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Organisation internationale de normalisation
International Organization for Standardization
Международная Организация по Стандартизации



TO THE ISO MEMBER BODIES

Our ref. TMB / ISO/TS/P 199

Date 2005-01-20

Dear Sir or Madam,

ISO/TS/P 199 Nanotechnologies

Please find attached herewith a proposal for a new field of technical activity submitted by BSI (United Kingdom).

According to subclause 1.5.6 of Part 1 of the ISO/IEC Directives, you are kindly invited to complete the attached ballot form and return it to the Secretariat of the ISO Technical Management Board before **20 April 2005**, or electronically as an attachment to tmb@iso.org if you wish to reply by e-mail. The ballot form (Form 02) could also be downloaded from the [ISOTC Portal](#) in the section [ISO forms](#).

Yours faithfully,

A handwritten signature in black ink, appearing to read "MA Smith", with a long horizontal stroke extending to the right.

Michael A. Smith
Secretary of the Technical Management Board

Encl:
TS/P 199
Ballot form (Form 02)

cc: Vice-President (technical management)

**PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY**Date of proposal
2005-01-13Reference number
(to be given by Central Secretariat)Proposer
BSI (United Kingdom)**ISO/TS/P 199**

A proposal for a new field of technical activity shall be submitted to the Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives (part 1, subclause 1.5). The proposer may be a member body of ISO, a technical committee or subcommittee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the ISO/IEC Directives (part 1, annex Q).

The proposal (to be completed by the proposer)**Subject** (the subject shall be described unambiguously and as concisely as possible)**Nanotechnologies****Scope** (the scope shall define precisely the limits of the proposed new field of activity and shall begin with "Standardization of ..." or "Standardization in the field of ...")

Standardization in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues. The methods of test are to include methods for determining physical, chemical, structural and biological properties of materials or devices for which the performance, in the chosen application, is critically dependent on one or more dimension of <100nm. Test methods for applications, and product standards shall come within the scope of the TC.

Purpose and justification (the justification shall endeavour to assess the economic and social advantages which would result from the adoption of International Standards in the proposed new field)

Purpose: to provide industry, research and regulators with a coherent set of robust and well founded standards in the area of nanotechnologies to assist the efficient and effective development of world and local markets for nanotechnology products, whilst at the same time providing regulators, and society in general, with suitable and appropriate instruments for the evaluation of risk and the protection of health and the environment.

Justification: many authorities predict that nanotechnologies will become the most important driver for economic growth in the 21st century. Applications of nanotechnologies will pervade all areas of life and will enable dramatic advances to be realized in all areas of communication, health, manufacturing, materials, and knowledge-based technologies. Industrial and consumer applications and uses of Nanotechnologies are expected to rise dramatically during the coming years, with the world market predicted to be in excess of one trillion dollars by 2015. Sustaining the growth necessary to achieve such a figure from current, relatively modest levels, will require considerable investment in technological and manufacturing/business related infrastructure, especially standards. The opportunities offered by nanotechnologies have been clearly recognized by the world's leading economies, with "federal" spending on nanotechnology research in Europe, the US and Japan in year 2003 reaching more than \$3 BN, a rise of approximately 10 fold on 1997. The current spend on nanotechnology research by business is impossible to estimate but is likely to be the same as the federal spend.

Programme of work (list of principal questions which the proposer wishes to be included within the limits given in the proposed scope, indicating what aspects of the subject should be dealt with, e.g. terminology, test methods, dimensions and tolerances, performance requirements, technical specifications, etc.)

Advances in nanotechnologies are expected to be extremely rapid during the coming years. In the early stages of development it will be crucial to provide industry and research with suitable tools to aid the development and application of the technologies. Care will need to be taken in the selection of appropriate instruments so as to enhance progress and not impede it. The programme of work will therefore develop over time. Initially the emphasis will be on developing infrastructural standards in the areas of: terminology and nomenclature to support efficient and unambiguous communication within and between industrial, scientific, regulatory, legal and intellectual property disciplines; basic metrology in support of nanotechnology standardization, to include techniques for the determination of length (including thickness of ultra-thin films), surface area, volume, flow, force, etc. at the nanoscale; physical, structural, chemical and biological characterization at the nanoscale, including standards for manufacture and calibration of equipment; and risk and societal issues including risk evaluation, societal (health, environmental and social) impact, including protocols for impact assessment of new products, new manufacturing facilities, new research directions, outsourcing, etc., and life cycle analysis of products and manufacturing facilities. The focus will then move to generic product standards, paralleling industrial and commercial requirements. Finally these two areas can be expected to combine with the development of product standards, with standards in these three areas - underpinning terminology and technology, generic product needs and product requirements - continuing to be developed over time.

Survey of similar work undertaken in other bodies (relevant documents to be considered: national standards or other normative documents)

Although some work on standards development in nanotechnologies is underway, principally development of a terminology document in the USA and of a Publicly Available Specification (PAS) vocabulary for nanoparticles within BSI, only three national nanotechnology committees are known to exist - in the UK, USA and Japan - with the oldest of these, NTI/1 in the UK, having been in existence for less than 9 months. Each of these bodies is engaged in developing their own strategy for standardization and none yet has a clearly defined work programme for the future. In addition, CEN has established a Technical Management Board Working Group charged with developing a strategy for nanotechnologies standardization for Europe. Some standards development relevant to nanotechnologies is being undertaken within existing ISO and CEN committees but it appears to be minimal and there is currently no effective coordination of this work. However, given the global nature and reach of nanotechnologies together with the very rapid rate of development within different sectors and trading blocks, it makes undeniable sense to establish the necessary structure within ISO, as soon as possible, to allow for the rapid development and deployment of international standards to support industrial development in a well-regulated and coordinated environment.

Liaison organizations (list of organizations or external or internal bodies with which cooperation and liaison should be established)

Standards organisations. A range of organisations with an interest in the subject E.G IUPAC, VAMAS, Asia Pacific Nanotechnology Forum, National Nanotechnology Initiative, European Nanobusiness Association.

Other comments (if any)

Given the magnitude of the potential world market offered by nanotechnologies, it is clear that an appropriate standards infrastructure needs to be in place as soon as possible to ensure that organizations can take full advantage of the opportunities as and when they become available. Indeed, in their position paper on The Need for Measurement and Testing in Nanotechnology, published in February 2002, the European Union High Level Expert Group on Measurement and Testing concluded that "Prosperous industrial sectors such as Precision Engineering, Micro- & Optoelectronics, as well as Bio-molecular technology will not be able to develop to their full potential without associated developments in measurement, testing and related disciplines." Additionally, a number of studies on nanotechnologies have highlighted the need for standardization, and standardization is highlighted as being critical for many of the "9 Grand Challenges" for the National Nanotechnology Initiative in the US. Furthermore, serious concern is beginning to be expressed in some quarters about potential negative health and environmental impacts of nanotechnologies, and it is therefore essential that regulators and health and environmental protection agencies have available reliable measurement systems and evaluation protocols supported by well founded and robust standards.

BSI offers to take the Secretariat and nominate the Chairman of a new TC on Nanotechnologies

Signature of the proposer

Trevor Vyze
Head of Technical Policy
BSI

Comments of the Secretary-General (to be completed by the Central Secretariat)



Signature
Michael A. Smith
Secretary of the TMB