Milestone MS4.1: Guidelines and info-package on standardization process for ACTRIS-2 partners and associated

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Content

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Purpose of the document

This document outlines mandatory steps and requirements when drafting standardization documents, and guides ACTRIS-2 partners and associates in selecting and proposing mature technologies, methods and techniques for future standardization.

General information on standard-making process

What are ISO and CEN?

ISO is the International Organization for Standardization, an independent, non-governmental standard-setting body composed of representatives from various national standards organizations. ISO has a membership of 164 national standards bodies from large and small, industrialized, developing and in transition countries, in all regions of the world.

CEN comes from The European Committee for Standardization and it is the European Standardization Body for the development of standards in all areas except telecommunications and electro-technical domains. The members are the National Standardization Bodies of 27 European Union countries plus seven Associate Members (organizations representing the interests of different business sectors, consumers, SMEs, trade unions, and the environment).

What is standardization? What is a standard?

A standard is a document developed by common agreement and approved by a recognized authority (body), that provides rules, guidelines and characteristics for activities or products, aiming to achieve an optimum degree of order in a given context. Standards can provide recommendations, requirements or rules referring to products, instruments, processes or services, and can also be used to describe how a measurement should be performed or how a certain test method should be implemented. Standards can also be used to establish a common terminology within a specific sector. Standardization is the elaboration and process of a standard.

Why do we need standards?

Standards are voluntary in application, unlike legislation. The legislation in turn, can refer to a standard as means of compliance with regulatory requirements. Compliance with the standard is recognized as a possible way of fulfilling regulatory obligations. From another perspective, a standard is a mean to argue that a product, instrument, process or service **has reached a required maturity** to follow standardized rules, guidelines and characteristics.

Standards can also be used to **promote new technologies** and best practices, spreading innovation and knowledge throughout their applicable domains.

When should we write standards?

If that specific standard responds to a need in the market:

> The standard organizations do not decide when to develop a new standard, but respond to a request from industry or other stakeholders such as consumer groups. Typically, an industry

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sector or group communicates the need for a standard to its national member who then contacts the standard organizations.

When the desired standard is based on global expert opinion

Standards are developed by groups of experts from all over the world, that are part of larger groups called technical committees. These experts negotiate all aspects of the standard, including its scope, key definitions and content.

How are ISO and CEN involved in the standardization process?

In ISO, a standard is developed by a panel of experts, within a technical committee (TC). Once the need for a standard has been established, these experts meet to discuss and negotiate a draft standard. As soon as a draft has been developed it is shared with ISO's members who are asked to comment and vote on it. If a consensus is reached the draft becomes an ISO standard, if not it goes back to the technical committee for further edits.

In CEN, all technical work is carried out under the management of the CEN Technical Board (BT). BT is responsible for setting up technical and project committees and monitoring the progress of the work. The BT is responsible for setting up rules for the development of European standards. Next, BT establish a Technical Committee(s) (TC) in order to develop the standards related to a specific sector. In the case when a certain number of standards are needed on a particular subject (e.g. lidar instrumentation, lidar quality assurance and lidar operation), a Project Committee (PC) is established instead of a TC. PC function in a similar way to TC but they are not allowed to decide on the inclusion of new work items in their programme and they are disbanded once they have finished the standardization work for which they were created. TC may set up one or more working groups in order to focus on specific tasks or to provide a draft standard.

What are the documents developed by ISO?

International standards

International standards are the main products of ISO. International standards are written by a technical committee or by one or several working groups. After a standard draft has been developed, it is shared with ISO's members to comment and vote on its acceptance.

Technical reports

These are issued when a technical committee or subcommittee has collected data of a different kind from that normally published as an International Standard such as references and explanations.

Technical and publicly available specifications

Technical specifications may be produced when "the subject in question is still under development or where for any other reason there is the future but not immediate possibility of an agreement to publish an International Standard".

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Technical corrigenda

These are amendments made to existing standards due to minor technical flaws, usability improvements, or limited-applicability extensions. They are generally issued with the expectation that the affected standard will be updated or withdrawn at its next scheduled review.

ISO guides

These are meta-standards covering "matters related to international standardization".

What are the documents developed by CEN?

European Standards (EN)

The main documents developed by CEN are the European Standards (EN). The development of an EN includes a public discussion/debate period (enquiry), followed by the approval by weighted vote by CEN members.

Technical Specifications (TS)

Second are the Technical Specifications (TS). Documents that are produced when there is no immediate need or not enough consensus for ENs, or the technology is not mature enough and the subject is still under debate or technical development.

Technical Reports (TR)

Technical Reports (TR) are a series of documents containing informative material such as the state of the art on a particular subject which is not suitable to be published as a EN of TS.

How to write a standard

Who is writing the standard?

Standards are not drafted by Standard Bodies but by experts in the specific field covered by the standard. The Standard Bodies only facilitate this process. Standard development is undertaken in technical committees. Experts participate in TC and PC via the National Standardization Body in their country and could come from trade associations (industry), professional institutions, government, consumer bodies, academia, education bodies, customers, certification bodies, etc.

What are the steps in developing a Standard?

European level

Once a proposal for new work has been accepted, it is allocated to a new or existing TC/PC. The TC/PC will elaborate a draft standard. Once a draft is ready, a public consultation will take place. This enquiry is a key stage in the process of ensuring transparency and acceptability of a standard.

The comments of the enquiry will be examined by the TC/PC and the draft will be amended. A report of this process will be drafted and will include justification for comments not accepted. The final draft will be subject to a formal vote. This is a weighted vote of all national standardization bodies that are member of CEN. The final draft will then be modified to an EN.

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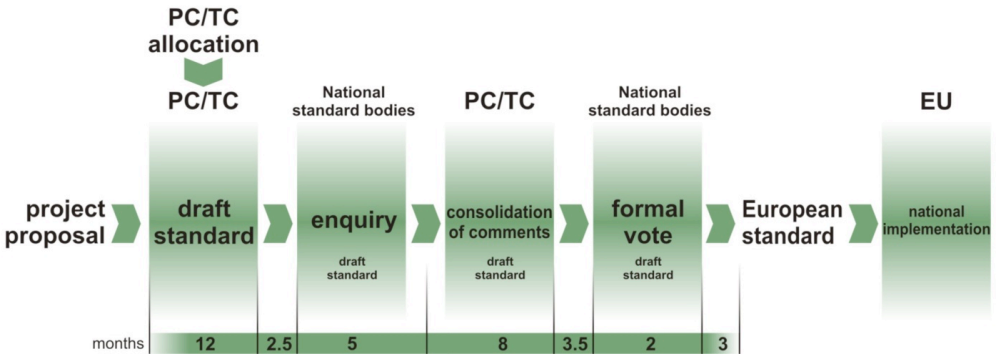


European Standards (ENs) are developed in a maximum timeframe of 3 years. This time starts to run once the TC/PC or the BT has taken the decision of registering the new work item.

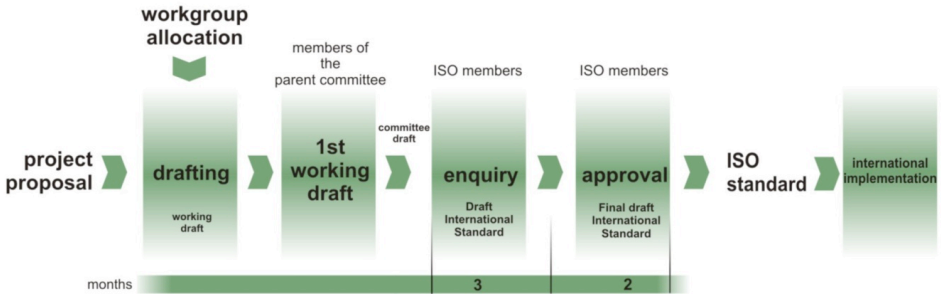
International level

The first step is to confirm that a new International Standard in the subject area is really needed. A new work item proposal (NWIP) is submitted to the committee for vote.

Usually a working group (WG) is set up by the parent committee to prepare the working draft (WD). The WG is made up of experts and a Convenor (usually the *Project leader*). During this stage, experts continue to look out for issues around copyright, patents and conformity assessment. Next, the draft from the working group is shared with the members of the parent committee.

The Draft International Standard (DIS) is submitted to ISO Central Secretariat by the committee secretary. It is then circulated to all ISO members who get 3 months to vote and comment on it.

The Final Draft International Standard (FDIS) is submitted to ISO/Central Secretariat (ISO/CS) by the committee secretary. The FDIS is then circulated to all ISO member for a two-month vote. The standard is approved if a two-thirds majority of the P-members of the TC/SC is in favor and not more than one-quarter of the total number of votes cast are negative. The ISO final document is submitted for publication.



Is it possible to transfer EU standards to ISO and vice versa?

The Vienna Agreement cover the development and adoption of identical ISO and CEN Standards, with the characteristics and usefulness resulting from both statuses, whereas the drafting work is carried out only once, in one organization.

The organization which wants to adopt an available publication from the other organization submits it to its own adoption procedures. Ideally, this publication should be adopted without change.

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Drafting a standard

How is a standard written?

A standard needs to be as detailed as necessary within the limits of its scope, taking full account of current technology and science, be prepared with user and consumer acceptance in mind and be comprehensible to qualified users.

What is the typical structure of a standard?

As a minimum, a standard shall include the following elements:

- **The title**

  The title must be clear and concise. It can include the following elements: an introductory element, a main element, a complementary element

- **The foreword**

  For exemplification, the forewords of ISO documents are standard texts drafted by ISO's Technical Management Board. ISO Central Secretariat (ISO/CS) inserts them during editing and publishing

- **The scope** defining the subject, and the area to which the standard applies, areas excluded, kind of document (specification, test method, guidelines...)

  The scope is mandatory and it describes what the document does (for example, This Standard: "specifies", "establishes", "gives guidelines for", "defines terms"

- **The main provisions of the standard** (the recommendations, measurement method, requirements...) - for CEN.

In addition to these sections a standard will usually include:

- **An introduction**, explaining, for example, what the reason for developing a standard is, and why it is helpful

  It may describe the content of the standard and give information on why the standard is needed. It can help users decide whether the standard meets their needs. Don't include any disclaimers or statements intended to limit the use of the standard.

- **Normative references**

  Are references to other documents (mainly European, ISO, IEC or other standards) which are indispensable for the application of the standard. The number of normative references shall be limited to the minimum needed and the referenced documents shall be available when the standard is published.

- **Terms and definitions** giving definitions necessary for the understanding of the terms that are used in the standard

  A definition is a single phrase that can replace the term wherever used. It should not take the form of, or contain, a requirement or recommendation.

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- **Clauses** - for ISO

  Clauses and sub-clauses form the main part of any standard. This is the section that tells users of the standard what they need to do to implement it.
  In all clauses, it should be clear about what is a requirement and what is a recommendation or other statement.
  ISO does not allow its standards to mandate the use of services such as testing, and certification (for example, by another company). The requirements should be written so that they can be verified by anyone.
  In ISO standards, it is best not to refer to trademarks or companies. Patented items can be referred to under certain conditions.

- **Annexes**, are used to provide additional information to the user of the standard

  Normative, which are an integral part of the standard (a test method that the user is required to follow)
  Informative, which contain additional information/examples to better understand the standard, but are not indispensable for the application of the standard.
  The normative or informative character of an annex shall be specified.

- **Bibliography**

  List of documents that provide background information to the user.

Based on the structure and the aim of a standard, a series of requirements are extracted in order to determine if a set of rules, guidelines, characteristics for activities or products, certain technologies, instruments or methods are appropriate to be proposed for standardization. These requirements are covered by an open checklist, meant to assess the technological level and aim of the subject.

Checklist to identify if a technology / technique / method qualifies for standardization

- What is the topic of the proposed standard?

  a short description of the topic, describing in few and simple words the most important aspects of the subject.

- Is the subject of the proposed standard (technology, method, etc.) mature enough to be subject to standardization?

  from an expert opinion in the research area covered by the proposed standard, is the technology reliable enough to be subject of a standardization; are the guidelines or rules well developed in order to completely cover the requirements of a standard; are the products mature enough - having a complete description of data formats, nomenclature, theoretical background, processing, associated error calculus and possible quality assurance; are the technologies ready to be subject to standardization; are the methods established, debated and accepted.

- Is the subject of the standard widely and intensely used?
- What would be the coverage of the standard?

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is the subject used at the EU level or international level

- What would be the added value of this standard?
  who are the main stakeholders and how will they use the proposed standard. Is the industry part of the stakeholders group.
- Are there any other standards available or under development on the same topic(s)?

Useful links

- ISO guidelines (http://www.iso.org/iso/PUB100342.pdf)
- ISO: how to write standards (http://www.iso.org/iso/how-to-write-standards.pdf)
- ISO standard development (http://www.iso.org/iso/home/standards_development/ resources-for-technical-work/support-for-developing-standards.htm)
- Types of documents developed by CEN (http://www.cen.eu/CEN/PRODUCTS)
- Responsibilities and functioning of a Technical Committee (www.cen.eu/go/tcs)
- Responsibilities and functioning of a Project Committee (www.cen.eu/go/projectcommittee)
- Liaison with a Technical or Project Committee (www.cen.eu/go/tclo)
- Development of Technical Specifications (www.cen.eu/go/specs)
- Development of Technical reports (www.cen.eu/go/tech_reports)
- Web site of the Environmental Helpdesk (www.cen.eu/CEN/services/ehd)
- CEN Guide 4: Guide for addressing environmental issues in product standards (www.cen.eu/go/guide4)
- CEN/CENELEC Guide 6: Guidelines for standards developers to address the needs of older persons and persons with disabilities (www.cen.eu/go/guide6)
- CEN/CENELEC Guide 11: Product information relevant to consumers - Guidelines for standard developers (www.cen.eu/go/guide11)
- A list of published standards and standards under development CEN (http://esearch.cen.eu/esearch/)
- A list of published standards and standards under development ISO (http://www.iso.org/iso/home/search.htm)
- Standards and Standardization, A practical guide for researchers, Dr. Peter Hatto, (https://ec.europa.eu/research/industrial_technologies/pdf/practical-standardisation-guide-for-researchers_en.pdf)
- Agreement on Technical Cooperation between ISO and CEN (http://boss.cen.eu/ref/Guidelines_implementation_VA.pdf)

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