ISO/TC 229 N 1724

BUSINESS PLAN

ISO/TC 229

Nanotechnologies

EXECUTIVE SUMMARY

Nanotechnology is the application of scientific knowledge to manipulate and control matter in the size range 1 nm to 100 nm, where entirely new physical and chemical, size-related properties and phenomena can emerge. This often results in new, exciting and different characteristics that generate an array of novel applications and products.

Nanotechnology is a revolutionary new technology and, potentially, a key economic driver for the twenty-first century. Nanotechnology promises significant social benefits, including enhancements in medical diagnosis and treatment, more efficient energy sources, lighter, stronger and cheaper materials and electronic products and cleaner, cheaper water.

The impact of nanomaterials has led to concern over potential environmental, health and safety risks associated with nanotechnology and its products. This has resulted in a large amount of documentation from ISO/TC 229 and associated organizations, related to toxicological effects of nanomaterials.

International standardization plays a critical role in ensuring that the full potential of nanotechnology is realised and that the products of nanotechnology are safely integrated into society. Standards help create a smooth transition from the laboratory to the marketplace, promote progress along the nanotechnology value chain – from nanoscale materials that form the building blocks for components and devices to the integration of these devices into functional systems and products – and facilitate global trade.

Five categories of horizontal standards are being developed; terminology and nomenclature standards provide a common language for scientific, technical, commercial and regulatory processes; measurement and characterisation standards provide an internationally accepted basis for quantitative scientific, commercial and regulatory activities; health, safety and environmental standards improve occupational safety, and consumer and environmental protection, and promote good practice in the production, use and disposal of nanomaterials, nanotechnology products and nano-enabled systems and products; materials specification standards will specify the relevant characteristics of manufactured nanoscale materials for use in various applications; and products and applications performance-based standards will highlight advantages of nano-enabled and nano-enhanced products.

Many of the documents produced by ISO/TC 229 are horizontal in nature, providing underlying support to a technology or range of technologies. However the applications of nanotechnology

have evolved significantly in the last two decades, and where other committees are not developing nanotechnology-related standards, ISO/TC229 will develop product and application performance-based standards (in collaboration with other committees if necessary).

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 160 countries supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

2 BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

The TC229 definition for nanotechnology [ISO/TS 80004-1:2015] is the application of scientific knowledge to manipulate and control matter predominantly at the nanoscale, where size-related properties and phenomena can emerge. The nanoscale [ISO/TS 80004-1:2015] is the size range approximately from 1 nm to 100 nm.

Dynamics:

Economic: Governments and industries in nations around the world have invested billions of dollars in nanotechnology. Many reports on the economics of nanotechnology have been published, with a wide variation in estimates for the size of the global market, and predictions of its future size. Continuing double digit growth in nanotechnologies-enabled products is predicted.

Technical: Nanotechnology is not just another step towards miniaturisation; there are fundamental differences in physical, chemical and biological behaviour at the nanoscale compared to bulk materials or individual atoms and molecules. Nanotechnology is an enabling technology that alone, or in combination with associated technologies, provides the means to generate significant improvements in performance and capabilities.

Regulatory: The novel properties of nanomaterials may pose risks to human health and the environment. Governments world-wide are concerned about the ability of regulatory frameworks to keep pace with the impact of nanotechnology and are looking to ISO to produce documentary standards to which regulation and regulators can refer.

Societal: Nanotechnology has raised some new technical and societal issues. Health, safety and environmental issues, ethical considerations, community engagement and perception are all being explored. Media interest is high and is a mixture of the novel science and potential benefits with concerns for health and safety issues. The general public is mostly positive even though the awareness and understanding of nanotechnology is still fairly low.

International: Nanotechnology is a global phenomenon with most developed economies establishing strategies and encouraging commercialisation. International nanotechnology collaboration is growing with the realisation that no single country can fund the research necessary for the effective and safe adoption of nanotechnology. International standards for nanotechnology are required to both encourage trade and to prevent technical barriers. In addition many countries have developed their own national nanotechnology standards.

Nanotechnology Marketplace

The last thirty years have seen a soring interest and support for nanotechnology internationally and there are numerous studies and reports detailing this growth. Nanotechnology is an enabling technology, crossing conventional boundaries between physics, chemistry, biology, information technology, and engineering. As the sizes of nanoparticles and relevant features of nanoscale devices are comparable to the size of biological entities (antibodies and proteins, peptides, and nucleic acids), the use of nanotechnology devices for biological and medical applications has made a number of breakthroughs and is developing rapidly. Nanotechnology should benefit every industrial sector and health care field. It should also help the environment through more efficient use of resources, energy generation and harvesting, and better methods of pollution control. Because nanotechnology is classified by the size of the materials being developed and used, the products of this technology might have little in common with each other — for example fuel cells, fabrics and drug delivery devices. What brings them together is the natural convergence of all basic natural sciences (biology, physics and chemistry) at the molecular level. Given the multitude

of processes and applications that are being developed and the wide range of application areas, it has become more usual to refer to nanotechnologies in the plural rather than to nanotechnology.

The significant increase in the production of nanomaterials in recent years, in particular carbon nanotubes (CNTs) and metal and metal oxide nanoparticles, has led to a number of TC 229 New Work Items involving the measurement of CNTs and the establishment of a Working Group (WG4) on Materials Specifications. The proliferation of applications, potential and actual, of nanotechnology has also led to the establishment of WG 5 'Products and applications'.

Nanotechnologies are expected to evolve through four overlapping stages of industrial prototyping and commercialization. The first, already begun, involves the development of passive nanostructures: materials with fixed structures and functions often used as parts of a product. Products containing nanomaterials already in the marketplace mainly involve manufactured nanoparticles (metal oxides, quantum dots, carbon nanotubes, etc) serving as raw materials, ingredients or additives in existing products. These products include paints, fuel cells, batteries, fuel additives, catalysts, lubricants, military battle suits, self-cleaning windows, sunscreens and cosmetics, explosives, propellants and pyrotechnics, disinfectants, abrasives and food additives. Thousands of new patents are being announced in this area each year and there are dozens of engineered nanoscale materials and particles at the research stage that could soon enter commerce.

The second stage, also already begun, focuses on active nanostructures that change their size, shape, morphology, surface chemistry, porosity, conductivity or other properties during use. For example, drug-delivery formulations that are activated to release therapeutic molecules in the body when they reach their targeted, diseased tissues. The third stage should see the further development of expertise with systems of nanostructures and the directing of large numbers of intricate components to specified ends (for example, the guided self-assembly of nanoelectronic components into three-dimensional circuits and whole devices). Medicine could employ such systems to improve the tissue compatibility of implants, or to create scaffolds for tissue regeneration.

In the fourth stage, nanotechnologies will expand to include molecular nanosystems--heterogeneous networks in which molecules and supramolecular structures serve as distinct devices. Computers and robots could be reduced to extraordinarily small sizes. Medical applications might be new types of gene therapies and anti-aging treatments and there might be new interfaces linking people directly to electronics.

The successful emergence and adoption of nanotechnologies depends in part on the creation of a supportive scientific, industrial and social environment.

The rapid development of nanotechnologies has resulted in a largely uncontrolled growth in the number of terms used in both nanosciences and nanotechnologies. A critical task for this ISO/TC has been and continues to be the development and assembly of a harmonized vocabulary for nanotechnologies, with a set of consistent definitions and supporting nomenclature, to facilitate communications and place legal and commercial transactions, standards and regulations on a firm foundation.

The accurate and reproducible measurement of the properties, performance and physico-chemical characteristics of nanoscale materials, devices and systems are essential for quality and process control, commercial transactions and effective regulation. Scientists, manufacturers, governments, regulators and health and environmental protection agencies, will need measurement systems and evaluation protocols supported by well founded and robust standards, both physical and documentary.

It is also widely recognized that nanotechnologies raise opportunities in the health, safety, environmental and regulatory domains. An assessment of the risks posed by nanotechnologies-based products throughout their life cycle is an important priority. There are an increasing number of studies on the effects of nanoparticles and other nanomaterials on human health and the environment, leading to a demand for specific metrology tools and standards for the effective measurement of exposure to nanomaterials, and for nanoparticle delivery methods. These tools are needed for use both in the environment (particularly for ecotoxicity studies) and in medical fields (particularly for assessing exposure to toxic materials).

In the light of developments in nanomaterial manufacturing at large scale, a clear need for quality and consistency of supply have been highlighted by a number of stakeholders. Development of traceable material specifications will facilitate relationships between different parties in the supply chain and will ensure consistent and sustainable development of nanomaterial markets.

After several decades of nanotechnology development, the applications market place is filled with nano-enabled and nano-enhanced products. Such products may compete with existing products or offer completely new solutions. In both cases, their performance, safety, durability and other aspects are of importance to the wider community.

2.2 Quantitative Indicators of the Business Environment

The last 20 years have seen numerous studies and reports on the economics of nanotechnologies, , including sources such as the OECD.

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

For nations to be at the forefront of the nanotechnologies revolution, a suitable commercial, regulatory and social environment must be provided to support nanotechnologies growth, investment and benefits. It is well established that the efficient and economic production of materials, devices and commodities relies fundamentally on accurate and reliable measurement, as well as on harmonised standards. Standardisation aids growth in productivity by supporting innovation, value generation, compliance and regulation.

Priority has been given to developing horizontal standards for terminology and nomenclature, measurement and characterisation, health, safety and the environmental (HSE), nanomaterial specifications, and products and applications. These priorities are designed to support research, commercialisation and trade in nanoscale materials, products and applications. In particular, and responding to societal concerns about the safety of nanotechnologies, the HSE standards will support the development of appropriate national and international regulatory regimes, including guidance documents, in the fields of occupational and environmental health and safety, promoting good practice in the production, use and disposal of nanomaterials, nanotechnology products and nano-enabled and nano-enhanced systems, products and services. These regimes will provide certainty and confidence for workers, consumers, manufacturers and users alike.

In the early years of the committee, many of the standards developed by TC 229 were anticipatory. Over the years, the area of nanotechnology has matured with a build up of know how and good practices in various fields from toxicology to communication with society, development of new materials and their applications. For this reason ISO/TC229 is aiming to develop more standards based on established technologies, procedures and practices through the use of robust checklists for new work item approval and interlaboratory comparison studies.

Outputs from the standardization efforts will support technological development, societal acceptance and market expansion by:

- developing robust terminology for nanotechnology-related communication
- identifying needs for, and encouraging the development of, instruments and test methods for use at the nanoscale;
- developing test methods to detect and identify nanoparticles, and to characterize nanoscale materials and devices;
- developing protocols for bio- and ecotoxicity testing;
- developing protocols for whole life cycle assessment of nanoscale materials, devices and products;
- developing risk assessment tools relevant to the field of nanotechnologies;
- developing protocols for reducing exposures to nanomaterials and for managing wastes containing nanomaterials;
- developing occupational health protocols relevant to nanotechnologies, in particular for industries dealing with nanoparticles and nanoscale devices;
- supporting regulation in the area of nanotechnologies;
- supporting communication of accurate and quantifiable information on nanotechnologies.
- supporting nanomaterials supply chain with clear material specifications and guidelines
- supporting innovation and commercialization through clear performance-based standards for nano-enabled and nano-enhanced products and applications.

As a 'horizontal' committee, ISO/TC 229 will not develop application-specific standards, except where there is clear demand and there is no existing committee working in the area. ISO/TC 229 also recognizes the role of other TCs with a horizontal vocation, such as TCs for particular measurement fields (surface analysis, particle characterization, etc.), which have historically provided the tools that allowed the development of nanotechnology and nanomaterials. ISO/TC 229 will work with its liaisons to help ensure that stakeholders in specific application areas have the requisite standardization tools to support their introduction and use of nanotechnologies to new applications and markets.

4 REPRESENTATION AND PARTICIPATION IN TC 229

4.1 Membership of ISO/TC 229

The current membership, Chairman and Secretary, work program, scope, ISO committees in liaison, organizations in liaison, Working, Task and Study Groups and a meeting calendar may be found at:

TC 229 ISO website

4.2 Analysis of the participation

Membership of TC 229 includes countries and representatives from all regions of the world. The committee will take steps to encourage additional members to join ISO/TC 229.

An important number of TCs and other organizations have established a liaison with ISO/TC 229, recognizing the pivotal role of ISO/TC 229 in the area of nanotechnology standardization. ISO/TC 229 has proposed and was entrusted with the creation of a Nanotechnologies Liaison Coordination Group (NLCG). The NLCG is hosted by ISO/TC 229 and provides a forum for ISO/TC 229 and its liaison members to maximize the benefits of their mutual liaison relations.

A key liaison is with the IEC/TC 113: "*Nanotechnology Standardization for Electrical and Electronic Products and Systems*', including two Joint Working Groups – in Terminology and Nomenclature and Measurement and Characterization. The liaison is governed by an Agreement of Cooperation, first concluded in 2007.

A second key liaison is with the Organisation for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN).

5 OBJECTIVES OF TC 229 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of TC 229

In accordance with ISO strategy, ISO/TC 229, develops robust standards and other deliverables relevant to nanotechnologies that:

- Support the sustainable and responsible development and global dissemination of these emerging technologies and nanomaterials (e.g. nanocellulose, graphene and carbon nanotubes);
- Facilitate global trade in nanotechnologies, and nano-enabled and nano-enhanced systems and products;
- Support improvement in quality, safety, security, worker, consumer and environmental protection, together with the rational use of natural resources in the context of nanotechnologies;
- Promote good practice in the production, use and disposal of nanomaterials, nanotechnology products and nanotechnology enabled systems and products.

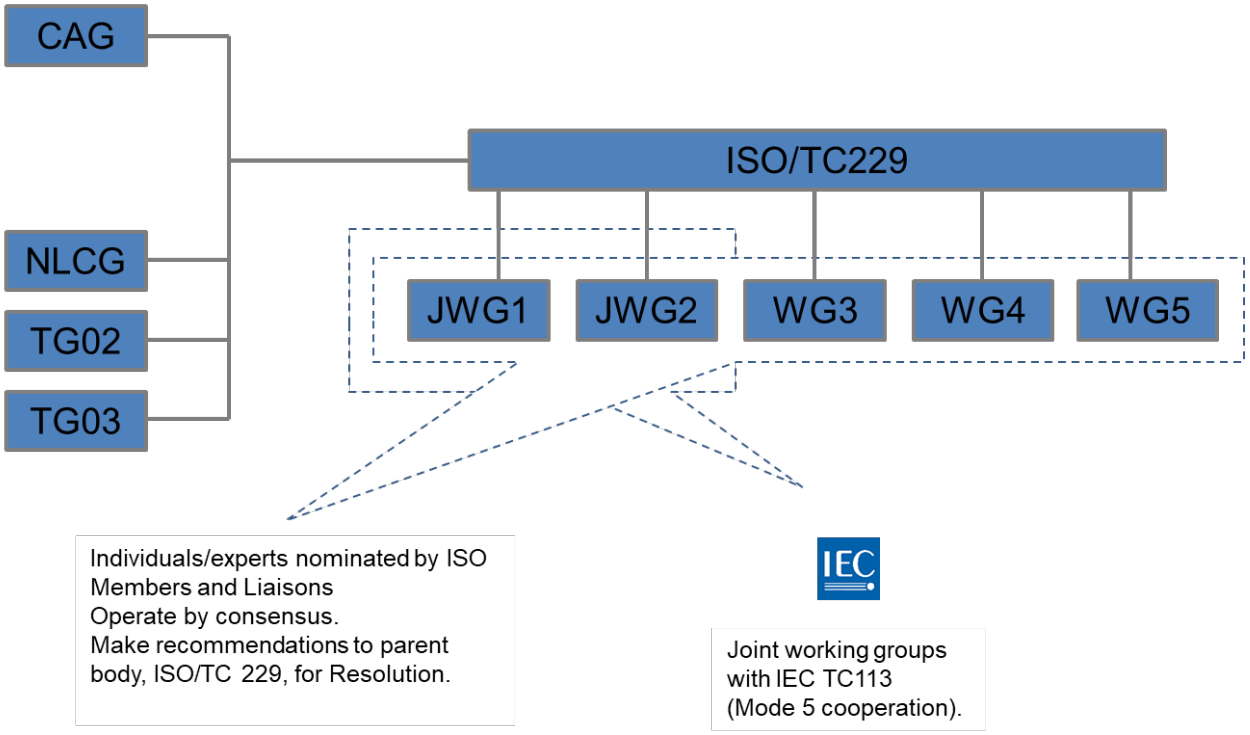
The work of the Technical Committee focused initially on the areas of terminology and nomenclature, metrology and test methods, and health, safety and the environment. In 2008 this was extended to include material specifications and in 2016 it was further extended to include nano-enabled and nano-enhanced products and applications.

ISO TC/229 will regularly review its strategy in order to support the overall objectives of ISO, in particular to help it achieve its Global Vision 'to be the world's leading provider of high quality, globally relevant International Standards through its members and stakeholders'.

5.2 Identified strategies to achieve TC 229's defined objectives.

A list of the Standards under development may be found at TC229 Work program. The diagram below shows the current TC229 structure, designed to support the efficient and orderly development of Standards.

ISO/TC229 Structure



The following table lists the key TC 229 strategies and the corresponding actions.

No.	Strategies	Actions
01.	Establish appropriate structures within ISO/TC 229 to support timely and optimal development of International Standards and other deliverables – Technical SpecificationsTechnical Reports, etc	1. Establishment of five working group (WG)s under TC JWG1 - Terminology and nomenclature Scope: To define and develop an unambiguous and uniform terminology and nomenclature for nanotechnologies to facilitate communication and promote common understanding JWG2 – Measurement and characterization Scope: To develop standards for measurement, characterization and test methods for nanotechnologies taking into consideration needs for metrology and reference materials WG3 – Health, safety and environment aspects of nanotechnologies Scope: To develop science-based standards in the areas of health, safety and environmental aspects of nanotechnologies WG4 – Material specifications Scope: To specify relevant characteristics of engineered nanoscale materials for use in generic/specific applications. WG 5 – Products and applications Scope: Development of performance-based standards for nano-enabled or nano-enhanced products and applications

		2. Establishment of Groups under the TC and WGs i. **Chairman's Advisory Group (CAG)** to provide strategic advice to the TC 229 Chair on matters and issues related to TC 229; to monitor the work programme of TC 229 to ensure that it supports the Roadmaps as approved by the TC; to address issues of internal coordination through recommendations to the appropriate committee structures; and to maintain the TC Business Plan; ii. **Nanotechnologies Liaison Coordination Group** to provide a forum to help coordinate and harmonise the work of relevant TCs and other organisations in the field of nanotechnologies and to identify cross-cutting gaps and opportunities and ways to address these; iii. **Nanotechnologies and Sustainability Task Group** to review the opportunities for nanotechnologies to address issues in the sustainability arena and to consider if and how standards might contribute to the successful implementation of these solutions for the benefit of mankind. iv. **Consumer and Societal Dimensions Task Group** to identify important issues in these fields and makes recommendations to TC 229 on topics including: (a) Priorities for standards development in the area of consumer and societal dimensions of nanotechnologies; (b) Promotion of TC 229 standards and informational outputs to end users and other relevant organizations in collaboration with appropriate partners, e.g., ISO COPOLCO, IEC, OECD, UNESCO; (c) Development of mechanisms for TC 229 to encourage and receive input from relevant consumer and other societal organizations; (d) Identification of topics in the area of consumer and societal dimensions of nanotechnologies for which it would be important for TC 229 to establish liaisons with other relevant standardization committees.
02.	Evaluating existing standards relevant to the field of nanotechnologies	Conduct comprehensive survey amongst relevant TCs and international and national standardization bodies: A survey was conducted in 2006 of the needs of members with a view to preparing a draft road map identifying and harmonizing priorities, and timescales for deliverables. The survey consisted of a structured questionnaire, with information sought on needs for: • Generic standards; • standards specific to particular materials or material types; • standards for test methods; • standards relevant to occupational and environmental health; • standards relevant to risk assessment and life cycle analysis; • other standards relevant to nanotechnologies. • performance-based standards for products and applications of nanotechnology This survey was repeated in 2011 and will be repeated periodically to ensure that changing needs are identified and addressed

03.	Construct and maintain roadmaps of standardization needs for each working group	Each WG to develop roadmaps with specific project timelines through to 2020 and beyond
04.	Collaborate with all relevant technical committees of ISO and IEC and other bodies to identify the best solution for standards development needs in the field of nanotechnologies	1. Formation of Joint Working Groups for work of mutual interest 2. Establish formal liaisons and appoint Liaison Officers for each TC and representatives at WG level
05.	Identify and prioritize areas needing research to support the development of standards	Conduct surveys. Liaise with organisations such as VAMAS (Versailles project on Advanced Materials and Standards), OECD, BIPM (International Bureau of Weights and Measures), national research bodies, etc.
06.	Work with national standards bodies to facilitate feedback and adoption of new nanotechnology standards by ISO members	1. Encourage national standards bodies to submit new work item proposals (NWIP) based on documents developed at the national level 2. Encourage national standards bodies to form mirror WGs to enable local experts to participate in providing input and contributions to projects under the respective WGs and facilitate feedback for ballots 3. Encourage national standards bodies to organize seminars to create awareness on the importance of developing nanotechnologies standards to assist the innovation process, to address the challenges in measurement at the nanoscale, and how they can help to address concerns over potential health and environmental impacts through the use of validated and standardised test methods and protocols to determine the hazards and risks posed by nanomaterials and nanotechnologies based products. 4. Encourage member bodies to uphold the principle of consensus by responding to ballots from a position of knowledge and to ensure that their responses reflect the views of their national experts. 5. Encourage and support members to ensure that their experts receive appropriate training in the principles and processes that govern the development of international standards.
07.	Promote awareness activities of TC 229 to industry, scientific communities and general public	1. Encourage member bodies to organize awareness seminars

6 FACTORS AFFECTING DELIVERY AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

The delivery of the TC 229 program depends on the willingness and availability of the various experts to participate. These people are extremely busy and the pace of development required for a rapidly expanding field such as nanotechnologies is placing considerable demands on their time. There is some evidence that the responsiveness at both the ISO and NSB level to activities such as ballots, draft preparation and review and attendance at meetings is a significant issue. In addition, the financial burden of attending frequent international meetings prevents, in some cases, an adequate national representation at TC 229 meetings. Joint Working Group meetings with the IEC also add to the number of meetings and the complexity of organisation. The TC will increasingly need to evaluate and, where appropriate, introduce alternative modes of working to ensure that its dynamic work programme is not jeopardised by human and financial resource limitations of its members. Several project and task groups already make use of tele- and web conferencing, which offer viable alternatives to face to face meetings. However, the global reach of the membership inevitably places some members at a time zone disadvantage during such conferences.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

7.1 Structure of the ISO committee

7.2 Publications and current projects of the ISO technical committee and its subcommittees