

Standards and Standardization Handbook

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EUROPEAN COMMISSION

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1. Introduction

Voluntary, documentary standards play a critical, but frequently overlooked role in facilitating and regulating industry and commerce. The importance of standards to established markets for products and services and to product and market development cannot be overstated. Without standards our technologically advanced societies could not have developed. Despite providing a basis for all industrial and commercial activity, standards do not dictate how products are designed and manufactured, though they might dictate product safety requirements through their incorporation into regulation. Standards derive their legitimacy from the voluntary and consensual nature of their development process. Most of all, standards provide utility – if someone uses a standard it is because it provides a reliable, though not necessarily the only or best, solution to a problem.

From the point of view of research and development, standards are one of the most important tools used to take new technologies to the market place. By transferring research findings into guidance documents, standards provide a bridge connecting research to industry. This connectivity is critical to successful commercialisation.

This handbook has been produced to provide members of the research and development community, and particularly those engaged in collaborative projects supported by the European Commission Framework Programmes, with a basic understanding of standards and the standardization process and of how standards can contribute to the dissemination and implementation of project outputs for the wider benefit of industry, commerce and consumers. Whilst standards can play an important role in the dissemination of project results, they are often overlooked in favour of other mechanisms, such as scientific publications, conference presentations and patents. The purpose of this handbook is therefore to highlight the complementary role that standards can play in making the results of research accessible to potential users, and to help guide researchers through, what is frequently, the unfamiliar territory of standards making.

2. What standards are, what they do and who publishes them

2.1. Standard

Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits [ISO.IEC Guide 2004, definition 3.2]

2.2. Consensus

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 involved seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.

NOTE Consensus need not imply unanimity [ISO.IEC Guide 2004, definition 1.7]

2.3. Function of standards

Standards can perform any of the following four functions:

Interoperability / Compatibility

As with e.g. nuts and bolts, railway gauges, electrical plugs and outlets, and interoperability standards for computers and telecommunications systems (e.g. ISO 261:1998: ISO general purpose metric screw threads -- General plan)

Quality

Fitness for purpose or safety (e.g. ISO 13485:2003 - Medical devices -- Quality management systems -- Requirements for regulatory purposes)

Variety reduction/optimization (based on best practice)

Leading to mass production and price reduction (e.g. ISO 9407:1991 - Shoe sizes -- Mondopoint system of sizing and marking)

Information / Measurement

Test and measurement methods for describing, quantifying and evaluating product attributes such as materials, processes and functions (e.g. ISO 11124-1:1993 - Preparation of steel substrates before application of paints and related products -- Specifications for metallic blast-cleaning abrasives -- Part 1: General introduction and classification)

Standards typically contain both normative and informative elements. Normative elements are those parts of the standard that shall be complied with in order to demonstrate compliance with the standard. Normative elements are indicated by the use of the word 'shall'. Informative elements in standards provide clarification or additional information and are normally contained in Notes and Appendices. Informative elements may not contain requirements (i.e. the word 'shall').

For RTD projects, standardization can support dissemination and implementation of suitable results by making them readily accessible to potential users in a consistent format. The standardization process will also help identify and address outstanding issues.

2.4. Role of standards

Standards play a critical role in:

- o ensuring the safety, quality and reliability of products, processes and services;
- efficient production;
- cost reduction through competition;
- \circ supporting regulation.

By providing a bridge that connects research to industry, standards are equally valuable as a tool for promoting innovation and commercialization through:

- the dissemination of new ideas and good practice;
- o validation of new measurement tools and methods;
- \circ $\;$ the implementation of new processes and procedures.

2.5. Types of standards

There are 3 types of documentary standard:

Formal standards

Those published by:

- National Standards Bodies (NSB): e.g. AFNOR (France), BSI (UK), DIN (Germany), JISC (Japan), etc. A list of the approximately 160 National Standards Bodies that are members of ISO (the International Organization for Standardization), together with links to each of them, is available at <u>www.iso.org/iso/about/iso_members.htm;</u>
- Regional standards bodies: CEN, CENELEC, ETSI (for Europe), Pacific Area Standards Congress (PASC), the Pan American Standards Commission (COPANT), the African Organization for Standardization (ARSO), the Arabic Industrial Development and Mining Organization (AIDMO), and others (see, for example, <u>www.cen.eu</u>);
- o International standards bodies: ISO, IEC & ITU (see <u>www.iso.org</u>, <u>www.iec.ch</u>, <u>www.itu.int</u>).

Informal standards

Those published by SDOs (Standards Development Organisations), e.g. ASTM, IEEE, SAE, SEMI, VDI, etc.

Private standards

These are developed by a company or trade association.

2.6. Status of standards

Standards are voluntary documents and there is no compulsion on anyone to use them. However, if they are agreed to in a contract or referred to in regulation, there might be a penalty, either civil or criminal, for not complying with them. In addition, although standards are voluntary, courts might decide that, in the absence of relevant regulation, non-compliance with a standard to which a 'reasonable man' might be expected to conform could be sufficient grounds to determine liability.

The voluntary nature of standards differentiates them from regulation, for which there is a legal requirement to comply:

Regulation

Document providing binding legislative rules that is adopted by an authority. *[ISO/IEC Guide 2:2004, definition 3.6]*

Whilst compliance with European standards (ENs), as with other standards, is voluntary, the 'New Approach' directives of the European Union use compliance with specific standards as a means of demonstrating compliance with the relevant regulation; hence the need for members of CEN to adopt ENs at publication and to withdraw conflicting national standards

National standard

Standard that is adopted by a national standards body and made available to the public *[ISO/IEC Guide 2:2004, definition 3.2.1.4]*

2.7. Standards and patents

Unlike patents, standards are open access documents with no charge or licence fee for their use, apart from the cost of purchase. When experts participate in standards development they do so freely, and normally waive their rights to protection of any intellectual property they contribute. However, although reference in standards to the use of patented material is unusual, and alternative, unpatented, means of complying with a standard should be given, where ever possible, it is not impossible. If technical reasons justify reference to the use of items covered by patent rights then it is necessary to obtain an undertaking from the patent holder that they will be willing to negotiate worldwide licences with applicants throughout the world on reasonable and non-discriminatory terms and conditions. If this undertaking cannot be obtained then the development of the standard shall cease. Further information on this issue may be found in the ISO/IEC directives see link below under Standardization). CEN is also a signatory to these procedures.

3. How standards are developed

3.1. Pre-normative research & co-normative research

The technical basis of a new standard is usually established through a programme of research termed Pre-Normative Research (PNR), i.e. research undertaken prior to standardization (normalization). Such research would be used to demonstrate the feasibility and reliability of the technique or process to be standardized and to investigate its limitations. Once the technique or process has been developed and its boundaries have been explored, then, for new and emerging areas of technology, it would be normal to prepare a 'pre-standard', such as a Publicly Available Specification (PAS) or Technical Specification (TS), so as to provide a document in a relatively short time frame for evaluation by potential users. The availability of a pre-standard provides a basis for further research, usually termed Co-Normative Research - i.e. research undertaken in conjunction with the standardization process, to establish a statistical basis for the technique or process, in particular its reproducibility (same user), repeatability (different users) and uncertainty.

3.2. Standardization

Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

NOTE 1 In particular, the activity consists of the process of formulating, issuing and implementing standards.

NOTE 2 Important benefits of standardization are improvement of the suitability of products (including services) and processes for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation.

[ISO.IEC Guide 2004, definition 1.1]

Formal standards

Are proposed, developed and approved by the members of the standards body (for some jurisdictions, development might be undertaken by a SDO) based on consensus.

The development of formal standards typically follows the processes and procedures laid out in the ISO/IEC Directives Part 1 (Procedures for the technical work) and Part 2 (Rules for the structure and drafting of international standards) – see:

www.iso.org/iso/standards development/processes and procedures/iso iec directives and iso supplem ent.htm.

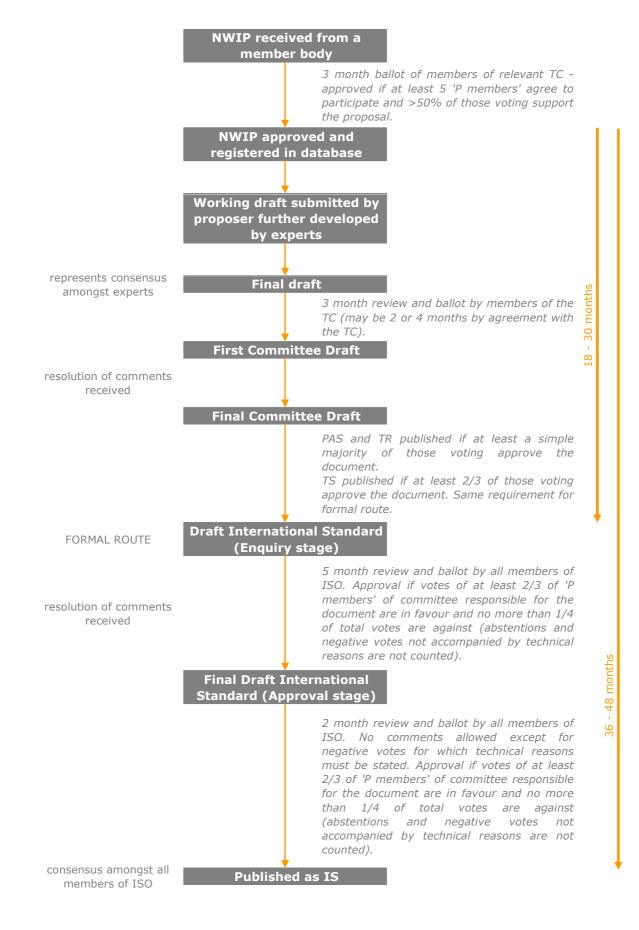
Formal standards are developed by independent experts, nominated by members of the standards organisation and working on a voluntary basis within Technical Committees that deal with standards in a particular area of technology or business – for a list of Technical Committees (TC) working in ISO see: <u>www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees.htm</u> – for a list of CEN Technical Committees see:

www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/default.aspx.

Approval of standards documents is the responsibility of the membership of the standards organisation and, depending on the status of the document, approval will either be given by the membership of the TC (for PAS, TS and TR) or by the full membership (for International and European Standards).

The diagram below shows the processes involved in developing the various international standards deliverables. Similar processes are used in regional and national standards bodies. Note that there is no equivalent deliverable in CEN or CENELEC to a Publicly Available Specification.

Development of international standards deliverables from NWIP (New Work Item Proposal) to publication of IS (International Standard):



3.3. Standardization & RTD project outputs

As indicated above, standardization can support dissemination and implementation of suitable outputs from RTD projects by making them readily accessible to stakeholders, and other interested parties, in an open and consistent format. For new and emerging areas of technology, the preparation of preliminary standards documents, such as Workshop Agreements, Publicly Available Specifications and Technical Specifications, provides users with a structured procedure that they can evaluate and which can be modified in the light of further experience. However, whilst such documents are subject to further development, users can have a high level of confidence that they represent existing 'good practice'. Indeed, subjecting the results of research to the formal standardization process will often help identify and address outstanding issues that might not previously have been apparent.

Of course, not all outputs of RTD projects will be suitable for the preparation of standards, but even where an output might not be suitable, it might well provide vital support to new or existing standards through, for example, the validation of a test method. Section 4 provides a 'decision tree' to help with identifying project outputs with the potential for standardization.

3.4. Examples of standardization outputs from European RTD projects

Excellent examples of how European RTD project outputs can contribute to standardization are provided by a number of coatings projects undertaken in the 1990s and early 2000s: MMST (multi-mode scratch testing); MICROLITE (chemical analysis of light element based coatings); CRATER (microscale abrasion testing of coatings); and INDICOAT (indentation in coatings). The work undertaken in these projects has supported the development and publication of the following CEN and ISO standards that are widely used in the testing of commercially produced ceramic and other coatings used in applications ranging from aero-engines to biomedical implants:

- EN 1071-3:2005 Advanced technical ceramics Methods of test for ceramic coatings Part 3: Determination of adhesion and other mechanical failure modes by a scratch test;
- ISO 20502:2005 Fine ceramics (advanced ceramics, advanced technical ceramics) Determination of adhesion of ceramic coatings by scratch testing;
- EN 1071-4:2006 Advanced technical ceramics Methods of test for ceramic coatings Part 4: Determination of chemical composition by electron probe microanalysis (EPMA);
- EN 1071-6:2007 Advanced technical ceramics Methods of test for ceramic coatings Part 6: Determination of the abrasion resistance of coatings by a micro-abrasion wear test;
- ISO 26424:2008 Fine ceramics (advanced ceramics, advanced technical ceramics) Determination of the abrasion resistance of ceramic coatings by a microscale abrasion test;
- ISO 14577-4:2007 Metallic materials -- Instrumented indentation test for hardness and materials parameters -- Part 4: Test method for metallic and non-metallic coatings.

3.5. Costs of standardization

Whilst participation in standardization activities is almost universally undertaken on a voluntary basis, the cost of participation in technical committees varies from country to country, with some National Standards Bodies making a charge to cover administration costs, whilst others do not. Similarly, some countries provide support for participation in meetings, particularly where this entails overseas travel, whilst others do not, and it is advisable to establish what rules apply in a particular country before committing oneself.

Whilst most of the work of standards development can be undertaken by correspondence via e-mail or through tele and web conferencing, it is usual for most projects to have one or more physical meetings during the development of a standard. For international standardization this might entail travel half way around the world for a meeting lasting no more than one or two hours, which for many organisations is completely out of the question. This applies particularly to experts from SMEs (Small and Medium Sized Enterprises), NGOs (Non-Governmental Organisations) and consumer groups, etc., and there is currently significant concern that stakeholders from such organisations are unable to play a full and active role in projects because of their limited resources. Indeed in some jurisdictions detailed consideration is being given as to how to facilitate the participation of these otherwise, seemingly disenfranchised stakeholders.

However, whilst participation in physical meetings might provide direct and immediate input to a project, participation via correspondence and other electronic means can often be far more effective, as it can usually be accomplished at a time and place to suit the individual. Both ISO and CEN, together with most National Standards Bodies and SDOs, maintain very effective password protected websites containing project and other relevant documents that the individual can work with at their leisure. The most important thing as far as any expert is concerned is that they comment fully at each stage of a document's development and if they are unable to do this, for whatever reason, then they should withdraw from the process rather than remain as a sleeping partner.

3.6. Common misconceptions about standardization

'ISO/CEN should develop a standard in such and such an area.'

ISO/CEN does not develop standards, its members do. Hence standards do not get developed without a member submitting a new work item proposal to the appropriate committee and without the proposal receiving sufficient support from the members of the committee, including at least 5 'P members' agreeing to nominate experts to help develop the document. Such requirements ensure that standards that are developed have international, rather than simply national relevance.

'As a nominated expert I need to reflect the opinions of my national committee.'

Experts are nominated as independent experts and are under an obligation to represent their expertise and not the interests of either their country or their employer.

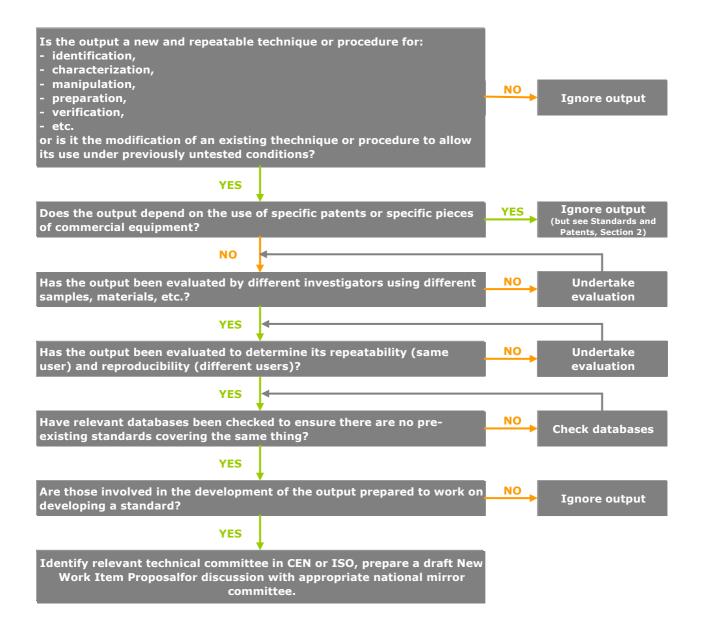
'Standards take years to produce.'

Both CEN and ISO have adopted strict timetables for standards development and it is now not possible for projects to exceed the maximum period of 4 years. Typically it takes 2 - 3 years from the submission of a New Work Item Proposal to the publication of a Technical Specification or Technical Report, depending on the complexity of the document, and 3 - 4 years for a full European or International Standard. PAS (in ISO only) can be published in around 12 months and CEN and International 'Workshop Agreements' can be published in 6 - 12 months from the original announcement of the workshop. Projects are deleted from a Technical Committee's work programme if they do not achieve certain stages within the permitted time. It is therefore important to ensure that, when planning a standard, essential preliminary work has been undertaken prior to submission of a New Work Item Proposal. Such work is generally referred to as Pre-Normative Research (PNR). Work undertaken during the development of a document, for example inter-laboratory studies to determine uncertainty budgets, is referred to as Co-Normative Research (CNR).

'Standardization inhibits innovation.'

Far from inhibiting innovation, standardization actually supports it by allowing innovators to focus on the essence of their innovation without the need to worry about peripheral elements that are not part of the innovative step but are essential to its realisation. Standards are agreed ways of doing things at the time of their development, and if better ways emerge, then they can be readily modified or withdrawn. All standards documents are reviewed at regular intervals to ensure they are still relevant. The first periodic review of full European and ISO standards occurs three years after publication, and this is repeated every five years thereafter. However, if evidence becomes available that a standard contains errors or is no longer relevant, then it can be modified or withdrawn at any time.

4. Decision tree for identifying RTD project outputs that have potential for standards development



5. Practical details of standards development

The membership of an ISO Technical Committee consists of '*P* members' (national members of ISO) that wish to 'participate' in the work, 'O members' (national members of ISO) that wish to 'observe' the work of the committee without actively participating in it, and 'L members' – Liaison members of another TC or external organisation that have an interest in the work of the committee.

P members can nominate experts to projects and have a responsibility to vote. They typically have a national 'mirror committee' that makes proposals for new work to be undertaken by the TC (NWIP – New Work Item Proposals), identifies and nominates experts to work on projects, provides comments on documents under ballot and recommends national responses to ballots. O members can submit NWIP but do not have the right or responsibility to vote on TC matters. L members can submit NWIP and can nominate experts to work on projects but, like O members, are not entitled to vote on TC matters. Note however, that O members of a TC, like all other members of ISO, have an opportunity to vote on and submit comments about documents at the 'Draft International Standard' (DIS) and 'Final Draft International Standard' (FDIS) stages in the development of an International Standard.

NWIP are typically, though not uniquely, submitted by P members, usually on the basis of existing national work – perhaps a national standard that the member believes would benefit the international community. The country or organisation submitting a NWIP is encouraged to provide a project leader (PL), who will work with experts nominated by other members to develop the document to the 'final working draft' (FWD) stage. The proposing country is also expected to provide a draft or outline of the document. In ISO, approval of a NWIP requires at least five P members to agree to participate in the work by nominating experts, together with at least a simple majority of those P members voting being in favour of the development (note that in all ballots, abstentions are not counted).

Approved Work Items (AWI) are developed by the nominated experts (acting as independent, not national, experts) within a project group (PG) under the leadership of the project leader. Projects are usually grouped together in Working Groups (WG) covering the same general area of work. Where a large volume of work is being undertaken in an area that does not impact on other parts of the Technical Committee's work, and which can be managed more effectively as a separate group, then this can be done in a Sub-Committee (SC). Sub-committees act in a semi-autonomous way and are essentially independent of the parent TC.

Both TC and SC can establish WG, approve NWIP, develop documents to the Committee Draft (CD) stage, etc. Work is generally undertaken using electronic means – e-mail, tele and web conferencing, though most project groups also have a physical meeting during the once or twice yearly Technical Committee plenary meetings. However, as attending such meetings can frequently entail considerable travel costs, many experts do not attend and either submit their comments electronically or by briefing another member of their national delegation who attends in their place.

Once the experts have reached consensus on the contents of the document, their Final Working Draft is submitted to the membership of the TC or SC for approval as a Committee Draft (CD). This is achieved through a three month ballot of P members (recent changes to the ISO/IEC Directives permit this to be 2, 3 or 4 months, depending on the circumstances). In this ballot, P members are required, through their mirror committees, to provide a national position (approve, reject, abstain), accompanied, where appropriate, with comments on the contents of the document. Comments, which can be of a general, editorial, or technical nature, are submitted on a standard 'comments template' and should be accompanied by a recommendation as to how each comment should be addressed. Committee Drafts are approved if they are supported by at least 2/3 of those voting (abstentions do not count).

Depending on what type of document was originally proposed, at this stage the CD can be published, either as a Publicly Available Specification (PAS), a Technical Report (TR) or a Technical Specification (TS). Note that only a simple majority of the P members voting is required for approval of PAS and TR. Alternatively, the more formal route towards a full International Standard (IS) is via the preparation of a Draft International Standard (DIS). However, whichever route is selected, it is necessary for any comments received to be satisfactorily resolved before publication or progression to the DIS stage. This is normally done at a 'comments resolution' meeting under the leadership of the project leader. Once all comments have been addressed to the satisfaction of the commenting member(s), the document is either sent for publication or submitted for its DIS ballot.

The DIS ballot is a five month ballot amongst all members of ISO, during which every member has the opportunity to review and comment on the document. The document is approved if at least 2/3 of P members of the Technical Committee responsible for it are in favour and no more than 1/4 of the total votes are against (abstentions and negative votes not accompanied by technical reasons are not counted). Comments received during the ballot must be resolved before the document is ready for its formal Final Draft International Standard (FDIS) vote. Note that the FDIS stage may be omitted if the document is approved without technical comments being submitted. The FDIS ballot is a two month ballot, during which all members of ISO have the opportunity to either approve the document, with editorial comments if necessary, abstain, or reject the document. Negative votes are only accepted if supported by technical comments. The requirements for approval of an FDIS are the same as those for a DIS.

The situation is somewhat different in CEN as all members of CEN (currently 31 countries – see <u>www.cen.eu/cen/Members/Pages/default.aspx</u>) are automatically members of all technical committees. However, in order to take part in the work of a particular committee, a member must appoint someone to the committee to be able to access relevant committee documents. In addition, unlike ISO, which operates on the principle of 'one member one vote', CEN operates a weighted voting system, which gives the larger economies a higher percentage of votes. Weighted voting applies to NWIP ballots for TS and EN and to the approval ballots for these two types of publication. Furthermore, although TS require approval through the equivalent of a CD ballot, in which all members of CEN may vote, there is no CD ballot stage for documents that are expected to be published as full European standards (EN). The equivalent of the DIS ballot is the Enquiry ballot and that of the FDIS ballot is the Formal Vote.

Consensus.

Whilst there are minimum ballot thresholds for a document to be published as an IS, TS, TR or PAS (in CEN, the minimum requirement for EN and TS is 71% of the weighted votes of those members voting, whilst TR require a simple majority of those members voting - there is no equivalent in CEN to the PAS), the over-riding objective should always be to reach a consensus amongst those involved. As indicated at the start of this handbook, consensus means that there is no 'sustained opposition to substantial issues by any important part of the concerned interests', but does not necessarily imply unanimity. The principle of consensus is vital to standardization, as it imparts legitimacy to the process and documents produced - people and organisations use standards not because they are forced to but because they are in general agreement with their contents. However, whilst consensus does not imply unanimity, it does require those involved to respond from a position of knowledge not ignorance. Hence members have a responsibility to ensure that they only support or reject documents if they have sufficient national expertise to make an informed judgement, and if they do not have the necessary expertise then they should always abstain. If not, there is a very real danger that poor quality or inaccurate documents will be approved and undermine both the standardization process and the principle of consensus. In reality, if a member cannot provide any comments on a document, they probably do not have the necessary expertise to review it and vote on it.

It is important to note that even where a member has nominated experts to a project they still have a responsibility to give other national stakeholders the opportunity to review and comment on the document produced, and are perfectly at liberty to reject the document if the national view is that it is inaccurate, incomplete or unnecessary.

6. List of acronyms

Acronym	Meaning	Notes
AIDMO	Arabic Industrial Development and Mining Organization	Regional standards body for Arabic countries.
ARSO	African Organization for Standardization	Regional standards body for Africa.
AWI	Approved Work Item	Standardization project that has been approved for development within a TC.
CD	Committee Draft	
CEN	European Committee for Standardization	www.cen.eu
CENELEC	European Committee for Electrotechnical Standardization	www.cenelec.eu
CNR	Co-Normative Research	Research work undertaken during the development of a standard. This would include, for example, work to determine the uncertainty budget of a test method.
COPANT	Pan American Standards Commission	Regional standards body for the pan-American countries.
EN	European Norm	<i>European Standard (ENs are adopted and implemented by all 31 members of CEN and CENELEC).</i>
ETSI	European Telecommunications Standards Institute	www.etsi.org
FWD	Final Working Draft	Document after it has reached consensus amongst the experts and before it goes out for ballot to the members of the TC.
IEC	International Electrotechnical Commission	www.iec.ch
IS	International Standard	Standard approved by all members of ISO.
ISO	International Organisation for Standardization	www.iso.org
ITU	International Telecommunications Union	www.itu.int
IWA	International Workshop Agreement	
NWIP	New Work Item Proposal	
PAS	Publicly Available Specification	
PASC	Pacific Area Standards Congress	Regional standards body for the Pacific area.
PG	Project Group	
PL	Project Leader	
PNR	Pre-Normative Research	Research work undertaken in preparation for the development of a standard. This might be, for example, research to demonstrate the repeatability and reproducibility of a particular technique or measurement method.
SC	Sub-Committee	Sub-committees are established to help make the management of a TC easier, for example where there is an area of the TC's work that can be undertaken independently of other work in the TC. SCs make their own decisions regarding NWIP, publication of PAS, TS and TR.
SDO	Standards Development Organisation	
TC	Technical Committee	
TR	Technical Report	
TS	Technical Specification	
WG	Working Group	





This handbook has been produced to provide members of the research and development community, and particularly those engaged in collaborative projects supported by the European Commission Framework Programmes, with a basic understanding of standards and the standardization process and of how standards can contribute to the dissemination and implementation of project outputs for the wider benefit of industry, commerce and consumers. Whilst standards can play an important role in the dissemination of project results, they are often overlooked in favour of other mechanisms, such as scientific publications, conference presentations and patents. The purpose of this handbook is therefore to highlight the complementary role that standards can play in making the results of research accessible to potential users, and to help guide researchers through, what is frequently, the unfamiliar territory of standards making.

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