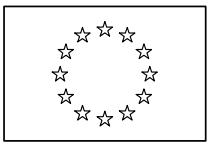

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

Directorate G - Industrial technologies

Standards and Standardisation

A practical guide for researchers

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Contents

1. Introduction

1.1 Purpose of the guide

This guide has been prepared for participants and prospective participants in European Framework and other research projects to help them identify, and make informed choices about, opportunities to use standardization for disseminating and/or implementing relevant outputs from their project. In addition to providing an overview of standards (sometimes referred to as 'documentary standards' to differentiate them from metrological standards) and the vital roles they play in modern society, the guide will help users:

- understand the requirements for, and processes involved in, the preparation of formal standards;
- identify outputs that might contribute to and benefit from the development of one or more standards;
- select the most appropriate standards deliverable for particular outputs;
- appreciate what is involved in the development and approval of their selected deliverable;
- identify suitable committees under which the project can be developed; and
- understand how, once published, the standard will be kept up to date.

This guide complements the 'Standards and Standardization Handbook' prepared by the same author and published by the Directorate-General for Research and Industrial Technologies in 2010[1].

1.2 Roles of standards in modern society

Voluntary, consensus based standards play a vital, though largely invisible role in national and international infrastructures, economies and trade. By providing agreed ways of naming, describing and specifying, measuring and testing, managing and reporting, standards provide:

- basic support for commercialisation, markets and market development;
- a recognised means for assuring quality, safety, interoperability and reliability of products, processes and services;
- a technical basis for procurement;
- technical support for appropriate regulation;

and can lead to variety and cost reduction through optimization and best practice.

There is no doubt that without standards the complex, technological world in which we live could not possibly operate. However, though standards are essentially ubiquitous, applying to virtually every aspect of our lives – from the highly innovative, e.g. internet protocols, to the mundane,

[1] Available from http://ec.europa.eu/research/industrial_technologies/pdf/handbook-standardisation_en.pdf

e.g. shoe sizes, and including aspects that even most people actively involved in standardization do not appreciate, e.g. 'Space systems -- Unmanned spacecraft -- Estimating the mass of remaining usable propellant' (ISO 23339:20101 - developed by ISO/TC 20/SC14 Aircraft and space vehicles - Space systems and operations), they are virtually invisible to the general public.

Whilst the majority of standards address technical issues, such as the composition, treatment and testing of steels for different applications, interconnectivity between different telephone and computer networks, and viscosity determination of lubricating oils, there has been an increasing recognition over the last few decades that voluntary, consensus based standards can contribute far more to business, and society in general, than simply technical specifications, testing methods, and measurement protocols. This recognition led to the development of generic management system standards, including the ISO 9000[2] series on quality management, the ISO 14000[3] series on environmental management and, most recently ISO 50001[4] on energy management. These, together with ISO 26000[5] on social responsibility and ISO 31000[6] on risk management, provide requirements for, or give guidance on, good management practices through either certifiable standards, such as ISO 90001 (implemented by over 1 million organisations in 176 countries) and ISO 14001 (implemented by nearly a quarter of a million organisations in 158 countries), or guidance documents, such as ISO 26000 and ISO 31000. These management standards can be applied to any organisation, from a multinational manufacturing or banking group to a small voluntary organisation**.** The tremendous impact of ISO 9001 and ISO 14001 on organizational practices and on trade has stimulated the development of other ISO standards and deliverables that adapt the generic management system approach to specific sectors or aspects, including, amongst others, education, food safety, information security, medical devices and ship recycling[7].

Of course ISO is not the only voluntary, consensus based standards organisation. However, its publications, extending to over 17000 standards, and current work in over 200 Technical Committees[8] does provide an excellent example of the breadth and depth of existing standards and standardization activities being undertaken for the benefit of business and society.

1.3 Who makes standards and why

Whilst standards are published by a large number and variety of both 'formal', i.e. National[9], Regional[10] and International[11], and 'informal', e.g. ASTM International[12], IEEE[13], SAE[14], SEMI[15],

[2] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/quality_management.htm
[3] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/environmental_management.htm
[4] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/specific-applications_energy.htm
[5] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/social_responsibility.htm
[6] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/risk_management.htm
[7] See http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/specific_applications.htm
[8] See http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees.htm

TAPPI[16], standards organisations, they all have one thing in common, which is that the standards published are selected and developed by stakeholders in the area and not by the organisations themselves. Thus it is the community of stakeholders comprising the membership of the standards organisation that decides what standards should be developed, what they should contain, and when and how they should be published, i.e. it is the communities that will most benefit from the existence of a standard that are ultimately responsible for its development.

As indicated below, the difference between formal and informal standards is in the representation of those involved in the development and approval processes. For formal standards (at least in terms of the formal approval processes), the processes operate through national representation, rather than through organisation or individual representation, as is the case for informal standards. Thus, even if sometimes experts drafting material are attending in their own right, it is the national body membership that approves or disapproves the resulting documents, whereas participation in and approval of informal standards is on an organisation and/or individual membership basis. However, in both cases the development and approval processes are based on the principle of consensus, i.e. 'general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments'. This definition of the term, from ISO/IEC Guide 2 (2004)[17], makes it clear that those responsible for a standard should take a proactive role in trying to engage with and address the views of all relevant interests, a process which is usually undertaken through formalised consultation.

1.4 Standards and regulations

Whilst regulations specify legally enforceable requirements, non-compliance with which may be subject to sanctions, standards are voluntary codes for which there are no legal obligations to comply. However, where there is clear deception regarding compliance with a standard, then civil action might be available to those, e.g. a customer, against whom the deception was perpetrated. Furthermore, as standards are often used as a means of demonstrating compliance with regulation, e.g. as with the 'new approach' Directives of the European Union[18], fraudulent claims of compliance with a relevant standard might result in criminal prosecution. In

[9] For a list of European National Standards Bodies together with their contact details see http://www.cen.eu/cen/Members/Pages/default.aspx
[10] The three European standards organisations are CEN (http://www.cen.eu/), CENELEC (http://www.cenelec.eu/) and ETSI (http://www.etsi.eu/)
[11] The three international standards organisations are ISO (http://www.iso.org/), IEC (http://www.iec.ch/) and ITU (http://www.itu.int/) .
[12] www.astm.org/
[13] http://standards.ieee.org/
[14] www.sae.org/standards/
[15] www.semi.org/standards
[16] www.tappi.org/Standards
[17] ISO/IEC Guide 2 (2004) Standardization and related activities -- General vocabulary
[18] See http://www.newapproach.org/

addition, whilst compliance with standards is notionally voluntary, in the case of litigation, failure to comply with an existing standard, compliance with which might have reduced or eliminated the impact of the occurrence which led to the prosecution, might be deemed as demonstrating negligence.

Whilst the content and structure of regulations are frequently subject to public consultation, at least in democratic jurisdictions/institutions, they are not necessarily the result of a democratic and consensual process, and there is still an obligation to comply, even for those individuals and organisations that do not agree with them. However, when an organisation agrees, voluntarily, to comply with a standard, it presumably does so because it considers the standard has legitimacy. That legitimacy is derived from the procedures used in the standards development and approval processes, in particular the active participation of those stakeholders likely to be impacted by publication of the standard, the use of consensus to agree and approve the content, especially the obligation, enshrined in the definition of consensus, 'to take into account the views of all parties concerned and to reconcile any conflicting arguments'. In addition, the fact that participation in standards making is almost invariably voluntary, and is therefore seen as altruistic rather than self-serving, also helps to support the notion of legitimacy.

1.5 Formal and informal standards

Standards are developed and published by many different groups and organisations using various degrees of consensus in their preparation and approval. **Formal** standards are standards that are approved or adopted by one of the **National**, **Regional** or **international** standards bodies, whilst **informal** standards are published by other Standards Development Organisations (SDOs), many of which are very well known and highly respected, e.g. ASTM International (previously the American Society for Testing Materials), IEEE (previously the Institute of Electrical and Electronic Engineers), SAE (Society of Automotive Engineers), SEMI **(**Semiconductor Equipment and Materials International) and TAPPI (formerly the Technical Association of the Pulp and Paper Industry). **Private** standards are developed for internal use by companies.

The core components of the formal standards infrastructure are the National Standards Bodies (NSBs). These are government recognised, though not necessarily government approved, bodies that have responsibility for publishing national standards. Whilst NSBs frequently facilitate the development of national standards through a Technical Committee (TC) structure, it is increasingly the case that the main role of national TCs is contributing to the development and approval of regional, e.g. CEN, and international, e.g. ISO, standards, which may then be adopted as national standards by their NSB. In the case of European standards, the national members of CEN have an obligation to adopt all ENs (full European standards) as national standards and to withdraw any conflicting national standards that are in their catalogue.

However, this is not the case for International Standards (IS), and even where a country has actively participated in the development and approval of an IS it is under no obligation to adopt it as a national standard. Additionally, national standards may also be developed by independent SDOs, although this normally requires them to be accredited by their NSB to ensure the development procedures satisfy certain minimum requirements (the US standardization system is based on this process).

Note that as far as Europe is concerned there are agreements between CEN and ISO (the Vienna Agreement) and CENELEC and IEC (the Dresden Agreement) which seek to avoid duplication of effort and under which (for example) a proportion (very high in CENELEC) of International Standards are adopted also as European Standards, usually without change.

The development of informal standards typically follows very similar procedures to those used for formal standards, with the main difference between the two being that development and approval is undertaken by the members of the SDO, acting either as individuals or representatives of their company or other organisation, rather than through a nationally constituted membership structure[19].

Whilst the development of informal standards might potentially offer advantages of flexibility, focus and speed of delivery, the formal standards process, as enshrined in the ISO/IEC Directives[20], which almost universally define the basic structures and processes for formal standards development, offers unrivalled rigour and transparency, if not to the outside world then certainly to those members involved in the work. In addition, technical committees developing formal standards, whilst having to comply with formal procedures also have significant autonomy with regards to project development procedures, and can avail themselves of a range of deliverables to satisfy different needs, as outline in the following section.

1.6 Types and examples of documents from formal standards bodies.

Standards fall into two general categories: *Normative* and *Informative.*

- Normative documents are those documents that contain *requirements* which must be met in order for claims of compliance with the standard to be certified;
- Informative documents, on the other hand, do not contain any *requirements* and it is therefore not possible for compliance claims to be certified.

Whilst the majority of standards are normative, they typically also contain informative elements, in the form of notes, examples, and informative annexes. However, to avoid the possibility of

[19] The third European Standards Organisation, ETSI, has such a structure but for its formal European Standards it also has engaged national bodies to carry our public enquiry and formal vote procedures

[20] http://www.iso.org/iso/standards_development/processes_and_procedures/iso_iec_directives_and_iso_supplement.htm

confusion or contradiction, informative elements, even in normative documents, cannot contain requirements, indicated by use of the word 'shall'.

In the case of standards published by ISO and CEN, informative documents are typically published as Technical Reports, not as full international or European Standards (IS or EN). Examples include[21]:

- ISO/TR 14969:2004 - Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003;
- ISO/TR 19961:2010 - Cranes -- Safety code on mobile cranes
- ISO/TR 15599:2002 - Digital codification of dental laboratory procedures
- CEN ISO/TR 13881:2011 - Petroleum and natural gas industries - Classification and conformity assessment of products, processes and services (ISO/TR 13881:2000)
- CEN ISO/TR 20881:2007 - Footwear - Performance requirements for components for footwear - Insoles (ISO/TR 20881:2007)
- CEN ISO/TR 17844:2004 - Welding - Comparison of standardised methods for the avoidance of cold cracks (ISO/TR 17844:2004)
- CEN/TR 10261:2008 - Iron and steel - Review of available methods of chemical analysis
- CEN/TR 16148:2011 - Head and neck impact, burn and noise injury criteria - A Guide for CEN helmet standards committees
- CEN/TR 14839:2004 - Wood preservatives - Determination of the preventive efficacy against wood destroying basidiomycetes fungi

Unlike other standards deliverables, Technical Reports are not subject to periodic ('systematic') review but can be withdrawn at anytime if they are considered no longer relevant.

There are also significant numbers of full international and European standards, primarily in the form of 'guidelines', which do not contain requirements. Examples include:

- ISO 24510:2007 - Activities relating to drinking water and wastewater services -- Guidelines for the assessment and for the improvement of the service to users
- ISO 14594:2003 - Microbeam analysis -- Electron probe microanalysis -- Guidelines for the determination of experimental parameters for wavelength dispersive spectroscopy
- ISO 10001:2007 - Quality management -- Customer satisfaction -- Guidelines for codes of conduct for organizations
- EN ISO 140-14:2004 - Acoustics - Measurement of sound insulation in buildings and of building elements - Part 14: Guidelines for special situations in the field (ISO 140-14:2004)

[21] A full listing of the more than 800 published ISO Technical Reports can be found at http://www.iso.org/iso/search.htm?qt=TR&searchSubmit=Search&sort=rel&type=simple&published=on and a full list of the more than 250 published CEN Technical Reports, including some CEN/ISO TR, can be found by searching for Technical Report under Document type at http://esearch.cen.eu/esearch/extendedsearch.aspx

- EN ISO 17776:2002 - Petroleum and natural gas industries - Offshore production installations - Guidelines on tools and techniques for hazard identification and risk assessment (ISO 17776:2000)
- EN ISO 11303:2008 - Corrosion of metals and alloys - Guidelines for selection of protection methods against atmospheric corrosion (ISO 11303:2002)
- EN 13625:2001 - Non-destructive testing - Leak test - Guide to the selection of instrumentation for the measurement of gas leakage
- EN 14412:2004 - Indoor air quality - Diffusive samplers for the determination of concentrations of gases and vapours - Guide for selection, use and maintenance
- EN 45510-6-6:1999 - Guide for procurement of power station equipment - Part 6-6: Turbine auxiliaries - Wet and wet/dry cooling towers

Normative documents are published as either Technical Specifications or full standards (IS or EN). Typical types of normative standards include 'measurement and test methods', e.g.

- ISO 12127-2:2007 Clothing for protection against heat and flame -- Determination of contact heat transmission through protective clothing or constituent materials -- Part 2: Test method using contact heat produced by dropping small cylinders
- ISO 14855-2:2007 - Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions -- Method by analysis of evolved carbon dioxide -- Part 2: Gravimetric measurement of carbon dioxide evolved in a laboratory-scale test
- ISO 13555-2:2003 - Diesel engines -- Procedure for checking the dynamic timing of diesel fuel injection equipment -- Part 2: Test method
- EN ISO 12156-1:2006 - Diesel fuel - Assessment of lubricity using the high-frequency reciprocating rig (HFRR) - Part 1: Test method (ISO 12156-1:2006)
- EN ISO 9455-13:1999 - Soft soldering fluxes - Test methods - Part 13: Determination of flux spattering (ISO 9455-13:1996)
- EN ISO 9241-307:2008 - Ergonomics of human-system interaction - Part 307: Analysis and compliance test methods for electronic visual displays (ISO 9241-307:2008)
- EN 1191:2000 - Windows and doors - Resistance to repeated opening and closing - Test method
- EN 14845-1:2007 - Test methods for fibres in concrete - Part 1: Reference concretes
- EN 772-19:2000 - Methods of test for masonry units - Part 19: Determination of moisture expansion of large horizontally perforated clay masonry units

'specifications', e.g.

- ISO/IEC 20970:2002 - Information technology -- Programming languages, their environments and system software interfaces -- JEFF file format
- SO 14961:2002 - Space data and information transfer systems -- Parameter value language specification

- ISO 8434-2:2007 - Metallic tube connections for fluid power and general use -- Part 2: 37 degree flared connectors
- EN ISO 13340:2001 - Transportable gas cylinders - Cylinder valves for non-refillable cylinders - Specification and prototype testing (ISO 13340:2001
- EN ISO 15614-7:2007 - Specification and qualification of welding procedures for metallic materials - Welding procedure test - Part 7: Overlay welding (ISO 15614-7:2007)
- EN ISO 9013:2002 - Thermal cutting - Classification of thermal cuts - Geometrical product specification and quality tolerances (ISO 9013:2002)
- EN 627:1995 - Specification for data logging and monitoring of lifts, escalators and passenger conveyors
- EN 12482-1:1998 Aluminium and aluminium alloys - Reroll stock for general applications - Part 1: Specifications for hot rolled reroll stock
- EN 442-1:1995 - Radiators and convectors - Part 1: Technical specifications and requirements

and ‘vocabularies’, e.g.

- ISO 8000-102:2009 - Data quality -- Part 102: Master data: Exchange of characteristic data: Vocabulary
- ISO 17066:2007 - Hydraulic tools – Vocabulary
- ISO 8640-1:2004 - Textile machinery and accessories -- Flat warp knitting machines -- Part 1: Vocabulary of basic structure and knitting elements
- EN ISO 8384:2001 - Ships and marine technology - Dredgers - Vocabulary (ISO 8384:2000)
- EN ISO 23953-1:2005 - Refrigerated display cabinets - Part 1: Vocabulary (ISO 23953-1:2005)
- EN ISO 13731:2001 - Ergonomics of the thermal environment - Vocabulary and symbols (ISO 13731:2001)
- EN 235:2001 - Wallcoverings - Vocabulary and symbols
- EN 14478:2005 - Railway applications - Braking - Generic vocabulary
- EN 1325-2:2004 - Value Management, Value Analysis, Functional Analysis vocabulary - Part 2: Value Management

As indicated in 1.2, ‘management standards’ can be either normative or informative. Examples include:

- ISO 10014:2006 - Quality management -- Guidelines for realizing financial and economic benefits
- ISO/IEC 9075-9:2008 - Information technology -- Database languages -- SQL -- Part 9: Management of External Data (SQL/MED)
- ISO 20828:2006 - Road vehicles -- Security certificate management

- EN ISO 27799:2008 - Health informatics - Information security management in health using ISO/IEC 27002 (ISO 27799:2008)
- EN ISO 20815:2010 - Petroleum, petrochemical and natural gas industries - Production assurance and reliability management (ISO 20815:2008, Corrected version 2009-06-15)
- EN ISO 11442:2006 - Technical product documentation - Document management (ISO 11442:2006)
- EN 15975-1:2011 - Security of drinking water supply - Guidelines for risk and crisis management - Part 1: Crisis management
- EN 13290-7:2001 - Space project management - General requirements - Part 7: Cost and schedule management
- EN 9131:2009 - Aerospace series - Quality management systems - Nonconformance documentation

Note that in addition to general management standards, some of which are indicated above, there are also 'management system standards, such as ISO 9000 - Quality Management, ISO - 14000 Environmental Management and ISO 51001 - Energy Management. The term 'Management system' refers to what an organization does to manage its processes, or activities, so that its products or services meet the objectives it has set itself, and Management System standards provide a model to follow in setting up and operating a management system. Specific examples of management system standards are:

- ISO 10012:2003 - Measurement management systems -- Requirements for measurement processes and measuring equipment
- ISO 14004:2004 - Environmental management systems -- General guidelines on principles, systems and support techniques
- ISO 50001:2011 - Energy management systems -- Requirements with guidance for use
- EN ISO 22000:2005 - Food safety management systems - Requirements for any organization in the food chain (ISO 22000:2005)
- EN ISO 9001:2008 - Quality management systems - Requirements (ISO 9001:2008)
- EN ISO 13485:2003 - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN 9100:2009 - Quality Management Systems - Requirements for Aviation, Space and Defense Organizations
- EN 9104-003:2010 - Aerospace series - Quality management systems - Part 003: Requirements for Aerospace Quality Management System (AQMS) Auditor Training and Qualification
- EN 9133:2004 - Aerospace series - Quality management systems - Qualification procedure for aerospace standard parts

Another deliverable in both CEN and ISO is the 'Workshop Agreement' (CEN Workshop Agreement - CWA - or International Workshop Agreement – IWA - respectively). Workshop Agreements are consensus documents developed as the output of a workshop, participation in which is open to all stakeholders. They are produced quickly to address specific market requirements in areas which are not the subject of more formal standardization undertaken within Technical Committees, and in this respect might be the ideal route for delivering a standard based on results from a research project[22]. Workshop Agreements have a limited lifespan (three years, with the possibility of one three year extension), at the end of which, or earlier if appropriate, they are either transformed into another type of standards deliverable, such as a Technical Specification or full standard, or withdrawn. The Workshop Agreement has been widely exploited by CEN (369 CWA published to October 2011) but much less widely by ISO (9 IWA published up to the same date). Specific examples are:

- CWA 16060:2009 - Environmental technology verification - Air emission abatement technologies
- CWA 16221:2010 - Vehicle security barriers - Performance requirements, test methods and guidance on application
- CWA 16335:2011 - Biosafety professional competence
- CWA 15965:2009 - Consumer confidence and nomenclature in the diamond industry
- CWA 15740:2008 - Risk-Based Inspection and Maintenance Procedures for European Industry (RIMAP)
- CWA 15375:2005 - Separators for marine residual fuel - Performance testing using specific test oil
- CWA 14641:2009 - Security Management System for Security Printing
- IWA 3:2005 - Image safety -- Reducing the incidence of undesirable biomedical effects caused by visual image sequences
- IWA 6:2008 - Guidelines for the management of drinking water utilities under crisis conditions
- IWA 8:2009 - Tableware, giftware, jewellery, luminaries -- Glass clarity -- Classification and test method

1.7 Standards as a means of disseminating and implementing the results of research

Standards are developed using a rigorous and robust process, which includes detailed peer review at different stages, in order to ensure that users can have confidence in the information, procedures, requirements and recommendations they contain. Standards are prepared so that individuals and organizations can apply the information contained for their own purposes.

[22] For further information about CEN Workshops and CEN Workshop Agreements see http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Pages/default.aspx

Therefore the information in a standard must be presented in a precise and unambiguous manner, making it clear to users what must be done in order to comply with the standard and what is optional. Standards are therefore first and foremost about applying the information contained for the benefit of the user, i.e. they specifically facilitate the dissemination and implementation of knowledge. The language used must be clear and unambiguous so that two or more people or organisations applying the same standard in the same situation would follow identical processes and, in the case of technical standards at least, come to the same result within a known margin of error. Thus the 'knowledge' in a standard is not only made available for those who wish to apply it but, in addition, the means of application is clearly explained in a language the user can understand and will not misinterpret. In this respect, standards differ from journal publications, which are specifically about knowledge dissemination and interpretation rather than knowledge dissemination and implementation.

Transferring the results of research into one or more standards could have a significant impact on the subsequent use of those results by industry and other researchers by making it clear not only what the results are but also how to implement them. Whilst not all research results can necessarily be transposed into standards, those that cannot might well provide valuable support to new or existing standards through, for example, the validation of test methods. Because standards development is done in cooperation with other experts in the field, the process of transferring research results into standards can often highlight issues that might not previously have been apparent. It will also ensure that, where necessary, due consideration is given to the validation of procedures and protocols and to establishing the trueness and precision of the results obtained.

2 Preparing for standardization

2.1 Recognising needs and opportunities for standardization

If, in the course of your research, you have found it necessary to develop a specific procedure or protocol to overcome a particular issue then it is possible, indeed likely that you have developed the basis of a standard. However, if you are simply using well established procedures to, for example, characterize a new material then it is unlikely that you have done anything to contribute to standardization. Of course, simply because you have developed a procedure or protocol does not necessarily mean that it has not already been developed and published as a standard; thus it is always wise to undertake a review of existing standards applicable to a particular area before embarking on a project. Simply because information about standards does not exist in the relevant academic literature does not mean they do not exist – there is a significant gulf between the academic and 'standardization' communities and it is quite feasible that many academics in a particular field are entirely ignorant of the standards relevant to it. However, given the availability and flexibility of internet search engines, it should be relatively easy to identify those standards relevant to a particular subject, though the detail contained in them can frequently only be established by consulting the original documents. This can often be done 'on-line' or by consulting library sources, but if these are not available then purchasing standards to find out what they contain can be a relatively expensive business.

2.2 Research results appropriate for standardization

To be suitable for providing the basis of a standard, a research output needs to be applicable to and have utility for one or more established groups of stakeholders – researchers, industry and/or regulators; it should have been evaluated by a number of independent organizations; and it should not require the use of equipment, software or other utilities which are available from only one, commercial organisation. Having said this, if the use of proprietary equipment or other resources allows particularly intractable issues of broad relevance to be addressed then there is nothing specifically prohibiting reference to such in a standard, although for inclusion in formal standards there is usually a requirement for an agreement to be concluded on general accessibility before the standard can be published.

Whilst it is not the intention of this guide to provide a comprehensive list of outputs that might be suitable for standardization, if, in the course of your project, you have developed a repeatable technique or procedure for preparation, characterization, identification, manipulation, verification, etc. or if you have modified an existing technique or procedure to allow its use at a different length scale or under an extended range of conditions, then it is likely that the output could provide the basis for a standard. Research outputs that are not suitable for standardization are, for example: data that is applicable to a particular system (though such data might provide the

basis for a case study or example for inclusion in a standard); or methods, processes or protocols that are dependent on the use of patented equipment, unless there are no alternatives[23]; methods, processes or protocols that you are currently trying to patent; and methods, processes or protocols that have not been validated or for which there is no interest in the stakeholder community.

2.3 Standards versus patents – which option and why?

The purpose of a standard is to provide a uniform approach to doing something through an open access, though not necessarily free to access, platform. Standards are developed for the general good of stakeholders and should not support the commercial or other interests of a single organization. The adoption of standards should support efficiency and overall cost reduction through competition whilst ensuring product quality, interoperability, safety and reliability. Standards represent agreement (consensus) between experts about the best way of doing something. They do not require an inventive step; rather they document 'good practice'.

Through their promotion of a single way of doing something, it is often suggested that standards inhibit innovation. However, it is clear that standards actually support innovation in many different areas by relieving innovators of the need to make decisions on what are often quite trivial matters, allowing them to concentrate on the essential essence of their innovation. In addition, as compliance with standards is, in most cases, not a legal requirement, innovators are free to make use of standards or not, as they see fit, and if their ideas are demonstrably superior to those contained in a standard then it is likely that businesses will adopt them, though it has to be recognised that the superiority of a product, process or service is only one factor in its adoption by 'the market'.

There is no charge for applying a standard, other than the cost of acquiring the document, though there might be costs associated with compliance. The cost of developing a standard is relatively low for the individual participants, being mainly the cost of attending and taking part in meetings, though there might also be fees for membership of the relevant SDO or national TC, which need to be factored in.

Patents, on the other hand, are designed to protect the intellectual property of an inventor and to limit the scope of competitors to gain access to the market for products or services based on that invention. If someone other than the patent holder wishes to make use of the invention they would normally need to pay a licence fee, the value of which would be the subject of negotiation between the parties. The cost of obtaining, maintaining and possibly defending a patent can be

[23] It should be noted that whilst it is not common practice to develop and publish standards which can only be implemented through the use of third party intellectual property, including patents, there is no general prohibition on this. However, the International and European standards organisations have a common policy regarding recommendations/deliverables that require licences for Patents to be practiced or implemented, fully or partly, guidelines for the implementation of which are given in Annex 1 of the ISO/IEC Directive, part 1 – see http://isotc.iso.org/livelink/livelink?func=ll&objId=4230455&objAction=browse&sort=subtype

considerable and a clear commercial benefit should be identified, either from direct exploitation, licensing or selling to another organisation, before embarking on acquiring patent protection.

Which option? Because patents require an inventive step, the first thing to determine is whether or not the output under consideration is based on a clearly identifiable 'inventive step' (something that is not obvious to 'those skilled in the art', i.e. something that another expert would not do as a matter of course as a consequence of their training). If such a step can be identified and it is considered that the financial benefits of protecting the invention significantly outweigh the costs of protecting it then it clearly makes sense to adopt the patenting route (note that the costs of protecting the intellectual property are not only those of the initial patent filing together with associated costs, but also the potential costs of protecting the rights that are assigned in any of the territories where protection has been granted, together with the cost of surveillance in those territories to ensure that the patent rights are not being violated. Additionally, it should not be forgotten that in countries where it is not protected, others will be free to exploit the invention, though they would not be allowed to export products based on the invention into countries where it is protected. However, in cases where there is no clear inventive step or where the inventive step is not deemed to have sufficient commercial potential to make the costs of patenting and patent protection viable, then the standardization route could be considered.

As indicated elsewhere in this guide, before a full standard can be approved it is necessary to have completed all pre-normative and co-normative research – PNR and CNR. As its name implies, pre-normative research is the research carried out to establish the validity and reliability of the subject matter to be standardized, whilst co-normative research is the research that is necessary to quantify the repeatability, reproducibility and uncertainty of the procedures that are incorporated in the standard. For other types of normative documents, Technical Specifications, Publicly Available Specifications and Workshop Agreements, which are used to promote a common approach to subject matter that itself is under development and to evaluate the utility, as well as the repeatability, reliability and uncertainty, of the procedures, the published document provides the basis for CNR by providing procedures for undertaking inter-laboratory comparisons and other investigations to evaluate the statistical bases of the method.

2.4 What is needed before starting? Verification and validation.

Before deciding to embark on a standardization project for a particular research output, it is essential that the results on which the standard will be based are reproducible and repeatable, i.e. give the same results, within statistical error, when repeated by a single user and by multiple users. This does not mean that a full uncertainty budget should have been established but that there must be a high degree of confidence that the procedures to be standardized can be validated and the results obtained can be verified. Without such PNR there is little point in

proposing the development of a standard, which is essentially a paper exercise, were the scope of application is carefully evaluated, what is not covered is equally carefully defined, the procedures to be incorporated are carefully scrutinized by other experts to ensure that they are appropriate and cannot be misinterpreted, the terms and symbols used are accurately defined, any 'normative references', i.e. other standards that are critical to the application and operation of the new standard are identified, all statements are appropriately justified, normative and informative elements are differentiate, requirements for compliance with the standard are clearly stated, etc.

2.5 Which type of standard deliverable?

In the case of European and international standards there are a number of different deliverables, depending on the maturity of the particular topic and the level of consensus that can be achieved. The deliverables for topics with the highest level of maturity are European Norms (EN) and International Standards (IS), both of which require a high degree of consensus, preferably unanimity, amongst the National Standards Bodies, and their experts, taking part in the development and approval processes. An IS is approved if, after voting amongst all members of ISO, at least a two-thirds majority of the votes cast by the P-members of the technical committee or subcommittee that developed the document are in favour, and not more than one-quarter of the total number of votes cast are negative. For EN, the situation is somewhat different because of the special status of these documents amongst the membership of CEN, i.e. when an EN is approved it must be implemented by all members of CEN and any conflicting National standards must be withdrawn. For approval of EN, weighted voting is used whereby the largest economies have the largest number of votes. EN are approved if at least 71% of weighted votes are in favour (abstentions are not counted). EN and IS are subject to review every five years (IS are first reviewed three years after publication then every five years thereafter) to ensure that they continue to be relevant and accurate. If they cease to be relevant they may be withdrawn at any time. Both IS and EN take typically 3 – 4 years from proposal to publication.

For topics that are still under development or which have not reached a sufficient state of maturity for the development of an IS or EN, there are three possible deliverables in ISO and two in CEN. These are international Technical Specifications (TS), international Publicly Available Specifications (PAS) and international Workshop Agreements (IWA). In CEN there is no equivalent to the Publicly Available Specification but there are equivalents to the other two, designated as CEN TS and CWA (CEN Workshop Agreement[24]). In both organisations, Technical Specifications are expected ultimately to become full standards, hence the approval criteria are similar to those for IS and EN, with the main difference being that, for international

[24] http://www.cen.eu/cen/Products/CWA/Pages/default.aspx

TS, voting only takes place amongst the 'P' members of the committee that developed the document. Like IS and EN, TS typically contain requirements that must be satisfied in order to demonstrate compliance. Unlike EN, there is no compulsion on members of CEN to implement CEN TS or to delete conflicting national standards. TS would typically be developed to make standardized procedures available for evaluation by a wide group of stakeholders in the expectation that the knowledge and experience gained will be incorporated into a full standard in due course. TS are subject to systematic review every three years but there is currently no limit on their over all life.

PAS are similar to TS but for subject matter that is at an even earlier stage of development. They are usually developed in a relatively short time frame, less than 12 months, and act as an early stage deliverable to encourage a move towards more formal standardization. For approval, PAS require a simple majority of votes cast by the 'P' members of the committee responsible for their development. PAS remain valid for an initial maximum period of 3 years, which may be extended for a single 3-year period, following which they must be revised to become another type of normative document, or be withdrawn.

Workshop Agreements are documents developed within the context of a Workshop in which market players and other stakeholders directly participate. They do not go through a national delegation as with other deliverables in both CEN and ISO, but in CEN's case they may be submitted to on-line public comment.. Workshop agreements are typically developed in a timeframe 10 - 12 months. They are ideal as fast deliverables for emerging areas – often linked to research and innovation - for which there is no relevant technical committee and they provide a document that can ultimately become a European or international standard.

There is one other deliverable available from both CEN and ISO and that is the Technical Report (TR), an informative document that does not contain any requirements and to which compliance cannot be demonstrated. TR are usually prepared to provide background to a technical area or to assist with the application or interpretation of a full standard, e.g. ISO/TR 14969 Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003. For publication, TR require the support of a simple majority of the P-members of the technical committee responsible for its development.

2.6 Under which standards organisation should a standard be developed?

Whilst the matter of which standards organisation should develop a particular standard might seem a somewhat academic question, selecting the right organisation can have important repercussions for those involved in the development of the document. There is also a need to consider the geographical spread of stakeholders likely to be impacted. In this respect the CEN and CENELEC Management Centre in Brussels can be a source of information and support

when choosing the right Standards Organization. A dedicated Research Helpdesk with links to all National Members, ETSI and ISO can provide tailored advice to identify the right standards activity and right standardization partner[25].

Obviously if the primary interest lies within Europe then it makes sense to develop a CEN document, whereas if there is broader international interest, then an ISO document clearly makes more sense. However, if the interest mainly resides in one country then it does not make sense to try to develop either a European on an international standard where a national standard would be most appropriate. Assuming that the options are ISO or CEN, then the criteria to consider are:

- Is there an existing technical committee whose scope encompasses the topic to be standardized? Whilst there are well over 200 technical committees in ISO and nearly 400 in CEN, for those where scopes appear to overlap, the principal work is frequently done in the ISO committees, whilst the CEN committee exists primarily to monitor the work in ISO and to adopt standards that it considers have special relevance to European stakeholders. In other cases where CEN and ISO committees appear to work in similar areas, the focus might be quite different. For example, ISO/TC 147 ‘Water Quality’ and CEN/TC 164 ‘Water Supply’ have complementary work programmes, with the former focusing on sampling and test methods for the determination of the levels of chemical, biological and radiological contaminants in water, and the latter concentrating on standardization of chemicals and products that come into contact with drinking water. As a support to the integration of standardization into European research or similar projects (EU Commission or Eureka), CEN authorizes the CEN Technical Committees to conclude 'Project Liaisons'[26] with FP7 projects, allowing a liaison representative to participate in Technical Committees and relevant Working Group meetings as an observer, without decision making power, upon condition that:
    - The project in question is a bona fide European research or similar project (EU Commission or EUREKA)
    - The project liaison applies for the duration of the project
    - The project signs an undertaking accepting CEN's exploitation rights policy and agreeing that no information brought to the project's attention will be disseminated or exploited in any form.
- Whilst both organisations use essentially identical procedures for standards development, ISO Technical Committees can meet almost anywhere in the world whereas CEN Technical Committees invariably meet in Europe. Thus choosing to work through an ISO committee might have significant travel cost and time implications, and whilst it is not essential to attend

[25] www;cen.eu/go/research

meetings of the project group developing a standard, it is certainly very helpful as so much more can be achieved in a face-to-face meeting than in a tele or web conference. Also, if you are the project leader then you really do need to be present at project group meetings if you are to manage the process effectively;

- In certain key areas, the European Commission has mandated the development of standards, mainly to provide a basis for safety testing of products but also in other areas such as supporting an emerging area of technology. Such mandates may provide financial support for the development of European standards, which can only be accessed through a European Technical Committee. The European Commission does not provide financial support for the development of international standards to satisfy the requirements of a mandate.

2.7 Joint working between committees and between standards organisations.

Where two Technical Committees within the same standards organisation have a common interest in a particular project to which both can make a meaningful contribution, then it is possible for the project to be developed in a joint working group to which experts from both committees are appointed. However, if the two committees are in different standards organisations, e.g. CEN and ISO, then more formal cooperation mechanisms are required. In the case of CEN and ISO, a formal agreement on cooperative working, known as the Vienna Agreement[27], has been established whereby the relevant technical committee in one or the other organisation takes the lead, by agreement, and the other technical committee contributes by nominating up to a specified number of experts to represent the interests of its members. The second committee also agrees not to work separately on the subject matter of the project ('standstill'). Once consensus has been reached amongst the experts from the two committees the document is balloted in both and will only become a joint publication if it is approved by both the ISO TC and the membership of CEN, for a TR or TS, or by both organisations, for an EN/IS. A similar agreement, the Dresden Agreement[28], exists between the IEC and CENELEC.

The development of a joint project under the Vienna Agreement is not the only way to achieve an identical document in both CEN and ISO. Another way is for an existing International Standard to be confirmed as a European Norm using the so-called Unique Acceptance

[26] see http://www.cen.eu/cen/Services/Innovation/WhyStandards/IntegratingStandards/Pages/ProjectLiaison.aspx
[27] see http://www.iso.org/iso/standards_development/processes_and_procedures/cooperation_with_cen.htm
[28] see http://iec.ch/about/globalreach/partners/regional/iec_cenelec_agreement.htm

Procedure[29], a procedure that essentially allows the 'fast tracking' of a reference document from another organisation as a CEN deliverable.

2.8 Standardization project characterization template

To help with the identification of project outputs that are suitable for standardization, a 'standardization project characterization template' – see Annex A – has been produced. This template will also help projects understand the various stages that are entailed in taking a particular output to a published standard and enable them to monitor progress towards their particular goal.

2.9 The new work item proposal and approval processes

Before a standardization project, other than a Workshop Agreement, can be implemented in either CEN or ISO it is necessary for a New Work Item Proposal (NWIP) to be approved by the members of the relevant committee. Whilst NWIPs can, in principle, be submitted by a number of different interest groups, including liaisons, the secretariat of the relevant committee, and by the management board of the standards organisation, the usual originators of NWIPs are the national member bodies (NMB) that actively participate in the work of the committee. Thus if you decide that a particular output is suitable for standardization, then you will first need to identify the Technical Committee within which the project can be developed. Having done this, you will need to approach the relevant 'mirror' committee of an appropriate NMB and persuade it to support the proposed standard and to submit a NWIP for it. Submitting a NWIP requires the NMB to commit to making resources available during its development, if approved, hence it will need to be convinced of the need for such a standard. Thus it would probably be best if the country chosen to submit the proposal had made a major contribution to the particular output or had a significant involvement in it.

For ISO projects, the NWIP must be submitted on a 'Form 4', shown in Annex B.1, whilst proposals for new projects in CEN are submitted on 'Form A', shown in Annex B.2. These forms detail the information that is required before a proposal will be assessed by the members of the committee to which it is directed. Whilst the chair and secretary of the national mirror committee submitting the proposal will normally assist with the completion of the form, it is possible that neither they nor any member of their committee will be experts in the specific subject matter of the proposal, hence one of the first tasks might well be to convince these national 'stakeholders' of the need for a standard on this subject. As the NWIP must contain a well argued 'purpose and justification' in order to be accepted by the members of the relevant committee, it would be sensible to have some strong arguments prepared before introducing the subject to the relevant NMB mirror committee. In addition to the more technical elements of the proposal, it is a

[29] see http://www.cen.eu/boss/Production/Production%20processes%20-%20Index/UAP/Pages/default.aspx#1

requirement of the ISO process, and clearly highly desirable for the CEN process, that an individual will be identified to lead the project if it is approved. This person would normally be a national of the country submitting the NWIP, and clearly it makes sense that they should have been closely involved in the research work that resulted in the proposal. As indicated elsewhere in this guide, the amount of work involved in leading the development of a standard is typically a few days, perhaps 15 - 20, depending on the type of deliverable and the complexity of the proposed standard. The amount of work will also depend on the quality of the research on which the document is to be based; the more detailed and thorough the research the smaller the amount of time that is likely to be required. One thing to be kept in mind is that, whilst the total time might be relatively small, taking on the responsibility for leading a standardization project is a reasonably long term commitment, as the leader will be involved throughout the whole process, from NWIP to finalising the document prior to publication, a process which typically takes 2 to 3 years.

NWIP are approved in an ISO TC if, following a three month ballot of members, at least 50% of the 'P' members voting support the proposal and 5 or more agree to participate in the project's development (note that it is only the 'P' members of the committee that have a vote, though other members, e.g. liaisons, can nominate experts to work on the project). Whilst this is the formal ISO procedure (the NWIP submission and approval are somewhat different in CEN[30], although the overall process is similar to that in ISO), different TC might have agreed different procedures for dealing with NWIPs prior to their formal ballot. For example, ISO/TC 229 – Nanotechnologies encourages members considering submitting a NWIP to first discuss it with the convenor of the relevant working group to ensure that it is consistent with both the working group and TC road maps and then, once a proposal has been prepared, the proposer is invited to submit it to the 'Task Group on Planning and Coordination' for a three week review, which will make appropriate recommendations to help ensure the success of the proposal, e.g. by strengthening the justification/market relevance, highlighting the need for supporting work, highlighting links to other work in the committee or other TCs, etc. Following further modification, if necessary, the NWIP is submitted for the formal three month ballot.

[30] see http://www.cen.eu/boss/Production/Proposal%20for%20new%20work/Pages/default.aspx

3 The standards development process

3.1 The ISO/IEC Directives and CEN/CENELEC Internal Regulations

The rules governing the structure and drafting of International Standards are given in the ISO/IEC Directives Part 2 Rules for the structure and drafting of International Standards[31]. This document, which may be downloaded from the link, complements Part 1 of the directives Procedures for the technical work[32].

The development of European standards within CEN and CENELEC follows very similar procedures and is governed by the CEN/CENELEC Internal Regulations[33].

3.2 The standards development substructure

Whilst the development of a particular standard is almost invariably the responsibility of a single Technical Committee[34], the actual work of developing the 'final working draft' is assigned to either a subcommittee (SC) or a working group (WG) of the parent committee. Subcommittees are established where the scope of a committee is such that there is a significant amount of relatively unrelated work being undertaken, the management of which can be better achieved through separate, semi-autonomous sub-committees. Like Technical Committees, Sub-Committees take their own decisions, such as approving New Work Item Proposals, approving Committee Drafts, establishing and disbanding Working Groups, etc, and, like TCs, each SC has its own chairman and secretary, together with a number of Working Groups in which related work items are developed. However, whilst a sub-committee structure can facilitate the management of a wide and diverse work programme, it is now recognised that it is usually better to divide the work amongst different Technical Committees rather than trying to maintain a very broad programme of work in one Technical Committee by establishing what are, to all intents and purposes smaller Technical Committees within it.

The drafting of standards takes place in project groups (PG), which are now almost invariably grouped into Working Groups that have responsibility for a particular aspect of the work of the TC or SC. For example, ISO/TC 229 – Nanotechnologies – has four working groups: terminology and nomenclature; measurement and characterization; health, safety and the environmental; and materials specifications, together dealing with perhaps 20 – 30 projects at any one time. Working Groups are led by a Convenor, sometimes but not always supported by a secretary, whose responsibility it is to manage the work assigned to the WG. As a subordinate group within a TC, WGs do not have decision making powers, though they are able to make

[31] See http://isotc.iso.org/livelink/livelink?func=ll&objId=4230456&objAction=browse&sort=subtype
[32] See http://isotc.iso.org/livelink/livelink?func=ll&objId=4230455&objAction=browse&sort=subtype
[33] See http://www.cen.eu/boss/supporting/Reference%20documents/Internalregulations/Pages/default.aspx

[34] Note that the development of Workshop Agreements does not follow the procedures described here. For further details see http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Pages/default.aspx

recommendations on technical and organisational matters to their parent TC or SC. In the past, it was not uncommon for a new WG to be established each time a New Work Item Proposal was approved, which led to large numbers of working groups, each with their own convenor and WG members, resulting in some challenging management issues for TC Chairmen and Secretaries. However, it is now more common for working groups to deal with all projects in a particular subject area within the scope of the TC.

Besides establishing PGs, WGs and perhaps SCs, a TC can also establish other groups, such as Task Groups (TGs) and Study Groups (SGs) to address specific issues. TGs and SGs do not develop standards but prepare recommendations on the issues they have been asked to address. Both are disbanded once their work has been completed.

A typical committee structure is shown in the diagram below.

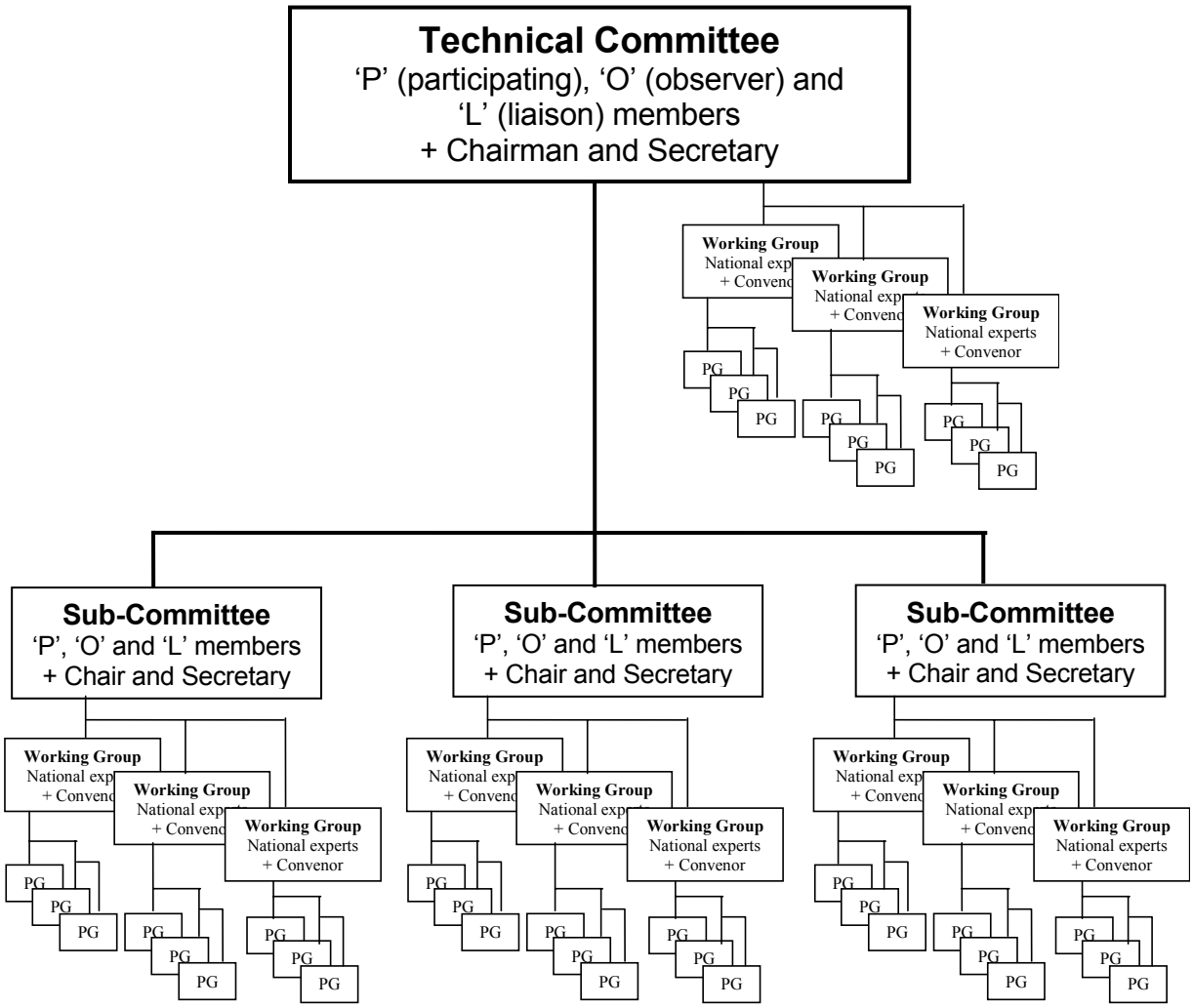

Fig 1. Diagram showing typical structure of a standardization Technical Committee

3.3 The role of experts, commitment required, and the role of consensus

As indicated in 2.8, approval of a New Work Item Proposal requires the support of a majority of members voting in the committee considering it (abstentions are not counted), together with a certain minimum number of members (5 in the case of ISO) agreeing to contribute to its development. Members demonstrate their willingness to contribute by nominating one or more experts to participate in the project group responsible for the particular work item. Although experts are nominated by their NMB, i.e. the members of the committee, they serve on the project group as experts in the particular subject under discussion and not as national representatives or representatives of their employers.

The role of the experts is to take the draft that is submitted by the proposer and, with the aid of the New Work Item Proposal and any comments submitted by NMB during the New Work Item Proposal ballot, develop a consensus document that satisfies the objectives of the proposal and the formatting and other requirements of the standardization body that will ultimately publish the standard. The work of the project group, which typically takes around 12 months to complete, though it might be significantly longer in some cases, is usually undertaken in both face-to-face meetings and by correspondence. The process is led by the Project Leader (PL) nominated by the proposer, and whilst some countries provide secretarial support to PLs, in most cases it is the responsibility of the individual to ensure compliance with the process laid out in the directives of the relevant standards body. To assist with understanding and applying the procedural requirements for project development in CEN/CENELEC and ISO/IEC, many NMB provide training for PLs and experts in the processes used in these standards organisations. Information is also available on the web sites of different standards bodies[35]. In addition, some Technical Committees also provide guidance for PLs and PG members (e.g. ISO/TC 229 sends PLs and experts appointed to all new projects the welcome letter and guidance notes shown in Annex D). However, it is the responsibility of both the PL and the PG members themselves, under the watchful eye of the WG convenor, to ensure the effectiveness of the process, and the quality of the final outcome – the Final Working Draft (FWD) - will critically depend upon the level of commitment of all involved.

Whilst progress can be significantly faster and more effective in face-to-face meetings, depending on the particular forum it might not be possible to have all of the nominated experts present at such meetings, and without careful organisation, the views of some experts might not be taken into account during such meetings. Whilst there are guidelines for addressing this particular issues, e.g. documents for discussion at project group meetings should be distributed at least two weeks in advance to allow experts unable to attend to brief someone else in their

[35] see, for example: http://www.iso.org/iso/my_iso_job.pdf and the 'New to standards?' tab at http://www.cen.eu/cen/Pages/default.aspx

delegation to speak on their behalf, to prepare written comments, or to participate via telephone of web based conferencing, such measures can only be effective if all members of the PG abide by the guidelines and take full advantage of the opportunities offered.

Although face-to-face meetings offer an excellent opportunity to make fast and effective progress, it is invariably the case that much, if not most of the project development will take place via correspondence, as this gives experts the opportunity to reflect fully, possibly in discussion with peers, on specific issues, and to respond at their leisure. In addition to 'correspondence', i.e. e-mails, many committees now also use alternative means of 'meeting', such as telephone and web conferencing. Whilst such 'remote' meetings should also be considered as part of the 'mix' for project development, when using these alternatives it is important to give careful consideration to the geographical spread and range of language skills of the experts involved. For example, for an ISO committee working in English and with experts from the Americas, Europe and Asia, a 'remote' meeting which is convenient to the experts in one region might be very inconvenient, e.g. take place in the middle of the night, for those in another, whilst for some experts, if not most, operating in a language which is not their mother tongue will be an additional burden. Project leaders therefore need to ensure that where 'remote' meetings are used for project development, such meetings are carefully planned, with clear objectives, a limited scope, and a clearly defined time slot. Documents, including agendas and documents for comment, for both face-to-face and 'remote' meetings, should always be distributed well in advance – two weeks as a minimum – to allow participants to prepare properly.

It is very important to document all decisions reached during meetings in order to avoid going over the same ground again and again. Such records are particularly important for face-to-face meetings at which substitute experts are in attendance or where comments from observers are permitted. Although, in an ideal world, only nominated experts should participate during project meetings, in practice this is not always possible and often other experts, or individuals who believe they are experts, will also be present (this is particularly the case for project meetings associated with 'plenary' meetings of the committee, where most if not all of the active project groups meet). In such circumstances, PLs might need to be forceful in their insistence that elements already agreed by the nominated experts are not re-opened for discussion by someone who has not been nominated to the project, and having a clear record of previous decisions can help to avoid difficult confrontations.

As stated above, the role of the PG is to develop a consensus document that satisfies the objectives of the proposal, as modified by the TC as a consequence of the NWIP ballot, and the formatting and other requirements of the standardization body that will ultimately publish the standard. They do this via a series of Working Drafts (WD) using an iterative process that leads to a Final Working Draft (FWD) that meets the objectives of the proposal and that everyone

involved in the PG finds acceptable. At each stage, if any of the nominated experts is strongly opposed to the document then it is the responsibility of the PL to try to resolve the differences between experts, whilst maintaining a focus on the technical accuracy and robustness of the draft under development. Whilst recognising that 'consensus' does not necessarily imply unanimity, it does require that there is no sustained opposition to any part of the document by any of the experts involved in its development, and in the extreme it might be necessary to inform the committee that it has not been possible to reach consensus and that the project should be abandoned. However, this rarely occurs and it is usually possible to reach consensus, even on quite difficult issues, by judicious editing or omission of contentious sections. Ultimately though, the quality of a document will depend upon the active participation of all of the experts nominated to the project, and where experts continually fail to contribute it is the responsibility of the PL, through the convenor of the relevant WG, to ensure that the nominating body is made aware of this, preferably in a communication from the committee secretary or chair, so that it can deal with the situation, either by speaking directly to the recalcitrant expert or replacing them with a new one.

3.4 Elements of a standard

3.4.1 Normative and informative elements

Whilst complying with a standard is usually a voluntary decision, there are typically things that must be done once a decision to comply has been taken. All of the things that must be done in order to comply with a standard are referred to as 'normative' requirements and are signified by the use of the word 'shall'. For example, where a particular measurement technique must be used, the text would say something like 'the measurement shall be made in accordance with …'. Where compliance with something in the standard is optional or where the use of alternative methods is acceptable, then this is usually signified by use of the word 'may'. For example, 'measure x using the method described in ISO YYYY. Note - alternative methods providing equivalent accuracy may be used.' It should be noted however that where doing something in a standard is optional then it cannot be a normative requirement, but a normative requirement might allow for the use of alternatives.

Besides normative elements, standards almost always also contain 'informative' elements, i.e. elements that provide information. Informative elements are usually included in the form of 'notes', 'examples' or 'informative annexes'. It should be noted that informative elements may not contain requirements, i.e., they may not use the word 'shall'.

Whilst most standards documents contain both normative and informative elements, some documents are purely informative. Such documents are usually published as Technical Reports - but see 1.6.

3.4.2 Structural elements

Because standards cover such a diversity of subjects and standardization needs – see 1.3 'Who makes standards and why' - there is no one structure that covers all standards. However, all standards will have the following elements, which will be specific to each document:

- A unique number which includes the source of the document and/or its status, together with the year of approval, e.g. ISO 9001:2008, EN ISO 13485:2003, EN 1071-3:2003, ISO TS 80004-1:2010, CWA 14243:2002.
- Title – this usually consists of up to three elements
    - an introductory element giving the general field to which the document belongs – often the title of the committee responsible for the document;
    - a main element indicating the principal subject of the document;
    - a complementary element giving the specific aspect of the main element that the document addresses

  Whilst being succinct, the title should be sufficient to distinguish the document from others in the same general field.

  For example: 'Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test'
- Scope - This defines the subject of the document and the aspects covered, and should indicate any limits of applicability of the document or of particular parts of it. It should reflect the title and the title should reflect the scope. It is important to agree the scope early in the development of the project so that all experts are fully aware of what it is they are trying to develop, what is and is not covered and who the target audience is.
  For example, the scope of ISO 9001:2008 – Quality management systems – Requirements is a follows:
  '1 Scope
  1.1 General
  This International Standard specifies requirements for a quality management system where an organization
  a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
  b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
  NOTE 1 In this International Standard, the term "product" only applies to
  a) product intended for, or required by, a customer,
  b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.'

The majority of technical standards likely to result from research projects will also have the following elements:

- Normative references – this lists other standards that form, or parts of which form, an integral part of the document and without reference to which it is impossible to comply with the standard. The need for a normative reference would be indicated by, for example, a statement such as 'determine property x in accordance with ISO YYYY'. Standards that are referred to in the document but to which compliance in whole or part is not a requirement of the document are not Normative references and should be listed in the bibliography.
- Terms and Definitions – this is a list of all non-standard technical terms used in the document together with their definitions. Alternatively reference may be made to other documents in which the terms are defined, e.g. by a phrase such as 'terms used in this document are defined in…..' Where reference is made to other standards containing the relevant definitions, then these standards should be listed as Normative references
- Symbols and abbreviations – this should list the meaning of all symbols and abbreviations used in the document. They should also be defined the first time they are used. Such a list is very important for ready reference when large numbers of symbols and/or abbreviations are used. Preparing such a list can also help to ensure that the same symbol is not used for two different things.
- Apparatus – this provides a generic description of the apparatus to be used, including range, sensitivity, operational limits, e.g., temperature, pressure, etc., where appropriate.
- Procedure – written in the 'imperative' form (do this, do that) not the 'narrative' form (this is done, that is done), making it clear what is mandatory in order to comply with the standard (by use of the word 'shall'), what is strongly recommended (by use of the word 'should'), what is optional (by use of the word 'may') and what must not be done (by use of the words 'shall not')

- Data analysis – explaining how the results are calculated from the measurements made and including statistical analysis, together with sources and treatment of errors.
- Reporting of results – listing what shall be reported and what should also be reported.
- Annexes – these provide additional detail that is not appropriate for the body of the standard, for example, because its inclusion would divert attention from the primary purpose of the document or because it provides supplementary information that is not essential to the application of the standard. An annex may be normative, containing requirements that must be met in order to comply with the standard, or informative. Informative annexes shall not contain requirements. The status of an annex is given both in the 'contents' and also immediately under the heading at the start of the annex.
- Bibliography – this lists all of the documents referred to in the text, which are typically numbered in the order in which they appear. Standards are normally listed separately from other sources. Normative references are not listed in the bibliography.

A standard may also contain an introduction giving specific information or commentary about the technical content of the document, and about the reasons for its preparation. Introductions are informative and shall not contain requirements.

Further details regarding the form and content of the elements comprising a standard are given in the ISO/IEC Directives Part 2[31].

3.4.3 Words with specific meaning in a standard

A few words that are in common usage have rather precise meanings when used in a standard and it is important that those involved in the development, review and application of standards understand what these meanings are and use the terms appropriately. These words are shown below (with their opposites in parentheses):

- 'shall' ('shall not') indicating a requirement;
- 'should' ('should not') indicating a recommendation but not an absolute requirement;
- 'may' ('need not') granting permission;
- 'can' ('can not') indicating a possibility

There are also some other words and phrases, again in common usage, that are not used in standards because they can result in ambiguity or confusion. These words are:

- 'must', which is replaced by 'shall'
- 'may not', which is replaced by 'shall not'

Possible alternatives to the above for use where it is not linguistically feasible to use the words indicated are given in Annex H of the ISO/IEC Directives Part 2[31].

3.5 Document development and review checklist

As an aid to participants in ISO/TC 229 involved in the development and review of standards for nanotechnologies, the committee has developed a 'document development and review checklist', which is shown in Annex E. This checklist, which is not specific to the field of nanotechnologies, was produced because it had become clear that many projects were being presented for ballot displaying the same basis errors. It was also clear from the lack of comments being submitted with ballot responses that many of those involved in the review of these documents were not familiar with the structure and drafting of standards. The checklist is not meant to cover every eventuality and it is essential that users familiarise themselves with the ISO/IEC Directives Part 2 – 'Rules for the structure and drafting of International Standards' or other regulations relevant to the particular standards body under which they are working. Those involved in the drafting and review of standards also need to exercise their scientific and technical knowledge, judgement and training to ensure the accuracy, robustness and completeness of the document being drafted or reviewed.

4 The approval and review process

4.1 Who, when and how

Once a project group has reached consensus on the detailed contents and structure of the Final Work Draft, their job is essentially complete and the document moves from the project stage to the committee stage. Although there are some differences in the formal processes in ISO and CEN, they essentially follow the same general trajectory towards final approval. In the following the ISO process is described and any significant differences in the CEN process are indicated.

Once a FWD has been submitted to the secretary of the TC responsible for its development, the secretary will, either personally or with the assistance of the convenor of the relevant WG, or other suitable person, review the general structure of the document to ensure that it has been prepared using the correct template and that there are no obvious problems with it. Some committees have a more formal review by an 'editorial panel' of the relevant working group, whilst other committees rely entirely on the Project Leader to ensure that the document is ready for ballot. In view of the number of recurring editorial errors that were being picked up during ballots, ISO/TC 229 agreed to arrange for all documents submitted for ballot to be reviewed by a qualified standards editor so that editorial issues could be addressed prior to ballot, thus allowing reviewers to concentrate on general and technical issues rather than being diverted by poor or incomplete editing.

Following acceptance of a FWD for ballot, the secretary of the committee makes it available to all members for review and voting, using the committee's password protected website. Unless agreed otherwise, this 'committee draft' ballot lasts for a period of three months (this may be as short as two months or as long as four by prior agreement). The purpose of the ballot is to allow the wider community of stakeholders, represented by the relevant mirror committees of the National Member Bodies of the Technical Committee, to study the document and make recommendations as to how it might be improved. This is a vital part of the consensus building process, under which all 'P' members of the TC have an obligation to consult relevant national stakeholders. Other members of the TC - 'O' members and liaisons - are also free to submit comments, although they do not have a formal vote at this or other stages of the process. All comments must be submitted on the appropriate template – see 4.2 below.

It is widely agreed that the technical quality of the final standard is critically dependent on this stage of the process, hence the wider and more detailed the consultation the better. The principle of consensus is based on giving all parties likely to be affected an opportunity to influence the contents of a document, and it is essential that the consultation really does seek 'to take into account the views of all parties concerned' (from the ISO/IEC definition of consensus – see 1.3) and that 'all parties concerned' take full advantage of the opportunity that it offers. However, reviewing a document can be an onerous task, particularly where it contains

a lot of technical detail and where most members of the Project Group have possibly been working in, what is for them, a second or even a third language, which can result in some challenging grammatical structures. The quality of the document presented for ballot can also be strongly affected by the amount of experience members of the project group, in particular the PL, have of preparing standards. For ISO and CEN, almost all documents are now prepared in English, and whilst the use of a common language makes life much easier in general, particularly for the English speaking nations, it can present significant challenges for reviewers whose first language is not English. Because of these language and 'structural' issues, it is vital that TCs, especially those working in new and emerging areas, put structures in place to help ensure the grammatical, structural and technical integrity of documents before they are released for ballot. This is why TC 229 developed its 'Document development and review checklist' – see Annex E - and also why it introduced the editorial check prior to accepting documents for ballot.

4.2 The commenting template and types of comment

In order to ensure that comments are submitted in a standard format and to maximize the value of the comments submitted, comments must be submitted on the approved 'comments template'. Both CEN and ISO use the same format for the submission of comments, a copy of which is shown in Annex F.

As can be seen, the template consists of seven columns. The first column gives the 'ISO 3166 two-letter country code' of the member body (MB) submitting the comment (note that comments come from the NMB, and individuals making them are not identified as it is assumed that the mirror committee responsible will have discussed each comment and come to a consensus about it); the second column identifies the clause, sub-clause or annex to which the comment refers; the third column identifies the paragraph (and preferably sentence) on which the comment is being made; the fourth column indicates whether the comment is general (ge), editorial (ed) or technical (te); the fifth column gives the comment and any justification for a proposed change to the text; the sixth column gives the proposed change; and the seventh column gives the response to the comment from the 'secretariat' of the committee – a task which is more usually delegated to the PL with the support of members of the PG. For all comments, completion of columns 1 (MB designation), 2 (part of the document to which the comment refers), 4 (type of comment), and 5 (comment and justification for any proposed change), are compulsory. In addition, if a change of text is proposed in column 5 but no form of words is provided in column 6, then it is highly likely that the comment will, justifiably, be rejected.

Of the information provided in the comments template, that given in columns 5 and 6 is the most critical for the future of the document. Column 5 needs to contain a succinct statement explaining and, where necessary, justifying the comment. For example 'poor grammatical

structure' or 'As with Annex A, this annex should not be a normative annex as the methods are not a requirement of the standard – the methods are only referred to in a note in the body of the document. Either make it a requirement of the standard to undertake these measurements or change this to an informative annex'.

As those who will be responding to the comments are rarely, if ever, competent mind readers, in all cases where the comment in column 5 requires a change to the text, proposed wording must be provided in column 6, unless it is absolutely clear what is necessary to address the comment. Thus for the two examples given above, the entries in column 6 should, for the first, provide the correct wording and, for the second might be something like 'Clarification needed. If it is a requirement of the standard to make these measurements then the results should be reported in 6'.

It was mentioned in 4.1 above that 'reviewing a document can be an onerous task'. One criticism often made by prospective reviewers is that completing the comments template makes commenting a very laborious process. However, whilst alternatives, such as the use of 'track changes', might seem an attractive alternative, the challenges of dealing with and keeping track of numerous versions of a document, all with different embedded comments, would be insurmountable (there might be twenty or more MB submitting many tens of comments each), hence a 'template' approach really is the only viable option that provides a common format, together with the appropriate traceability to allow the process to be verified, should that prove to be necessary.

4.3 Voting options and approval requirements

Member bodies have a number of options when responding to a committee draft ballot: approve without comments; approve with comments; disapprove with comments with an option to change to approve if the comments are addressed; disapprove with comments – no agreement to change to approve even if comments addressed; or abstain. The decision on how to vote is the responsibility of the Member Body, advised by its national mirror committee, and there is no obligation to approve a document even if one or more nationally nominated experts has participated in its development.

As with all stages of the standardization process, it is vital that members respond to ballots in an appropriate manner. Whilst it is recognised that each member has a right to respond to ballots as it sees fit, in order to ensure that the over arching principle of consensus is not distorted or invalidated, it is vital that members respond from a position of knowledge, and if they lack appropriate knowledge then the only appropriate course of action should be to abstain. For New Work Item Proposal ballots, a positive response should reflect an opinion that the subject is relevant, timely and suitable for standardization by the relevant committee, whilst a negative response should imply that, in the opinion of national experts, the subject is

either inappropriate or not yet ready for standardization. Where there is no national interest and no expertise, then again the only appropriate response should be to abstain. In the circumstances where there is no national interest but experts consider that the subject might be valuable to other members, then approval would seem appropriate.

In the case of documents for ballot, e.g. at CD or DIS stages, similar arguments apply. Thus a vote to approve should only be submitted if a member has relevant national experts who, having reviewed the document, recommend such a response, with or without comments. In the case where relevant national experts, after having reviewed the document, believe it has serious shortcomings, then the response should be disapproval, and comments submitted that substantiate this position. Where a member has no relevant expertise or where there is no national interest, then the response should be to abstain.

The need for experts to review documents before a ballot response is submitted cannot be over stated. Whilst such action might appear an obvious prerequisite of informed consent, it is widely recognised that some MB approve, without comment, documents that are clearly deficient. This suggests that, for these MB, no one qualified to comment has reviewed the document concerned and that it has a default response of 'approve' unless advised otherwise by the relevant mirror committee. Whilst recognizing an imperative to demonstrate to the, political, funders of a MB that it is fully participating in international activities, a positive response without good reason can seriously undermine efforts to ensure that only high quality, relevant, documents are published. At the same time, such a response seriously undermines the important principle of consensus on which all standards are based. It might therefore be suggested that members introduce an additional, albeit unwritten question to the ballot form 'have you reviewed the document and do you have the expertise to comment on it?'. If the answer to either of these questions is no then the only possible response to the ballot should be to abstain.

Although standards are invariably presented as consensus documents to which there is an 'absence of sustained opposition to substantial issues by any important part of the concerned interests', realistically it might not be possible to achieve the support of, or at least an absence of opposition from, all stakeholders, hence for a document to move to the next stage, it must be approved by at least a specified minimum percentage of members submitting positive or negative votes - abstentions are not counted. PAS and TR require the approval of a simple majority of members voting, whilst TS and IS are confirmed if at least 2/3 of members voting give their approval.

4.4 Resolution of comments

The comments template is a critical component in the standards development process as it provides a detailed record of the comments submitted, and by whom, and, in particular, how

they were addressed ('resolved'). Depending on the number and nature of the comments received, resolving them can be done either by correspondence, whereby the PL responds to each of the comments by filling in column 7, seeking approval for these responses from the experts nominated to the PG. Where the comments are more challenging, and particularly where they are of a technical nature, it is usual to address them during a 'comments resolution' meeting, where the members of the PG collectively agree on how to respond to each comment. The response can vary from accept, partially accept (with justification) or reject (with justification).

Once responses to all comments have been agreed, the document is modified accordingly and is then ready for the next stage in the process. If there have been a large number of changes introduced, particularly where these affect the technical content, the Chair and Secretary of the committee, who are responsible for ensuring the quality of the documents produced and the robustness of the 'process' used in their preparation, may jointly decide that the document is sufficiently different from what was originally balloted to justify a second 'committee draft' ballot, in which case, the whole commenting and balloting process is repeated. This would also be the case if there had been a significant number of negative votes, and is mandatory in cases where a document has been rejected but the committee has decided to continue to try to reach consensus.

4.5 Publication

Once a document has been approved by the (P) members of the committee, and all of the comments received have been satisfactorily resolved, it is ready either to be published as a PAS, TR or TS, or, for an International Standard, to move to the next stage of the approval process. No matter what the ultimate status of the document, it now ceases to be the formal responsibility of the Technical Committee and becomes the responsibility of ISO.

After checking the document and determining whether or not a French translation is required prior to the Draft International Standard (DIS) stage (also known as Enquiry Stage), ISO makes the document available (in both English and French Versions if deemed to be necessary) to all members of ISO for a five month comment and ballot, during which any MB of ISO may submit comments (again using the 'comments template') and vote on the document. Documents are approved as DIS if more than 2/3 of the P members of the TC which originally approved the document vote in favour and no more than one quarter of the total number of votes cast are negative; as with other ballots, abstentions are not counted. The comments received are submitted to the secretariat of the relevant committee for resolution, which is formally undertaken in consultation with the chair and the PL, though in reality this task is usually delegated to the original PG.

The next stage depends on the outcome of the voting. If there were no negative votes, the document, modified as appropriate to take account of the comments received, moves to publication. However, where a document is approved with negative votes having been submitted, the document, again modified to take account of the comments received, undergoes a Final Draft International Standard (FDIS) stage (also known as the Approval Stage), where it is made available to all members of ISO for a two month ballot. However, the voting and commenting options for this stage are more limited than for earlier stages, and comprise approv (no comments permitted except for those of a minor editorial nature), disapprove (which must be supported by technical reasons), or abstain. The criteria for publishing the document are the same as for the Enquiry Stage, except that, in addition to abstentions, all negative votes not supported by technical reasons are not counted. Any comments received are submitted to the secretariat of the TC for consideration at the first systematic review of the standard – see 4.6 below.

In the event that the DIS ballot results in a negative vote, the TC Chair and Secretary, in consultation with the ISO Central Secretariat (formally the CEO) agree either to circulate a revised enquiry draft for voting, or to circulate a revised committee draft for comments, or to discuss the enquiry draft and comments at the next meeting.

4.6 Systematic review – what, when and how

Standards are only of value if they remain technically accurate and relevant to the business or other interests of the stakeholder communities that use them. In order to help ensure their continued utility and legitimacy, all standards are subject to systematic review. The criteria for the systematic review ('maintenance') of ISO documents are given in the ISO/IEC Directives Supplement – Procedures specific to ISO[36] and are summarized below:

- PAS are valid for an initial maximum period of 3 years. The validity may be extended for a single period of up to 3 years, at the end of which they must be published as another type of normative document, or be withdrawn. PAS have a maximum life span of six years.
- Technical Specifications are subject to review not later than 3 years after publication. The aim of this review is to re-examine the situation which resulted in the publication and, if possible, to achieve the agreement necessary for the publication of an International Standard to replace the Technical Specification. Failing this, a TS may be extended for another three years, or withdrawn. There is no limit on the number of times a TS can be reconfirmed, provided it is reviewed at least every three year.
- Technical Reports are regularly reviewed by the committee responsible to ensure that they remain valid. Withdrawal of a Technical Report is decided by the technical committee or

[36] See http://isotc.iso.org/livelink/livelink?func=ll&objId=4230452&objAction=browse&sort=subtype

subcommittee responsible but there is no formal limit to the life span provided it remains valid.

- International Standards are subject to their first systematic review a maximum of three years after publication and then at least every five years thereafter. There is no limit to the number of times an IS can be reconfirmed.

Any document may be withdrawn at any time if it is found to contain serious technical flaws or deemed to be no longer valid.

4.7 Procedural differences between CEN and ISO

Whilst there are a number of subtle but minor differences between the procedures in CEN and ISO, the principal differences are:

- Any national member of CEN can vote at any stage in the development of a document – NWIP, approval of TR and TS, and Enquiry and Approval of an EN. In ISO, it is only the 'P' members of the TC that can vote at the NWIP, and approval of PAS, TR, TS, and CD stages, with the full membership of ISO only having a vote at the Enquiry (DIS) and Approval (FDIS) stages for the development of an IS.
- There is no equivalent stage in the development of an EN to the Committee Draft ballot in ISO – the Enquiry ballot (equivalent to the DIS ballot in ISO) is the first formal ballot stage in CEN after the approval of a NWIP for an EN;
- All ballots in ISO are on the basis of one member one vote. In CEN, this principle only applies to the NWIP and approval stages for a TR. In both CEN and ISO, approval of a TR for publication requires a simple majority of votes cast (abstentions are not counted in either organisation).
- In CEN, 'weighted' voting applies at all ballot stages for TS and EN – NWIP, approval of a TS, Enquiry and Approval of an EN - with a minimum of 71% of the weighted votes cast being required to approve.
- In ISO, approval of TS, CD, DIS and FDIS require a 2/3 majority of votes cast by 'P' members of the relevant TC, together with, at the DIS and FDIS stages, no more that 25% of the total votes cast opposing approval.
- In CEN there is no equivalent to a PAS in ISO.

5 Examples of successful standardization resulting from Framework Projects

Whilst a number of European Framework projects have resulted in the development of European and international standards, including CEN Workshop Agreements, many of these projects were undertaken in the context of the Standards, Measurement and Testing programme in Framework 4 (1994 – 1998), which 'aimed, through RTD in the field of measurements and testing, to improve the competitiveness of European industry, to support the implementation of other Community policies and to meet the needs of society', and its predecessor, the Measurement and Testing programme of Framework 3 (1990 – 1994). Some examples of SMT projects that resulted in standards being published include:

- SMT4-CT96-2134, which helped to produce and validate ISO 15061:2001 Water quality -- Determination of dissolved bromate -- Method by liquid chromatography of ions;
- SMT projects REMAST and MMST were together the starting points for the standardisation of the scratch adhesion evaluation test for ceramic coatings – EN 1071-3:2005 and ISO 20502:2005;
- SMT thematic network project 'HAMMER' on Grain Size measurements for hardmetal tool materials provided the baseline for input into ISO standards development through ISO TC199 - Powder Metallurgy. Although development of a standard was not a specified deliverable of the project, with strong industrial support and input, a new standard in two parts, ISO 4499-1 and 4499-2, was eventually produced, with three further parts under development.

Examples of more recent projects that have resulted in, or are working to deliver, standards, particularly CWAs, can be found under the 'Innovation and research' pages[37] of the CEN website. In addition to identifying a number of relevant past and ongoing projects under the 'Read our best practices' page, the site also contains a new guide on 'Linking standardization and research', which can be downloaded from the 'Background documents' page and which contains much that readers of the present guide will find of value.

[37] see http://www.cen.eu/cen/Services/Innovation/Pages/default.aspx

Annex A

Standardization project characterization template

Name and acronym of FP project:
Specific research result identified as relevant to standardization:
Template completed by: **Date:**

Characteristic	Criterion	Response/Status
Specific research result	Why is the result relevant to standardization and what purpose could it serve?	
	Who are the possible contributors in the consortium?	
	Are they prepared to participate in developing a standard in this area?	
	What are their expected benefits?	
	Do they see any obstacles and, if so, what are they?	
	Are there IPR issues involved?	
	What are the estimated costs of taking the result to a finished standard?	
	Have appropriate searches been undertaken to establish whether relevant National, European or International standards in the area already exist or are under development? If so, provide a list of standards and relevant technical committees	
	How will the new standard complement existing documents?	
Type of standard deliverable planned – please specify	Workshop Agreement (WA)	
	Publicly Available Specification	
	Technical Report	
	Technical Specification	
	Full standard	
Development route	National	
	European (CEN/CENELEC/ETSI)	

	International (ISO/IEC/ITU)	
	Other - please specify	
	Has a relevant Technical Committee (TC) for the project been identified? If so please specify	
	If a WA is planned has the TC route been fully evaluated?	
	For a WA has a National Standards Body (NSB) been identified to help plan and host the workshop? If so please specify	
	Who will lead the development of the standard or WA?	
New Work Item Proposal (NWI P) /Business Plan	Has a New Work Item Proposal or Workshop business plan been prepared?	
	Has this been submitted to an appropriate NSB? If so please specify.	
NWIP stage	Has the NSB submitted the NWIP to the relevant TC If so please specify the TC	
Standardization project	Has the standardization project been approved for development? If so what is the expected publication date?	
Pre-approval	Is the document under ballot? If so please specify ballot stage and closing date of ballot.	
Approval	Has the document been approved?	
	What was the result?	
	Are there comments to be resolved?	
	Are there additional ballot stages before publication? If so specify what they are and when they are likely to be completed.	
Publication	Has the document been published? If so please state when. If not please indicate publication date.	

Annex B

ISO and CEN NWIP forms

ISO Form 4

NEW WORK ITEM PROPOSAL	
Date of presentation	Reference number (to be given by the Secretariat)
Proposer	**ISO/TC / SC N**
Secretariat	

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

See overleaf for guidance on when to use this form.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are given overleaf.

Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title) English title French title (if available)
Scope of proposed project
Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance) ☐ Yes ☐ No If "Yes", provide full information as annex
Envisaged publication type (indicate one of the following, if possible) ☐ International Standard ☐ Technical Specification ☐ Publicly Available Specification ☐ Technical Report
Purpose and justification (attach a separate page as annex, if necessary)
Target date for availability (date by which publication is considered to be necessary)
Proposed development track ☐ 1 (24 months) ☐ 2 (36 months - default) ☐ 3 (48 months)
Relevant documents to be considered
Relationship of project to activities of other international bodies

Liaison organizations	**Need for coordination with:** ☐ IEC ☐ CEN ☐ Other (please specify)

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☐ An outline is attached. It is possible to supply a draft by

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☐ Yes ☐ No

Proposed Project Leader (name and address)	**Name and signature of the Proposer** (include contact information)

Comments of the TC or SC Secretariat

Supplementary information relating to the proposal

☐ This proposal relates to a new ISO document;

☐ This proposal relates to the amendment/revision of an existing ISO document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Voting information

The ballot associated with this proposal comprises a vote on:

☐ Adoption of the proposal as a new project

☐ Adoption of the associated draft as a committee draft (CD)

☐ Adoption of the associated draft for submission for the enquiry vote (DIS or equivalent)

Other:

Annex(es) are included with this proposal (give details)

☐

Date of circulation	Closing date for voting	Signature of the TC or SC Secretary

Use this form to propose:

a) a new ISO document (including a new part to an existing document), or the amendment/revision of an existing ISO document;

b) the establishment as an active project of a preliminary work item, or the re-establishment of a cancelled project;

c) the change in the type of an existing document, e.g. conversion of a Technical Specification into an International Standard.

This form is not intended for use to propose an action following a systematic review - use ISO Form 21 for that purpose.

Proposals for correction (i.e. proposals for a Technical Corrigendum) should be submitted in writing directly to the secretariat concerned.

Guidelines on the completion of a proposal for a new work item

(see also the ISO/IEC Directives Part 1)

a) Title: Indicate the subject of the proposed new work item.

b) Scope: Give a clear indication of the coverage of the proposed new work item. Indicate, for example, if this is a proposal for a new document, or a proposed change (amendment/revision). It is often helpful to indicate what is not covered (exclusions).

c) Envisaged publication type: Details of the types of ISO deliverable available are given in the ISO/IEC Directives, Part 1 and/or the associated ISO Supplement.

d) Purpose and justification: Give details based on a critical study of the following elements wherever practicable. *Wherever possible reference should be made to information contained in the related TC Business Plan*.

1) The specific aims and reason for the standardization activity, with particular emphasis on the aspects of standardization to be covered, the problems it is expected to solve or the difficulties it is intended to overcome.

2) The main interests that might benefit from or be affected by the activity, such as industry, consumers, trade, governments, distributors.

3) Feasibility of the activity: Are there factors that could hinder the successful establishment or global application of the standard?

4) Timeliness of the standard to be produced: Is the technology reasonably stabilized? If not, how much time is likely to be available before advances in technology may render the proposed standard outdated? Is the proposed standard required as a basis for the future development of the technology in question?

5) Urgency of the activity, considering the needs of other fields or organizations. Indicate target date and, when a series of standards is proposed, suggest priorities.

6) The benefits to be gained by the implementation of the proposed standard; alternatively, the loss or disadvantage(s) if no standard is established within a reasonable time. Data such as product volume or value of trade should be included and quantified.

7) If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated.

If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

e) Relevant documents and their effects on global relevancy: List any known relevant documents (such as standards and regulations), regardless of their source. When the proposer considers that an existing well-established document may be acceptable as a standard (with or without amendment), indicate this with appropriate justification and attach a copy to the proposal.

f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.

CEN Form N

Proposal for a new work item

Title:

Proposer:

Information to be supplied by the proposer of the NWI

A1 Subject

A1.1 **Scope**:

A1.2 **Keywords** (Descriptors) characterizing the scope
(multiple ticks are possible and/or necessary)

- Product ☐	- Requirements ☐	- EN ☐
- System ☐	- Characteristics ☐	- CEN/TS ☐
- Service ☐	- Guidance ☐	- CEN/TR ☐
Interface ☐	- Test method ☐	- other (e.g. CEN Guide) ☐
	- Terminology etc. ☐	

A2 Market relevance

A2.1 **Frame conditions**

Subject of mandate from EC or EFTA: ☐ *Reference of mandate*

Transposition of International Standard: ☐ *Reference of IS*

Adoption of draft provided by European professional body: ☐ *Name of organization* + *Reference of document*

Other: ☐ Please specify:

A2.2 **General market needs**

Safety ☐
Environment ☐
Consumers ☐
Economy ☐
Barriers to trade ☐
Other: ☐

A2.3 **Special aspects** (problems or difficulties to be solved by the standard, impacts and

benefits to be expected from the standard; *please describe shortly*):

A2.4 **Urgency**

☐ high ☐ medium ☐low

A3 Resources and timeframe

- First working draft(s) available *) ☐
- Suitable source document(s) available *) ☐
- Pre-normative research necessary ☐
- Strong interest of stakeholders in terms of financing expected ☐
- Active participation of stakeholders expected ☐
- Expertise available ☐
- External (e.g. EC) financing expected ☐
- Timely consensus expected ☐

*) To be added to the proposal

A4 Participation

- Proposer prepared to participate actively ☐
- Proposer prepared to run secretariat ☐
- Proposer prepared to take over convenor- or project leadership ☐
- Special liaison proposed:. ☐

A5

Name:

Function:

Organization:

Signature ..... **Date:**

Annex C

Glossary of terms

Term	Meaning	Abbreviation
Approved Work Item	A work item that has been approved for development within a TC but on which work has not yet started.	AWI
CEN CENELEC Management Centre	The structure based in Brussels that undertakes the day to day management of the CEN and CENELEC processes.	CCMC
CEN Technical Board	The executive, decision making body of CEN	CEN BT
Committee Draft	A draft of an international standard that is under consideration by or has been approved by an ISO TC or SC but has not yet been balloted as a Draft International Standard	CD
Draft International Standard	Draft standard that has been issued by ISO/CS for ballot by ISO members.	DIS
European Committee for Electrotechnical Standardization	European standardization body for electotechnical matters.	CENELEC
European Committee for Standardization	European standardization body for matters not dealt with by CENELEC or ETSI	CEN
European Standards (European Norm)	Standards document that has been developed through the enquiry and approval process of CEN, CENELEC or ETSI or has been approved via a faster process, such as the Unique Acceptance Procedure (UAP)	EN
European Telecommunications Standards Institute	European standardization body for telecommunications.	ETSI
Final Draft International Standard	Draft of an international standard issued by ISO/CS for final ballot by ISO members prior to publication.	FDIS
International Electrotechnical Commission	International standardization body for electrotechnical matters	IEC
International Organisation for Standardization	International standardization body for most matters not dealt with by IEC and ITU and by intergovernmental standards making organisations, such as FAO, OECD, etc.	ISO
International Standard	Standards document that has been approved by the international community of National Member Bodies making up the membership of ISO, IEC or ITU.	IS
International Telecommunications Union	International standardization body for telecommunications.	ITU
ISO Central Secretariat	The structure based in Geneva that undertakes the day to day management of the ISO process.	ISO CS
ISO Technical Management Board	The executive, decision making body of ISO	ISO TMB
Member Body	In CEN, CENELEC, ISO and IEC, the national	MB

	organization, usually the National Standards Body, representing a nation in standardization activity	
National Standards Body	National body responsible for the cataloguing and publication of national standards. Can be part of the structure of government or a non-governmental organisation. National Standards Bodies are almost always the national Member Bodies in ISO.	NSB
New Work Item Proposal	Proposal, submitted by a member of a Technical Committee or other eligible entity for a new standardization project	NWIP
Project Group	Group of experts within a Working Group formally designated to develop a standard through the working draft stage	PG
Project Leader	The person identified by the initiator of a NWIP to lead the project and confirmed by the TC.	PL
Publicly Available Specification	A standards deliverable of lesser status than a full international standard, intended for fast development and approval by an ISO Technical Committee	PAS
Sub-committee	Subsidiary autonomous group within a TC having responsibility for standards development within a particular area of the work of the TC. SCs are established where they facilitate managing the overall work programme of the TC.	SC
Technical Committee	Technical body, operating under the auspices of a Standards Development Organisation, with responsibility for developing standards in a particular subject area	TC
Technical Report	An informative document approved by simple majority voting of a Technical Committee and published by the relevant standards body	TR
Technical Specification	A normative document of lesser status than a full standard, requiring approval by a 2/3 majority vote in an ISO committee and by a 71% majority weighted vote in CEN and published by the relevant standards body.	TS
Work Item	Item of work under development within a TC or SC as a standard, TS, TR or PAS	WI
Working Draft	A draft standard under development by PG or WG experts	WD
Working Group	Subsidiary group within a TC that has drafting responsibility for one or more WIs in a specific area	WG

Annex D

ISO/TC 229 Welcome letter and guidance notes for PLs

Welcome letter

Dear Colleague

On behalf of the members of ISO/TC 229, I would like to thank you for agreeing to be appointed as the Project Leader for the New Project on ……, which will be developed within Working Group ….., the convenor of which is …… As you will appreciate, the work of the committee is critically dependent on the input of experts, such as yourself, and we are most grateful to you for agreeing to contribute your knowledge and expertise to the development of the proposed standard.

If this is your first experience of standardization work in ISO I would like to draw your attention to the wealth of information about Standards Development available on the ISO website – www.iso.org/ . In particular, you might like to look at "My ISO job" (http://www.iso.org/iso/my_iso_job.pdf), which provides a valuable overview of the work of standards development and the roles of the different people and structures involved. The rules for the structure and drafting of standards, and the procedures for technical work, are covered by the ISO/IEC Directives (http://www.iso.org/iso/standards_development/processes_and_procedures/iso_iec_directives_and_iso_supplement.htm), the template on which documents should be developed is available at http://www.iso.org/iso/standards_development/it_tools/iso_templates.htm , whilst details of the various technical committees involved in standards development, the standards they have published and their existing work programmes, etc., are available at http://www.iso.org/iso/standards_development/it_tools/iso_templates.htm . Please take a few minutes to look around the web site – I am sure you will find lots to interest you.

In view of the large number of individuals involved in the work of ISO/TC 229 and its expanding programme work, it is very important that we adopt an effective means of communication, and for this we rely upon the ISO Livelink website. This password protected website contains all of the available information about the committee, including its programme of work, draft work items, etc. Now that you have been appointed as a Project Leader, your NSB (National Standards Body) will issue you with a user name (your e-mail address) and a password to allow you to gain access to the area of the website devoted to the working group in which your project will be developed.

Project Leaders and Working Group secretaries are asked to use the website to display all documents relevant to the members of the working group and its constituent projects. These should be arranged in four folders: 01 General Documents; 02 Meetings; 03 Projects; and 04 Project Group subfolders. Of these, I think the first two are self explanatory but 03 and 04 need a word of explanation. Folder 03 should contain the latest draft of each document that is being developed, hence it should only contain one document from each project that is under development. All other documents relevant to the different projects should be placed in the project subfolders in folder 04. Hence if you wish to see the latest draft of your particular project you should go to folder 03, whereas if you want to see previous versions, or comments from other members of the project group, etc, you should go to the relevant project subfolder in folder 04.

The only other information available on the Working Group part of the website is a chronological list of documents (“N numbered document list”), which lists all Working Group documents (but not project group documents) posted to the website. The benefit of this is that it uniquely identifies all documents and allows members to readily access a particular document even if they do not know which folder it is stored in! This list is maintained by the Working Group secretary. Project Leaders are asked to maintain a similar list of documents in each subfolder. When you post a new document to your sub-folder you should send a “document notification” e-mail to all members of your project group. In order to do this, and so that you know who has been nominated to your project, it is vital that you keep an up to date list of experts and their contact details. The committee secretary, Jose Alcorta, will provide you with this information at the time your project is approved and he will update this information when NSBs send additional or revised nominations to him.

The development of projects typically takes place using three channels of communication – e-mail, tele- or web-based conferences, and face to face meetings. Whilst the first two of these are vital to the progress of the work and to meeting the timescales imposed by ISO, and should be used to drive the project forward, face-to-face meetings provide an excellent opportunity to get to know your fellow experts and to make rapid progress with developing your particular document. These meetings are usually held in conjunction with the committee’s twice yearly plenary meetings. At these we try to devote at least half a day to each project so that the nominated experts, under the guidance of their project leader, can discuss their projects in detail and resolve any issues that have come up in previous e-mail or tele/web-conference discussions. These meetings also provide the opportunity for working group convenors to lead a discussion on future work, cooperation with the other working groups in the committee or in other ISO technical committees. These discussions take place during the working group “strategic meetings”, to which we also devote half a day. In addition, “plenary week” meetings provide invaluable networking opportunities where you can meet and talk with colleagues from the other members of ISO TC 229, and many of its liaison organisations, not only about you own specific project but about all of the other projects that the committee is developing. As a Project Leader it is very important that you attend these meetings to meet with your project group, receive their input and lead the discussions. However, if you are unable to attend, for whatever reason, please advise the working group convenor and ensure that someone in you National delegation, or a colleague on your Project Group, is well briefed and able to take your place.

Thank you once again for agreeing lead this important work. If you have any questions about your project please direct them to your working group convenor, and if they are more general in nature then please contact the secretary of your National Committee.

I look forward to meeting you.

With kind regards

Chairman ISO/TC 229 - Nanotechnologies

ISO/TC 229 Guidance for Project Leaders

Thank you for agreeing to act as a project leader for ISO TC 229. Your role is to manage the development of your project and to come to a consensus with the members of your project group – international experts nominated by their national standards bodies (NSBs) for their expertise in the subject matter of the project. Please note that consensus, i.e. no sustained opposition, is not identical to unanimity. However you should strive to get your various experts to agree on both the content and structure of the document.

It is also your responsibility to ensure that the project is delivered on time. When a New Work Item Proposal (NWIP) is approved, ISO central secretariat (ISO CS) sets deadlines for the various stages in the development of the standard and it is your responsibility to ensure that these are met. These deadlines are typically 12 months from approval of a NWIP to delivery of the final draft for ballot, and three months to review and resolve comments received following the committee draft (CD) and draft international standard (DIS) ballots.

If this is your first time as a project leader you should familiarize yourself with the ISO/IEC directives part 2 “Rules for the structure and drafting of International Standards”, and with “My ISO job”, both of which you can obtain from www.iso.org (or from the main page of your WG Livelink site under "Featured Items"). You should also contact your national standards body to determine if they offer any training courses to support you in your work.

The following bullet points are provided to guide you through the various stages of project development.

- You should start by preparing a schedule for development of the project, with milestones, approximate dates for meetings, teleconferences, completion of first, second and final drafts, etc. This does not need to be done using any particular software – an Excel spread sheet is adequate provided that you can update it if and when necessary.
- Assuming the proposer (you perhaps) provided a draft document that was circulated with the New Work Item Proposal ballot, prepare responses to any comments received – this should be done using the official comments form. Send the completed form to the WG secretary for posting to the website.
- Contact all experts nominated to your project team to introduce yourself and advise them of the schedule for the work. Contact details will be provided by the committee secretary. However, it is your responsibility to keep the list updated when additional members join or anyone leaves. It will be helpful to maintain a list of current experts on the website.
- Advise members that the comments received during the balloting process, together with your responses, are available on the website and will be reviewed either at a meeting, tele/web conference, or by correspondence.
- If the project will meet within about 1 month of the first draft being posted to the website you will be able to discuss the comments and your responses face to face with your project group. Otherwise it would be useful to arrange a tele/web conference within this timescale so that members can discuss them and begin to come to an agreement. At the same time you might like to invite members to provide their own comments on the document.
- You will need to agree with the WG secretary whose responsibility it is to arrange a teleconference.
- Once the work is underway you might like to use tele/web conferences to focus on one particular part of the document. This can be a very effective means of obtaining agreement. However, do remember that if you have representation from around the globe some members might be participating at unsocial hours so it is often better to mix tele/web conferences with e-mail communication.

- If members cannot attend any meeting or teleconference you should ask them to submit their comments to you in writing at least one week before the meeting is scheduled so that you can review them and discuss them with the remainder of the group.
- It will be helpful to keep a record of which members respond so that you can decide whether you need to contact anyone on an individual basis to determine their views.
- Following either a physical meeting or teleconference you should prepare a revised draft, preferably using the ISO template, and circulate to members for review and further comment. The ISO template is available for download from the WG website.
- Please ensure that the latest draft of your document is posted to folder three of the project website and that the preceding version is transferred to folder four. This should be done by the WG secretary who will assign WG/PG N numbers to the various documents to maintain a record of the development of the project.
- When you have gained consensus amongst the experts as to the contents and structure of the document you should submit the final draft to the convenor of the working group for review and forwarding to the committee secretary for (a three month) ballot as a Committee Draft (CD). All members of the committee, not only those involved in the development of the project, have an opportunity to comment and vote on the CD.
- After the CD ballot, the committee secretary will send you a file of comments and you have three months to resolve these with the assistance of your project group. Again it is advisable to review the comments and make your own proposals for resolve them before distributing to your PG.
- If the document is to be published as a Technical Specification (ISO TS) or Technical Report (ISO TR), there will be no further ballots and the document will be published once you have resolved the comments to the satisfaction of the experts in the working group and you have incorporated the agreed changes into the Committee Draft.
- If the document is to be published as an International Standards (IS) then once the comments have been resolved and incorporated into the CD, a Draft International Standard will be prepared and balloted (a five month ballot in which all members of ISO, and not only those involved with the committee, take part).
- As with the CD ballot, the comments received during the DIS ballot will need to be reviewed and resolved before the preparation of a Final Draft International Standard (FDIS). This is sent to all members of ISO for a two month ballot during which members vote either to approve, reject or abstain. If a member rejects a document they must provide technical reasons for their objection. If they votes in favour they cannot make any comments on the contents of the document.

Physical meetings

Whilst physical meetings may be held at any time, it must be recognised that they can represent a significant drain on financial resources and some members of the project team might not be able to participate. It is therefore recommended that, wherever possible, physical meetings are held in conjunction with the twice yearly plenary meetings of the committee. At these meetings half a day is usually available for each project team to discuss its work. If managed properly this should be sufficient time to make good progress. However, even at plenary meetings it is likely that some nominated experts will not be able to participate, in which case they should be asked to nominate and brief a deputy to speak on their behalf. In addition, other interested experts and members of the committee might wish to attend a project meeting to find out what is going on. Therefore, when you hold a physical meeting, it is important to identify, through a role call of delegates, who is present as a formally nominated expert, who has been asked to speak on behalf of a nominated expert, and who is attending as an observer. Whilst it is up to you whether or not you allow observers to comment on technical issues, it is very important to ensure that the discussion focuses on the nominated experts present, and that all of them have an equal opportunity to participate in the proceedings. The following bullet points highlight some of the things you need to do in preparation for and whilst conducting a physical meeting:

- A calling notice must be issued to all nominated experts at least two months before the meeting, giving details of the date, time and venue of the meeting. This should be issued in conjunction with the working group secretary.

- Any documents for consideration at the meeting must be distributed to all experts at least two weeks prior to the meeting date to give prospective participants adequate time to prepare;
- Additional papers may be tabled at the meeting but it will be up to you to decide whether these should be considered;
- A role call of experts and other attendees should be taken;
- Following the meeting you should prepare a short report giving details of the principal decisions taken. This should be circulated to nominated experts for comment together with a revised draft of the document incorporating all agreed changes.

List of Acronyms

AWI	Approved Work Item
CD	Committee Draft
DIS	Draft International Standard
FDIS	Final Draft International Standard
IEC	International Electrotechnical Commission
IS	International Standard
ISO	International Organisation for Standardization
ISO CS	ISO Central Secretariat
NSB	National Standards Body
NWIP	New Work Item Proposal
PG	Project Group
TR	Technical Report
TS	Technical Specification
WD	Working Draft
WG	Working Group

Annex E

Document development and review checklist

Introduction

This check list has been prepared to help project leaders, and others involved in the preparation or review of standards, identify issues to be addressed before the document can move to the next stage of the development process. It is not meant to cover every eventuality and it is essential that users familiarise themselves with the ISO/IEC Directives Part 2 - Rules for the structure and drafting of International Standards. Those involved in the drafting and review of standards will also need to exercise their scientific and technical knowledge, judgement and training. It will also be helpful to keep the following questions in mind throughout the development and review processes:

- is this feasible?
- would this allow me to repeat the method without ambiguity?
- does this make sense in the light of what went before?
- where is the justification for this statement or conclusion?

The checklist is not meant to replace proper reference to ISO/IEC Directives, or to be used in place of the formal ISO comments template, but rather to act as an ‘aide memoire’. It is hoped that its use will help improve the quality of documents presented for ballot by aiding the identification and resolution of common issues at an earlier stage in the development process.

Users of the checklist might find it helpful to record their observations under the ‘Observations’ column.

Item	Questions	Answer	Guidance	Observations / Validation Note
General Considerations				
Template	Is the document in the ISO template? If not then it should be put into the correct format.	Yes ☐ No ☐ N/A ☐		
References supporting technical statements	Are all informative references from non-standards publications numbered in the order in which they appear?	Yes ☐ No ☐ N/A ☐	Note that references to standards publications are identified by number and listed in a bibliography, where they are ordered alphabetically.	
	Are all references necessary for the detailed understanding of the document or justification of technical statements?	Yes ☐ No ☐ N/A ☐		
	Are there any technical statements in the document that need to be justified by a reference where none is currently given?	Yes ☐ No ☐ N/A ☐		
Extracts from other publications (e.g. quotations, figures, tables, etc)	Has the permission of the copyright holder been obtained for the inclusion of extracts from other publications in the document?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 1, 2.13	
Language	Is the document generally written in the 'third person', with procedures written in the 'imperative', i.e. do this, do that?	Yes ☐ No ☐ N/A ☐	Use of the 'third person' and the 'imperative'; Use of the words 'may', 'shall' and 'should'. See ISO/IEC Directives, Part 2, Table H.1 Some words have very specific meaning in standards, e.g. the word 'may' gives permission to do something and shall only be used in this respect, for example to indicate where one of two different things may be done. It shall not be used to infer a possibility that something could occur, for which the word 'might' or 'can' should be used. Where something must be done to comply with the standard, i.e. is a requirement of the standard, the word 'shall'	

Item	Questions	Answer	Guidance	Observations / Validation Note
			is used. 'Must' should not be used. Where something is strongly recommended but not obligatory then the word 'should' is used.	
Technical considerations	Are all technical details accurate?	Yes ☐ No ☐ N/A ☐		
	Are there any contradictory elements, e.g. a requirement in one place to measure temperatures to ±5º C and in another to maintain the temperature between x and x-2º C.	Yes ☐ No ☐ N/A ☐		
Requirements – verifiability	Are all requirements verifiable, or are there any unverifiable requirements, e.g. best efforts shall be used to maintain a constant temperature – what are 'best efforts' and how can it be demonstrated they were used? Requirements may not be included in informative elements, e.g. notes and informative annexes?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.3.3	
Cross references	Are cross-references to other parts of the document correct?	Yes ☐ No ☐ N/A ☐		
Specific Elements				
Title	Does the title fully reflect the contents and intent of the document?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.1.1	
Introduction	Does the introduction support the context of the document in a purely informative way?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.1.4 Note that an introduction is a voluntary element – and should only be included if it supports the context or content of the document An introduction shall not contain provisions of the standard and shall therefore not include requirements and recommendations.	

Item	Questions	Answer	Guidance	Observations / Validation Note
	Does it contain any information that should be included in the body of the document or that is not relevant to supporting the context and/or content of the document?	Yes ☐ No ☐ N/A ☐		
Scope	Does the scope reflect the title (and the title the scope) and explain what the document does and does not do in an accurate and succinct manner?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.2.1 The scope shall not contain provisions of the standard and shall therefore not include requirements and recommendations.	
Normative references	Are all of the normative references 'necessary for the application of the document'?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.2.2 To be included as 'normative references' it is necessary that such references are referred to 'normatively' within the document, typically through the use of the word 'shall', e.g. 'the method describe in ISO xxx shall be used'.	
Terms and definitions	Are all terms written in lower case, and do any definitions start with a definite or indefinite article (the, or a/an), which is incorrect?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, Annex D. It contains examples of what to do when citing or adapting terminology from another document. Note that definitions should not contain multiple sentences, lists or examples (the latter may be given in a Note underneath the definition) and that a definition itself should be able to replace the term in the sentence(s) where it appears.	
Symbols	Are all symbols in the document properly defined and used for one quantity only?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 1, 6.3.2 (Symbols and abbreviated terms) It is helpful to include all symbols in a specific list that users can easily refer to.	
Acronyms	Are all acronyms written out in full at	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, D.1.4, for	

Item	Questions	Answer	Guidance	Observations / Validation Note
	their first use?		how an acronym can be presented in a term and definition. It is helpful to include all acronyms in a specific list that users can easily refer to, particularly if the user is unlikely to be familiar with them all.	
Units	Are all quantities assigned their correct (SI) units?	Yes ☐ No ☐ N/A ☐		
Equipment	Is all equipment referred to in a generic way or are there references to commercial equipment from specific manufacturers/suppliers?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.6.3 and 6.6.4, for guidance on the use of trade names and patent rights.	
Calibration	Is the traceable calibration of all equipment used for demonstrating compliance to the standard included as a requirement?	Yes ☐ No ☐ N/A ☐		
Procedures	Are all procedures, experimental and calculation, written as a logical sequence of steps using 'imperative sentences', e.g 'do this', 'do that', and not as a narrative, e.g. so and so is done, which is incorrect?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.3.5 and ISO 78-2 for guidance on drafting test methods. Where additional procedures are required that are not formally part of the specific procedure covered by the standard then they ~~should be included in one or more annexes~~, either as normative annexes, where the procedure is required to demonstrate compliance with the standard, or as informative annexes, where the procedure is optional and does not need to be carried out	

Item	Questions	Answer	Guidance	Observations / Validation Note
			When reviewing procedures, it is helpful to imagine carrying out precisely what is required in the order given. This will usually enable procedures that are ambiguous or in the wrong order to be identified.	
	Are all procedures and calculations necessary?	Yes ☐ No ☐ N/A ☐		
	Are there any ambiguities where it is not clear precisely what must be done in order to comply with the standard?	Yes ☐ No ☐ N/A ☐		

Item	Questions	Answer	Guidance	Observations / Validation Note
Errors (tolerance)	Are all relevant sources of error identified and considered?	Yes ☐ No ☐ N/A ☐		
	Is it clear what overall accuracy can be achieved with the method provided?	Yes ☐ No ☐ N/A ☐		
Reporting results	Is it explained in detail what shall be reported and what may be reported?	Yes ☐ No ☐ N/A ☐		
Annexes	Are all annexes referred to in the body of the document?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.3.8 and 6.4.1. If not they should either be referred to at an appropriate point(s) or deleted. Normative annexes shall have normative requirements and are essential to the application of the standard. Informative annexes provide information that is not essential to the application of the standard and which would, if included in the body of the document, detract from the application of the standard.	
Bibliography	Are all of the items listed referenced in the document, are they numbered in the order in which they are referred to, and are all references in the document listed in the Bibliography?	Yes ☐ No ☐ N/A ☐	See ISO/IEC Directives, Part 2, 6.4.2. The bibliography should not contain general bibliographic references that have been used in the preparation of the document but are not specifically referred to within it. Note that standards publications should be ordered alphabetically and then by identifier number.	

Annex F

ISO commenting template

Template for comments and secretariat observations

Date:	Document:

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/ Note** (e.g. Table 1)	**Type of com-ment**[2]	**Comment (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations** on each comment submitted

1 **MB** = Member body (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

NOTE Columns 1, 2, 4, 5 are compulsory.