabling measurement science and technology (near the bottom of the graphs), that form the basis for progress in certain application areas (middle of the graphs). For each field, the graphs show the targets towards which the progress is expected to lead.

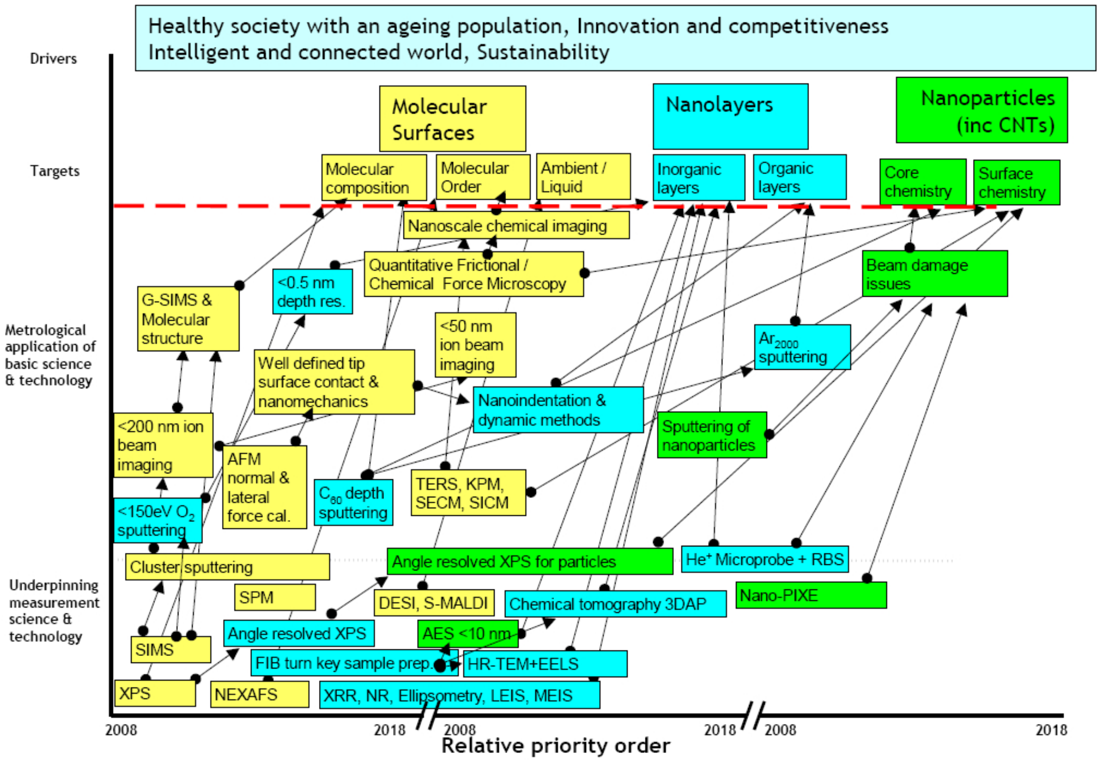
ROADMAP FOR NANO DIMENSIONAL METROLOGY



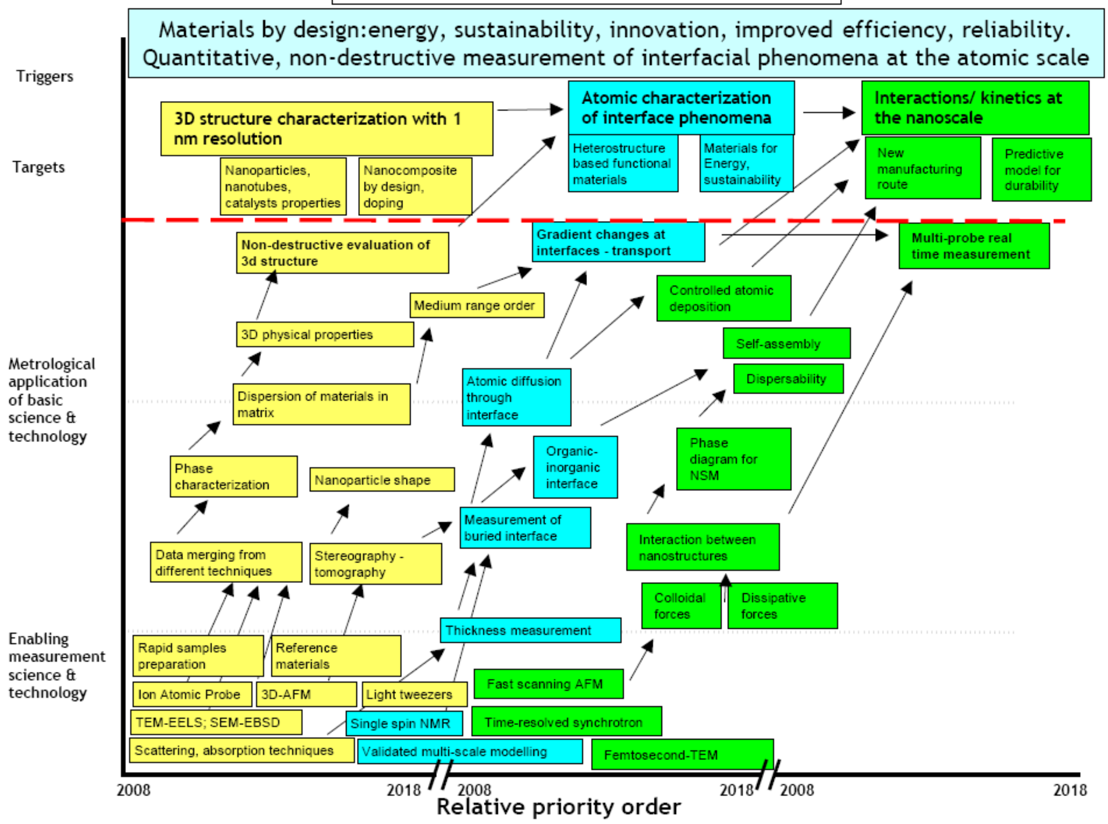
ROADMAP FOR NANO MECHANICAL METROLOGY

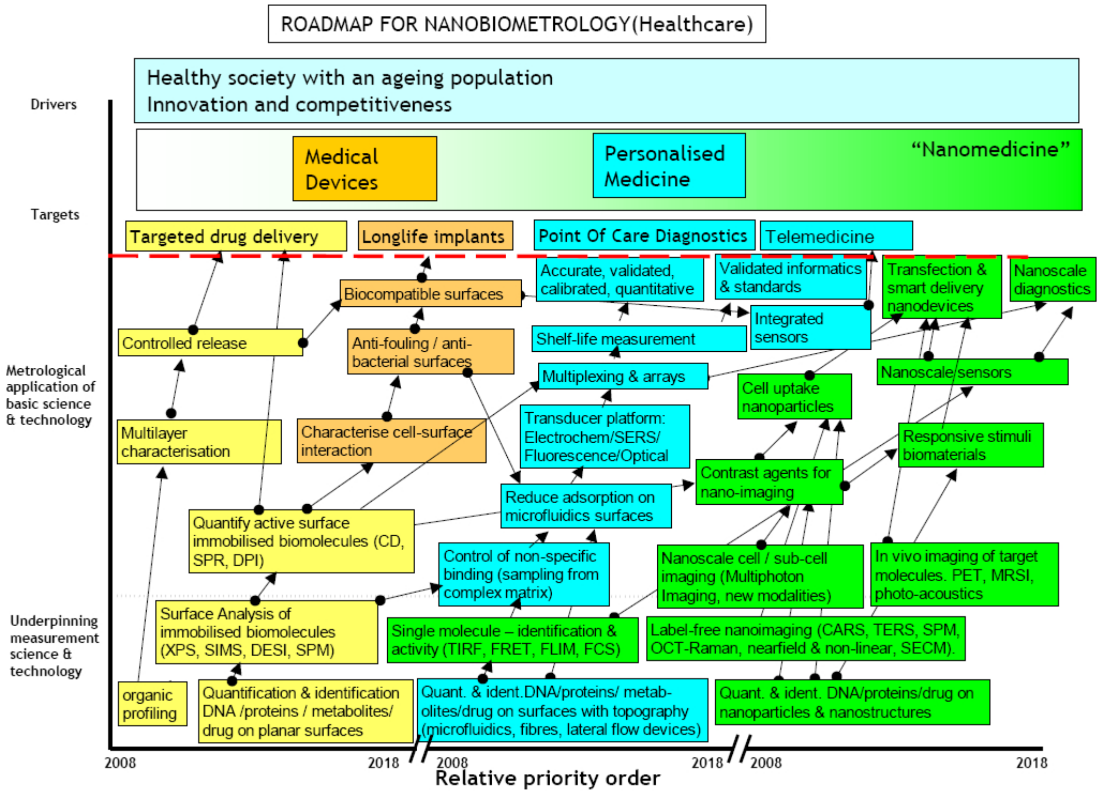


ROADMAP FOR NANO-CHEMICAL



ROADMAP FOR NANO-STRUCTURED MATERIALS




ROADMAP FOR NANOBIOMETROLOGY(Healthcare)
Drivers
Healthy society with an ageing population
Innovation and competitiveness
Targets
Medical Devices
Personalised Medicine
"Nanomedicine"
Targeted drug delivery
Longlife implants
Point Of Care Diagnostics
Telemedicine
Metrological application of basic science & technology
Controlled release
Biocompatible surfaces
Anti-fouling / anti-bacterial surfaces
Multilayer characterisation
Characterise cell-surface interaction
Accurate, validated, calibrated, quantitative
Validated informatics & standards
Integrated sensors
Shelf-life measurement
Multiplexing & arrays
Transducer platform: Electrochem/SERS/ Fluorescence/Optical
Reduce adsorption on microfluidics surfaces
Transfection & smart delivery nanodevices
Nanoscale diagnostics
Nanoscale sensors
Cell uptake nanoparticles
Contrast agents for nano-imaging
Responsive stimuli biomaterials
Quantify active surface immobilised biomolecules (CD, SPR, DPI)
Control of non-specific binding (sampling from complex matrix)
Nanoscale cell / sub-cell imaging (Multiphoton Imaging, new modalities)
In vivo imaging of target molecules. PET, MRSI, photo-acoustics
Underpinning measurement science & technology
Surface Analysis of immobilised biomolecules (XPS, SIMS, DESI, SPM)
Single molecule – identification & activity (TIRF, FRET, FLIM, FCS)
Label-free nanoimaging (CARS, TERS, SPM, OCT-Raman, nearfield & non-linear, SECM).
organic profiling
Quantification & identification DNA /proteins / metabolites/ drug on planar surfaces
Quant. & ident.DNA/proteins/ metab-olites/drug on surfaces with topography (microfluidics, fibres, lateral flow devices)
Quant. & ident. DNA/proteins/drug on nanoparticles & nanostructures
2008
2018
2008
2018
2008
2018
Relative priority order

Acronyms

CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CNR	Co-normative Research
CWA	CEN or CENELEC Workshop Agreement
EC	European Commission
EN	European Standard
ESO	European Standardization Organization
ETSI	European Telecommunications Standards Institute
ETP	European Technology Platform
EU	European Union
FP	Framework Programme (for Research and Technological Development)
IEC	International Electrotechnical Commission
ISO	Intrernational Organization for Standardization
NIST	National Institute of Standards and Technology
OECD	Organization for Economic Co-operation and Development
PAS	Publicly Available Specification
PNR	Pre-normative Research
TC	Technical Committee
TR	Technical Report
TS	Technical Specification

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