Discussion Paper: Outline of ISO process for developing standards

The procedures for the technical work are given in the ISO/IEC Directives, Part 1, 2011. This document can be found at: www.iso.org/directives . An overview of International Standards and "private standards" can be downloaded at: http://www.iso.org/iso/private_standards.pdf. Some extracts from the latter are included in this discussion paper.

Background

ISO is the International Organization for Standardization. It is a worldwide federation with a membership of 160 national standards bodies from countries large and small, industrialized, developing and in transition, in all regions of the world. ISO's portfolio of more than 18 500 standards provides business, government and society with practical tools for all three dimensions of sustainable development: economic, environmental and societal.

The ISO member is a "national standards body" (NSB) expected to be the organization most representative of standardization in its country and typically with a formal national remit from their government for voluntary standardization. In the ISO membership, there is a good deal of diversity among NSBs that make up the formal ISO standardization system. In developing countries, for example, NSBs are often government departments with a formal remit for membership in ISO, whereas in developed countries, NSBs are often non-governmental organizations recognized by their government as the entity responsible for such voluntary standardization.

In some countries, there may be numerous standards bodies, each responding to the needs of one or more industry sectors, but with one national standards body coordinating their activities and responsible for membership in ISO. In some of these cases, the ISO member may not itself develop standards, but has the responsibility to coordinate national standardization activities and the authority to impart the status of " national standard " to standards developed by other bodies in their country.
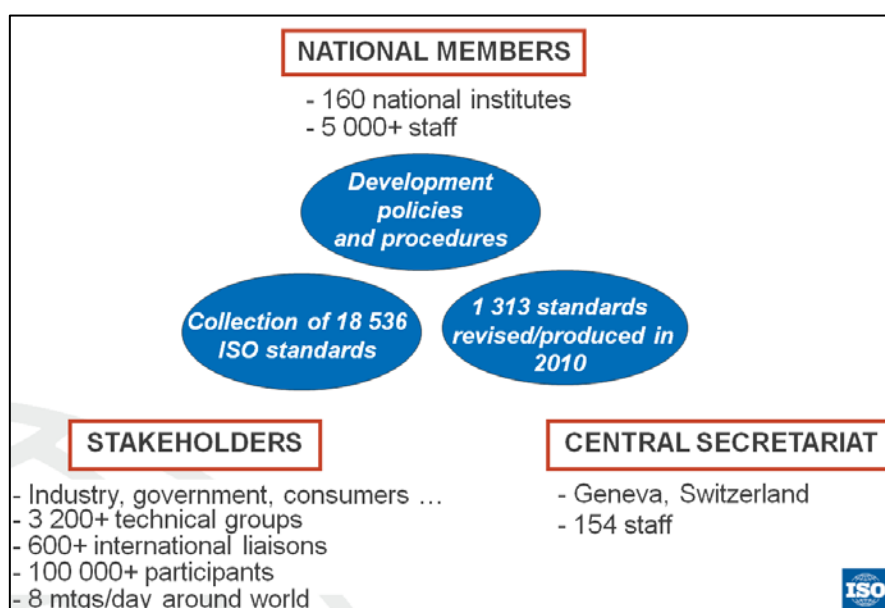
Effectively all ISO members comply with the principles set out in annex 3 of the WTO TBT agreement Code of Good Practice for the preparation, adoption and application of standards. In accepting the TBT Agreement, WTO Members agree to ensure that their central government standardizing bodies accept and comply with the Code of Good Practice and agree also to take reasonable measures to ensure that local government, non-governmental and regional standardizing bodies do the same. The Code is open to acceptance by all such bodies. Obligations by these NSBs having adopted the Code include conducting public consultations on draft national, regional and international standards, making their work programme and catalogue publicly available and appropriately addressing comments and complaints.

Features such as ISO NSB national coordination and representation ; NSBs' associated remits from their governments ; NSB disciplines of the TBT Code of Good Practice, and ISO's adherence to the principles of international standards set out in the TBT Agreement's second triennial review, all contribute to ISO's broad recognition as a developer of " formal " international standards.

ISO also collaborates extensively with two other formal international standardizing organizations, namely the International Electrotechnical Commission (IEC) and the ITU (International Telecommunication Union). In 2001, the three organizations established the World Standards Cooperation (WSC) as a means to coordinate policies and shared objectives, and to provide direction on converging areas of technology.

ISO has a specific status with many UN agencies, including the WHO and FAO. (*FAO presently has liaisons with 24 TCs.*) ISO is also an observer at the WTO Committee on Trade and Environment (CTE), the Committee on Technical Barriers to Trade (WTO TBT) and the Committee on Sanitary and Phytosanitary Measures (SPS).

In December 2010, an ISO committee (ISO/TC 34/SC 16, *Food products — Horizontal methods for molecular biomarker analysis*) granted IPPC, *The International Plant Protection Convention*, the status of category A liaison. Liaison organizations are able to actively participate in the ISO standardization process.

ISO and OIE, *The World Organisation for Animal Health*, are currently working on a formal agreement regarding liaisons and cooperation in specific areas.

ISO endeavors to collaborate with other organizations that develop standards having important global reach and relevance through, for example, partnership arrangements (e.g. with the Institute of Electrical and Electronics Engineers (IEEE) in the areas of health informatics (e-health) and information and communication technologies.
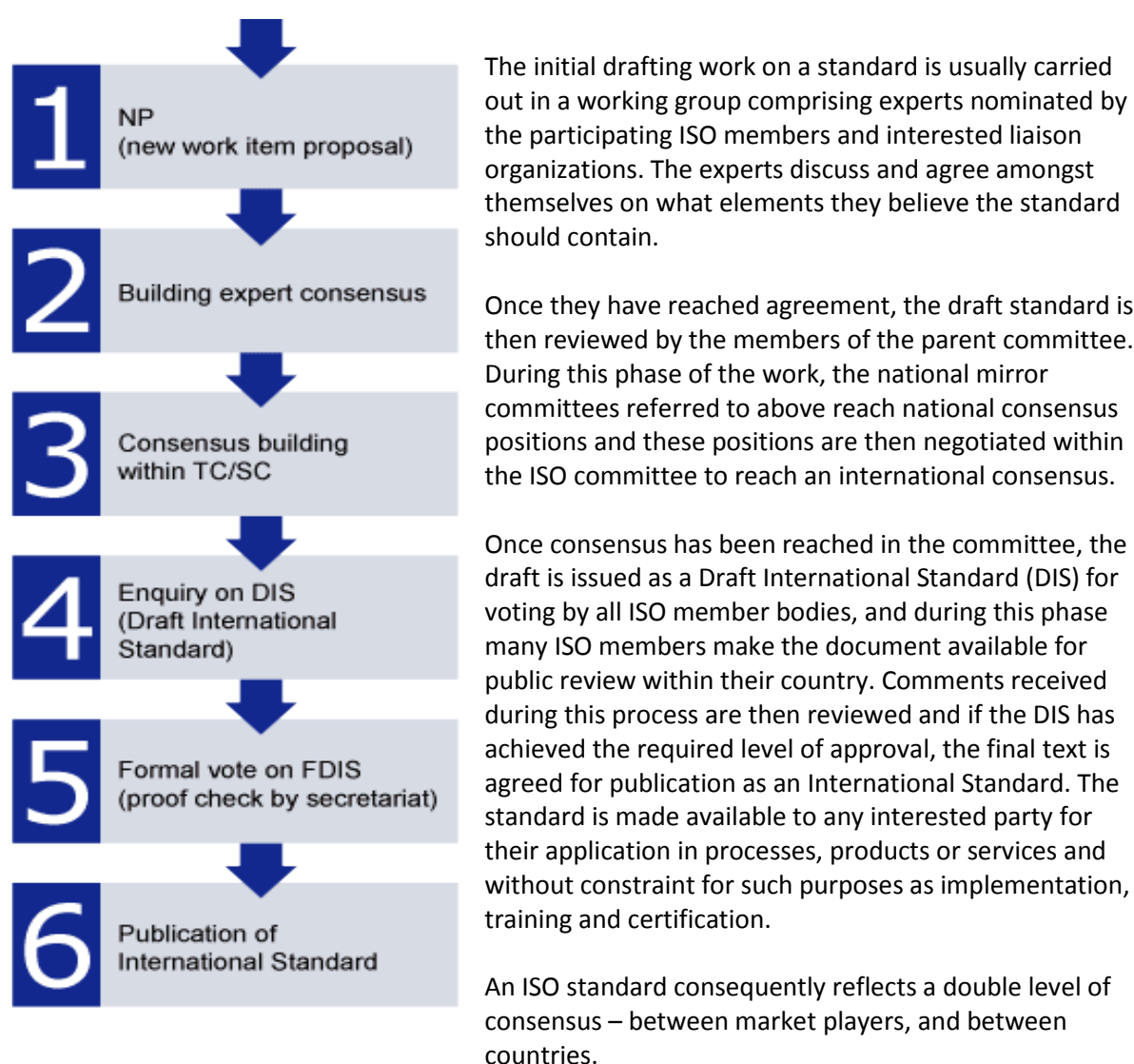
ISO's standards development process

ISO standards are developed in response to needs recognized by market players whether they are industry, government, consumers or others. There are basically two steps: 1) concensus among experts and 2) concensus at the national level.

The first step in the process seeks to verify that an ISO standard on a specific subject will bring added value. The process involves broad consultations to ascertain that there is indeed support for the proposed development of an ISO standard on a particular topic and, in particular, that the market players and other stakeholders will commit appropriate resources to the development of the standard.

If the acceptance conditions are met, the proposal formally becomes a standards project assigned to a relevant ISO technical body, which will have been established with a defined scope and sector, through an open and consensus-based process. ISO standards are developed through a hierarchy of technical committees and subcommittees (currently more than 700) and their associated working groups (currently more than 2 200). The "participating" members of technical committees and subcommittees are those ISO members that have expressed the wish to participate actively in the work. These participating members typically form national mirror committees bringing together representatives of all interested parties at the national level, including industry, government, consumers, academia and others as appropriate. ISO members may also opt to be observers or non-members of committees according to their national interests.

ISO's procedures provide mechanisms by which other international and broad regional organizations may participate in the work and some 700 organizations, including most of the United Nations agencies, are engaged with relevant ISO committees in the development of ISO standards.

1 NP (new work item proposal)

2 Building expert consensus

3 Consensus building within TC/SC

4 Enquiry on DIS (Draft International Standard)

5 Formal vote on FDIS (proof check by secretariat)

6 Publication of International Standard

The initial drafting work on a standard is usually carried out in a working group comprising experts nominated by the participating ISO members and interested liaison organizations. The experts discuss and agree amongst themselves on what elements they believe the standard should contain.

Once they have reached agreement, the draft standard is then reviewed by the members of the parent committee. During this phase of the work, the national mirror committees referred to above reach national consensus positions and these positions are then negotiated within the ISO committee to reach an international consensus.

Once consensus has been reached in the committee, the draft is issued as a Draft International Standard (DIS) for voting by all ISO member bodies, and during this phase many ISO members make the document available for public review within their country. Comments received during this process are then reviewed and if the DIS has achieved the required level of approval, the final text is agreed for publication as an International Standard. The standard is made available to any interested party for their application in processes, products or services and without constraint for such purposes as implementation, training and certification.

An ISO standard consequently reflects a double level of consensus – between market players, and between countries.

The process shown above outlines the main steps in the preparation of an International Standard. More information on the rules governing these steps is provided in the ISO/IEC Directives Part 1 and the ISO Supplement to the Directives, both of which are available online at: www.iso.org/directives

Detailed flowcharts for various ISO deliverables (including International Standards, Technical Reports and Technicial Specifications) can be seen under: www.iso.org/tipsandtools. Screen shots are shown below.
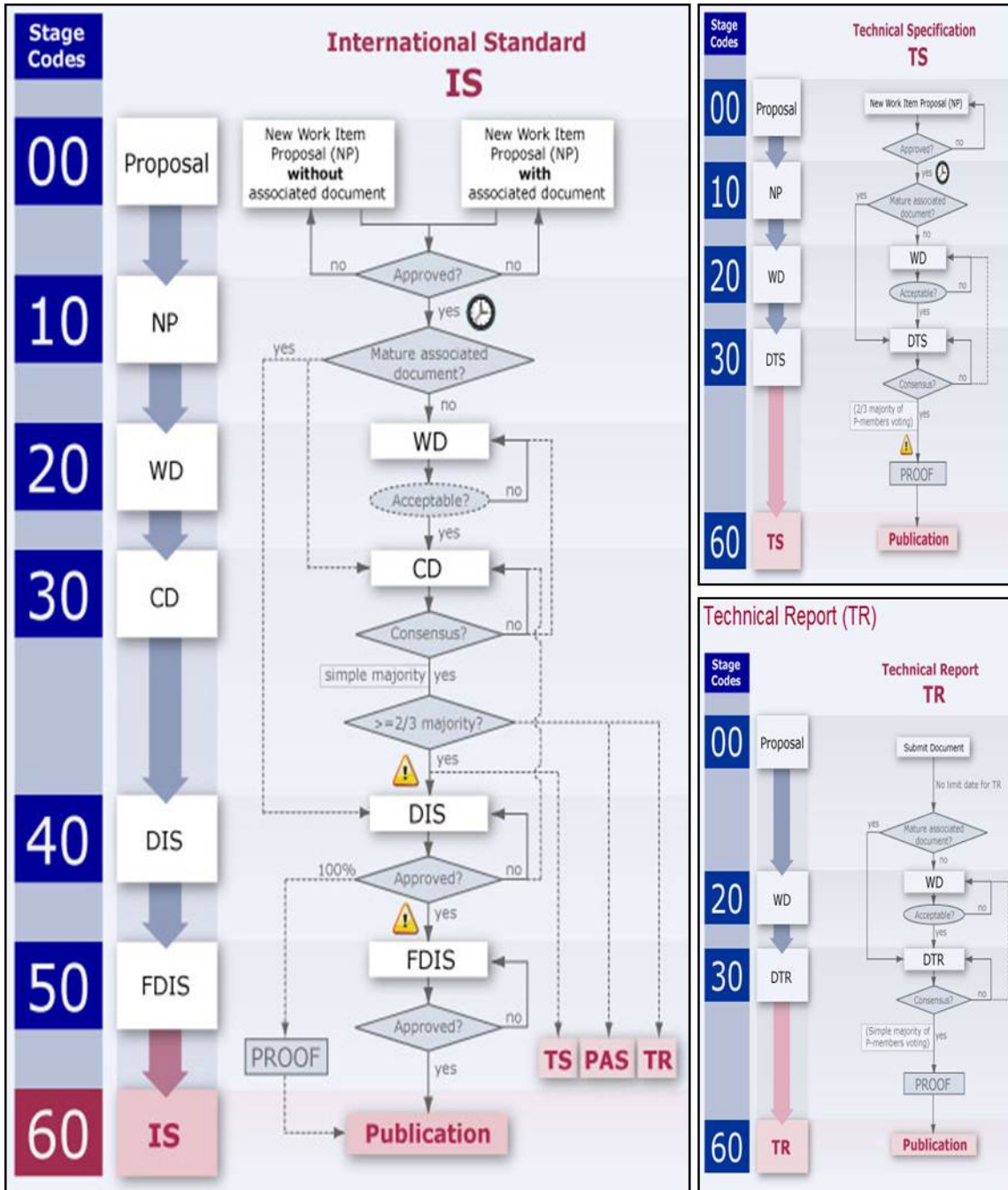
Time Frames

At the present time, ISO has 3 time frames for developing International Standards*: 2, 3 and 4 years. These time frames start from the moment a new proposal has been accepted by the member bodies. It is hoped that in the future the time to publication can be reduced; pilot studies are presently being tested.
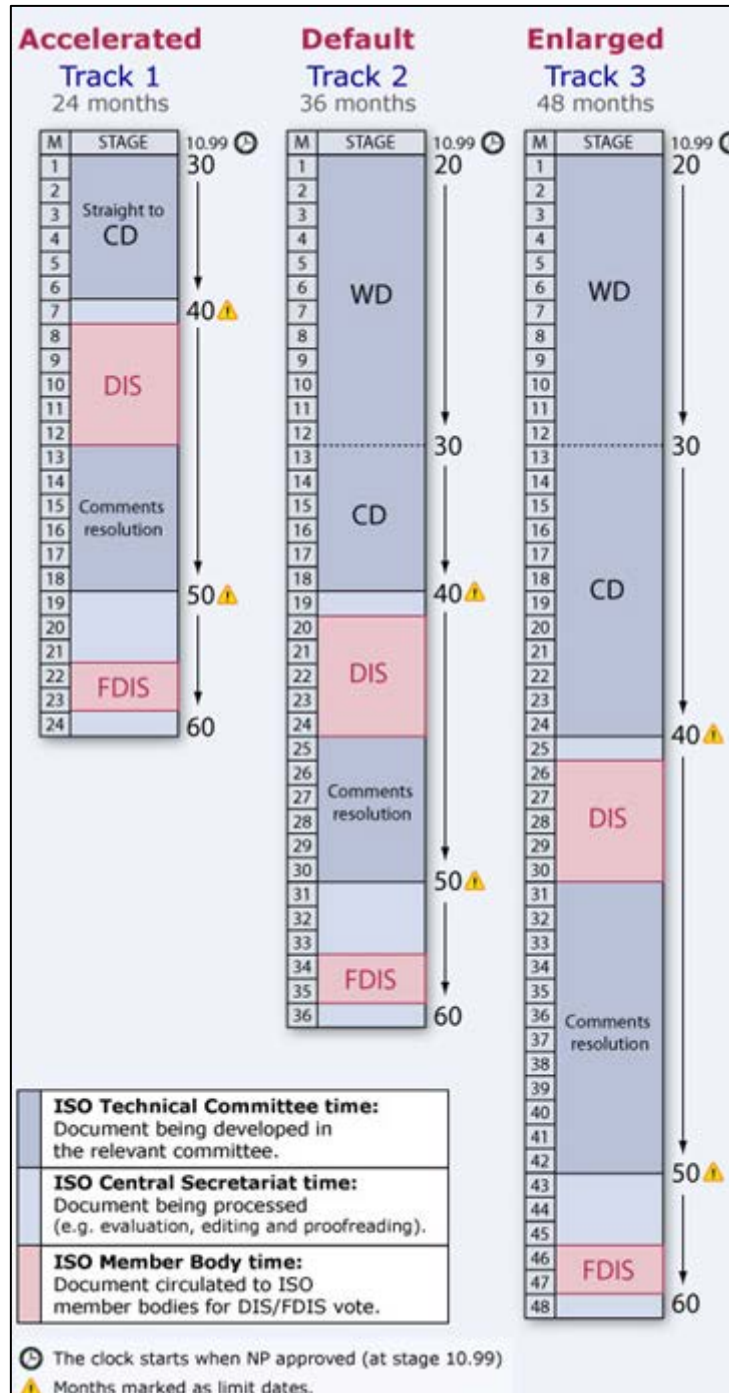

WD = Working Draft; CD = Committee Draft; DIS = Draft International Standard; FDIS = Final Draft International Standard

* An "International Standard" is one type of deliverable. Other deliverables include Technical Specifications, Publicly Available Specifications, Technical Reports, Guides and International Workshop Agreements. These are explained in:
http://www.iso.org/iso/standards_development/processes_and_procedures/deliverables.htm

IT support for the process

ISO has developed a wide range of tools in order to facilitate project management across all the stages of development. A resume is illustrated below.

The standards development chain & electronic balloting
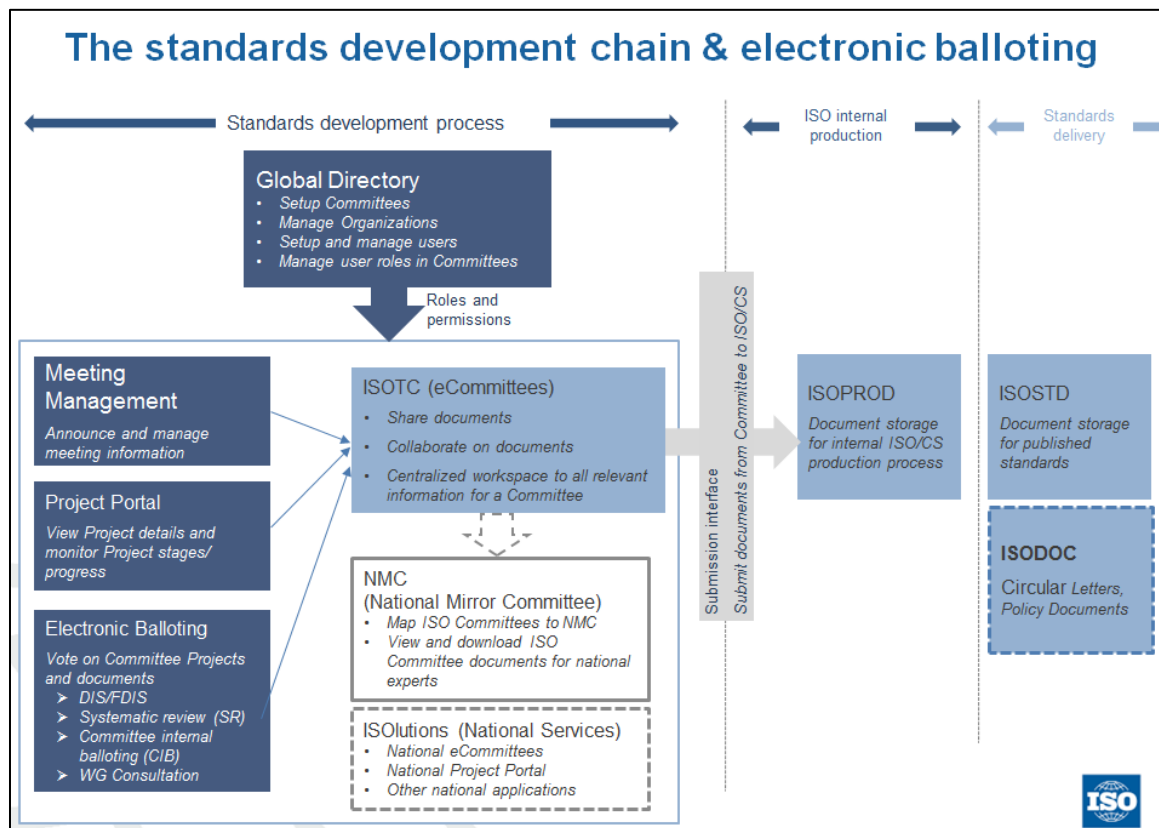
Experts are registered in the Global Directory by their member organizations. For example, an expert registered for TC 34/WG 12 (*Food products — Application of ISO 9001:2000 in the agriculture*) would contribute to the development of documents under this working group*.*

The expert has access to all the documents stored online for this project in what we refer to as "eCommittees". Access rights are linked to the Global Directory and are password-controlled.

Where a standard is along the chain of development can be viewed through a "project portal" at any time. That way, it is not just the project leader who knows how far a project has advanced! *(or if the project is behind schedule...)*

Voting is handled electronically at all levels. Member bodies can submit comments on the drafts. These are taken into consideration by the working group who may choose to implement some but not all of the comments. A record of the decisions taken (and why) is posted to ensure transparency.

Systematic Reviews

In order to maintain standards, systematic review ballots are launched on a regular 5-year basis. If needed, these reviews can be undertaken earlier. The members report back on whether the standard has been implemented in their countries, and indicate whether or not the standard needs to be revised.