SAND2019-13243C

New Business Proposal: ISO 35001 road map: supporting documents

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Sandia National Laboratories

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SAND XXXX-XXXX

Session Objective

To initiate dialogue on a road map for Working Group 5 after ISO 35001 is officially published.

Best Practice Implementation???

ISO 35001 History

Analogous Standard

European Committee for Standardization (CEN) Workshop Agreement (CWA)

2007: CWA 15793 -

2008 adopted

2011 renewed

2011: CWA 16335 – Biosafety Professional Competencies

2012: CWA 16393 – Guidance Document to CWA 15793

CWA 15793 HAS EXPIRED

Advance global laboratory biorisk management

ISO 35001

2014: Working Group 5 begins ISO 35001 development

ISO 35001 is principally based on CWA 15793

ISO 35001 designed to be consistent with other ISO management system standards: ISO 14001 & ISO 45001

ISO 35001 establishes performance requirements for lab biorisk management

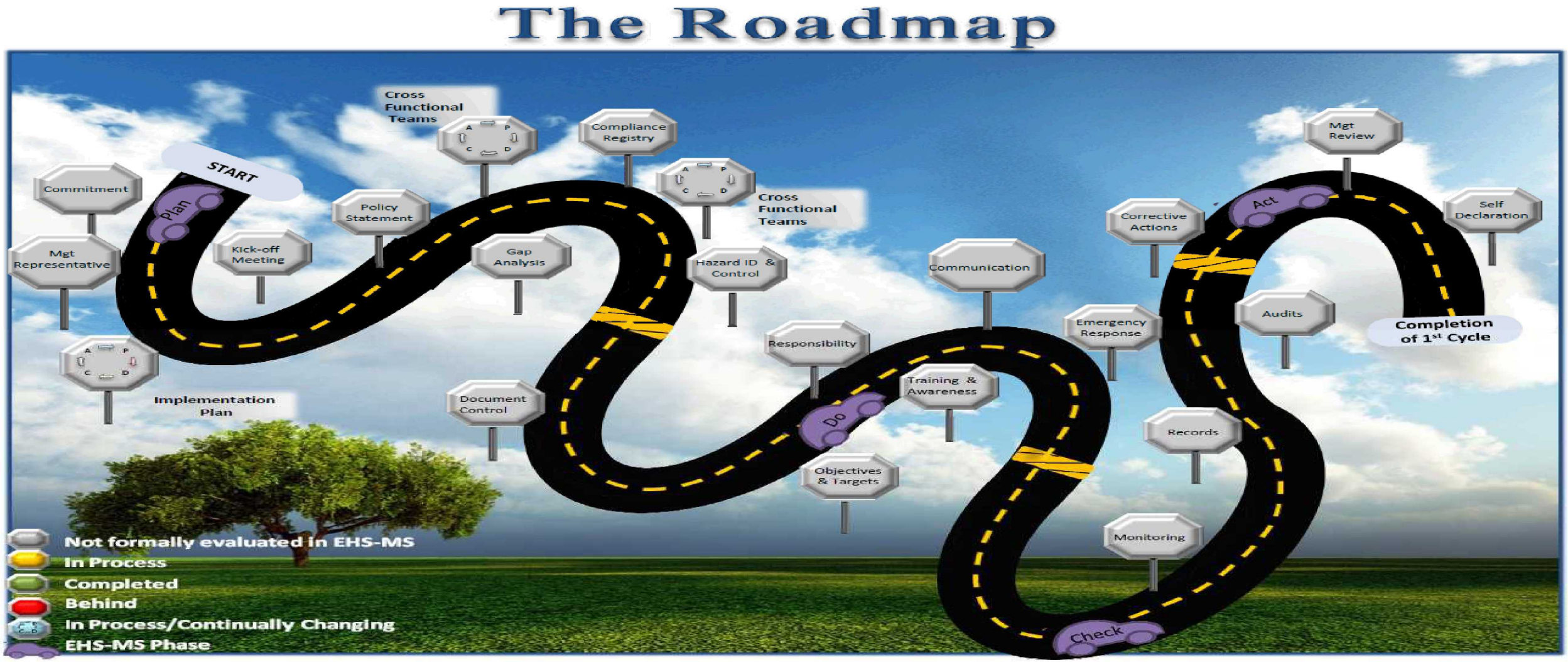
An informative implementation annex was approved in the initial scope, but deferred due to time constraints

ISO 35001 Elements Include

- Biorisk Management Policy
- Hazard Identification, risk assessment and risk control
- Roles, responsibilities and authorities
- Training awareness and competence
- Operational control
- Emergency response contingency plans
- Inventory monitoring and control
- Occupational medicine
- Accident and incident investigation
- Inspection and audit
- Biorisk management review

Successful implementation of ISO 35001 requires specialized expertise in biorisk management.

How might WG5 outputs enable global adoption of ISO 35001?



Source: P. Olinger, USDA ARS Symposium, Feb. 19, 2019

Informative document precedents

ISO 45001

Occupational Health and Safety

The standard is based on OHSAS 18001, conventions and guidelines of the International Labour Organization including ILO OSH 2001, and national standards.

Includes an informative Annex that serves as Implementation Guidance for the Standard

ISO 35001

Laboratory Biorisk Management

The standard is based on CWA 15793, but does not presently include an Annex clarifying implementation guidance, as was envisioned in the original proposal.

Analogous materials exist:

- CWA 16335 - Biosafety Competencies
- CWA 16393 - Guidance Document to CWA 15793

OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2019

Standard

- Developed for laboratories carrying out veterinary diagnostic tests and surveillance, as well as vaccine manufacturers and regulatory authorities.
- Primary objective is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products.
- Four major chapters
- **Chapter1.1.4 – Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities**

Companion Chapter

- **Chapter 2.1.3 – Managing Biorisk: Examples of Aligning Risk Management Strategies with Assessed Biorisks**
- Outlines requirements and responsibilities to be addressed in the management of biorisk in veterinary laboratories
- Provides two working examples of the risk assessment process in a fictional laboratory setting

Discussion Question

What additional needs might WG5 focus on?

How might we fulfill these needs?

Based on what the Working Group determines it wants to accomplish, the options available to for additional ISO 35001 products are list below, and explained in greater detail over the next few slides.

The following slides will review types of deliverables developed by ISO.

- ISO Standards
- ISO/TS Technical Specifications
- ISO/TR Technical Reports
- ISO/PAS Publicly Available Specifications
- IWA International Workshop Agreements
- ISO Guides

Points sourced from ISO website

International Standards

An International Standard provides rules, guidelines or characteristics for activities or for their results, aimed at achieving the optimum degree of order in a given context.

It can take many forms. Apart from product standards, other examples include:

- test methods,
- codes of practice,
- guideline standards and
- management systems standards.

Points sourced from ISO website

Technical Specification

- A Technical Specification addresses work still under technical development, or where it is believed that there will be a future, but not immediate, possibility of agreement on an International Standard.
- A Technical Specification is published for immediate use, but it also provides a means to obtain feedback.
- The aim is that it will eventually be transformed and republished as an International Standard.

Points sourced from ISO website

Technical Report

- A Technical Report contains information of a different kind from that of the previous two publications.

- It may include data obtained from a survey, for example, or from an informative report, or information of the perceived "state of the art".

Publicly Available Specification

- A Publicly Available Specification is published to respond to an urgent market need, representing either the consensus of the experts within a working group, or a consensus in an organization external to ISO.
- As with Technical Specifications, Publicly Available Specifications are published for immediate use and also serve as a means to obtain feedback for an eventual transformation into an International Standard.
- Publicly Available Specifications have a maximum life of six years, after which they can be transformed into an International Standard or withdrawn.

Points sourced from ISO website

International Workshop Agreements

An International Workshop Agreement is a document developed outside the normal ISO committee system to enable market players to negotiate in an "open workshop" environment.

International Workshop Agreements are typically administratively supported by a member body.

The published agreement includes an indication of the participating organizations involved in its development.

An International Workshop Agreement has a maximum lifespan of six years, after which it can be either transformed into another ISO deliverable or is automatically withdrawn.

Points sourced from ISO website

Guides

Guides help readers understand more about the main areas where standards add value.

Some Guides talk about how, and why, ISO standards can make it work better, safer, and more efficiently.

Points sourced from ISO website

BACKGROUND

Types of deliverables

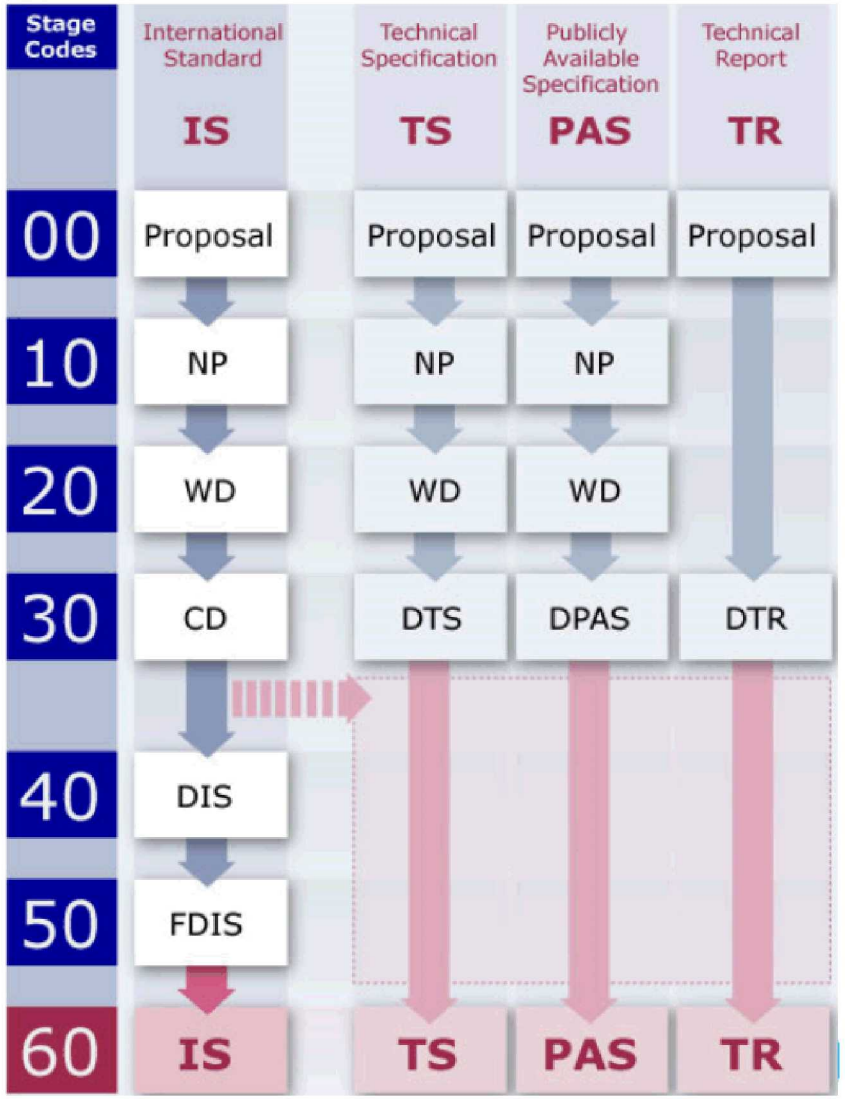
http://www.iso.org/iso/home/standards_development/deliverables-all.htm?type=standard

Can contain requirements

- **ISO**
  International Standards
- **ISO/TS**
  Technical Specifications
- **ISO/PAS**
  Publicly Available Specifications

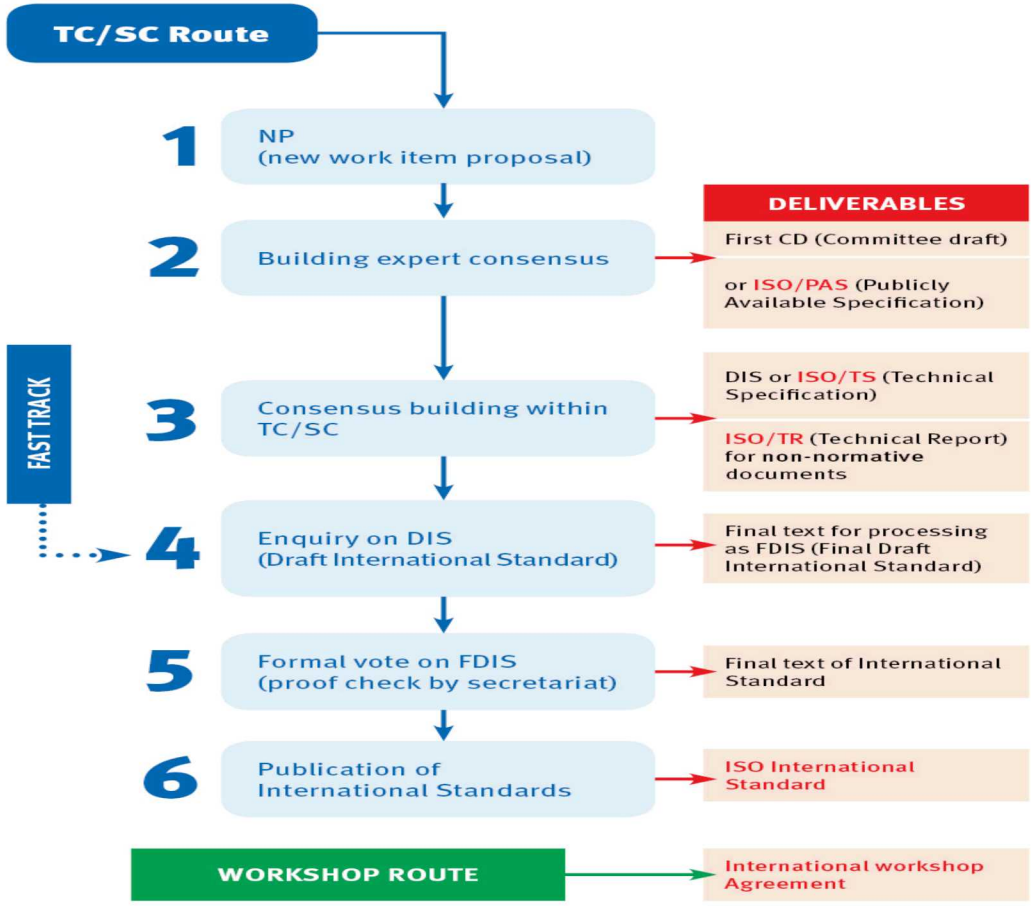
Informative only

- **ISO/TR**
  Technical Reports



Points sourced from ISO website

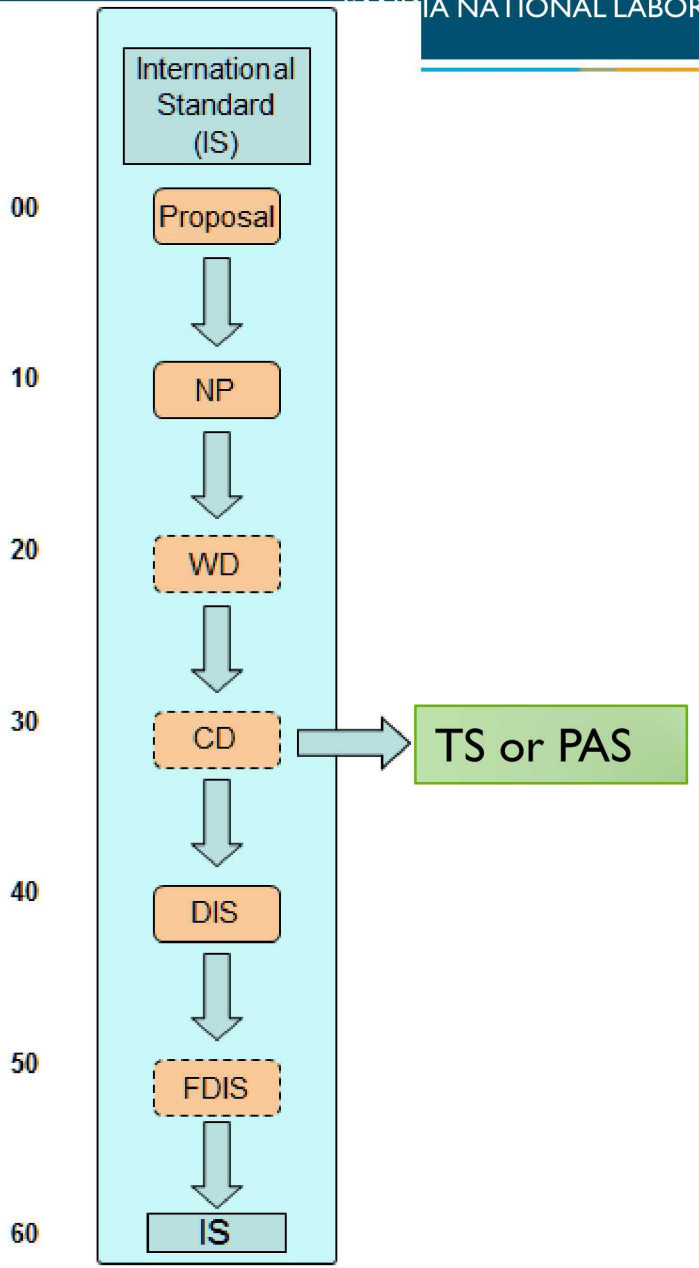
Process



Points sourced from ISO website

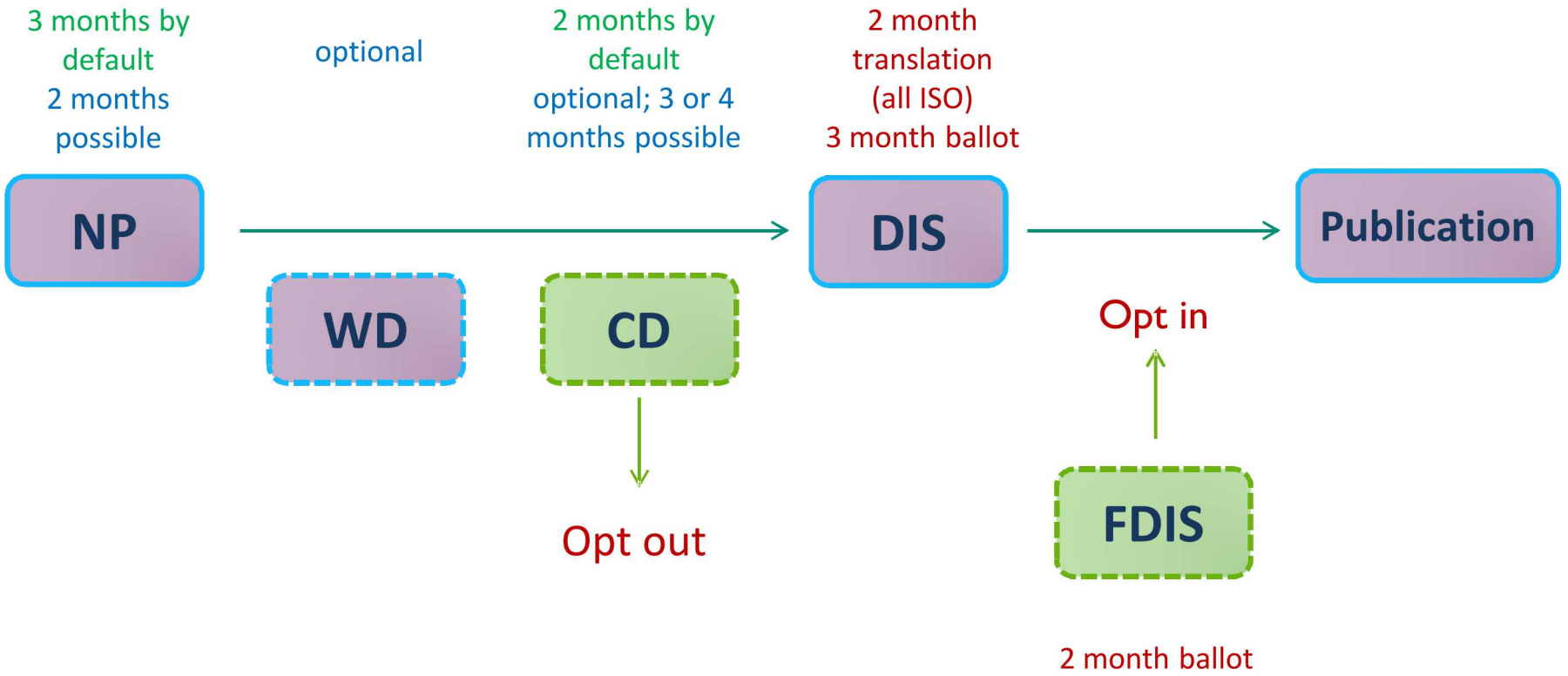
Main Stages of IS

- 00 Preliminary stage (optional)
- **10 Proposal stage**
- **20 Preparatory stage**
- 30 Committee stage (optional)
- **40 Enquiry stage**
- 50 Approval stage (optional)
- **60 Publication stage**



Points sourced from ISO website

Main stages, reminder



Timeframes (tracks)

At start of project - choose:

Accelerated: Track 1

12 months to DIS

24 months to publication

Default: Track 2

24 months to DIS

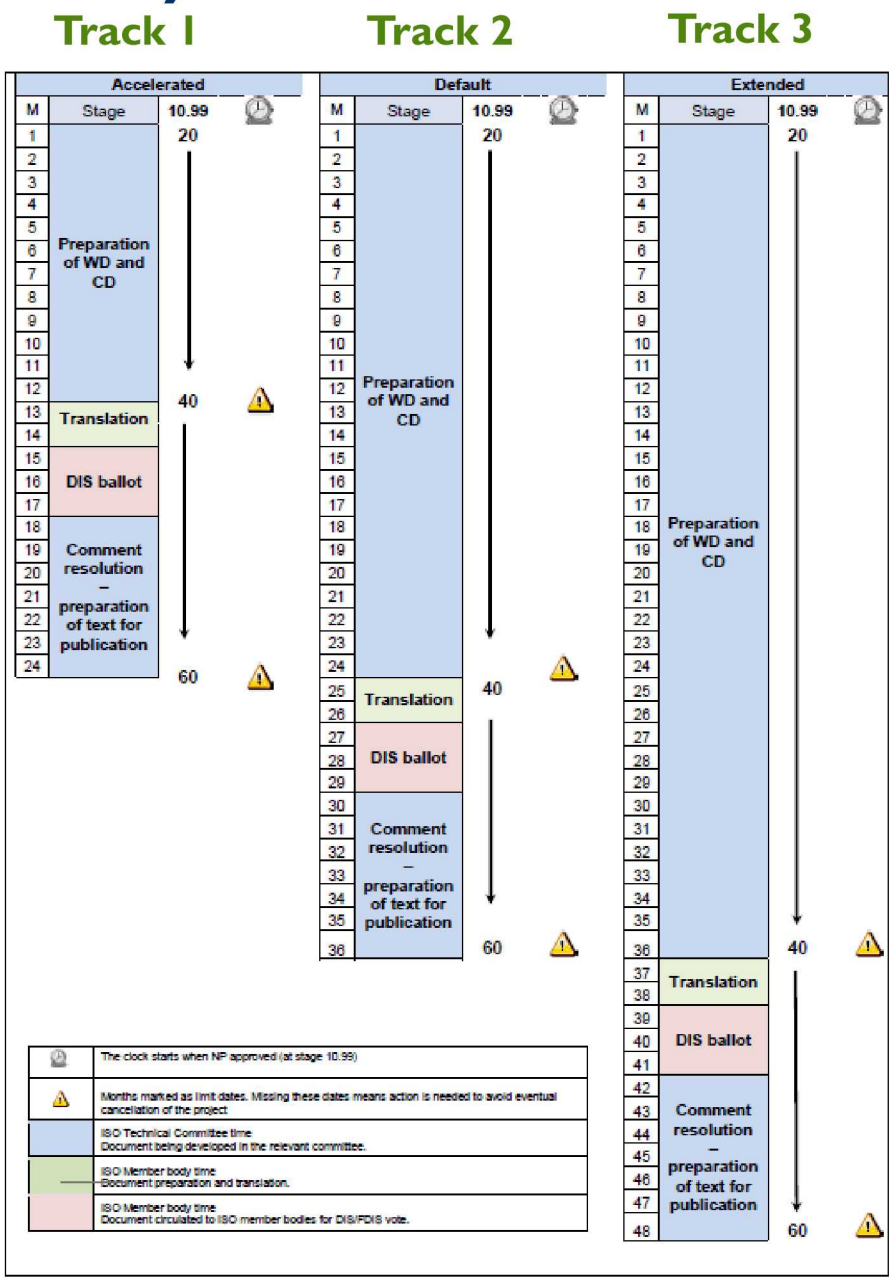
36 months to publication

Enlarged: Track 3

36 months to DIS

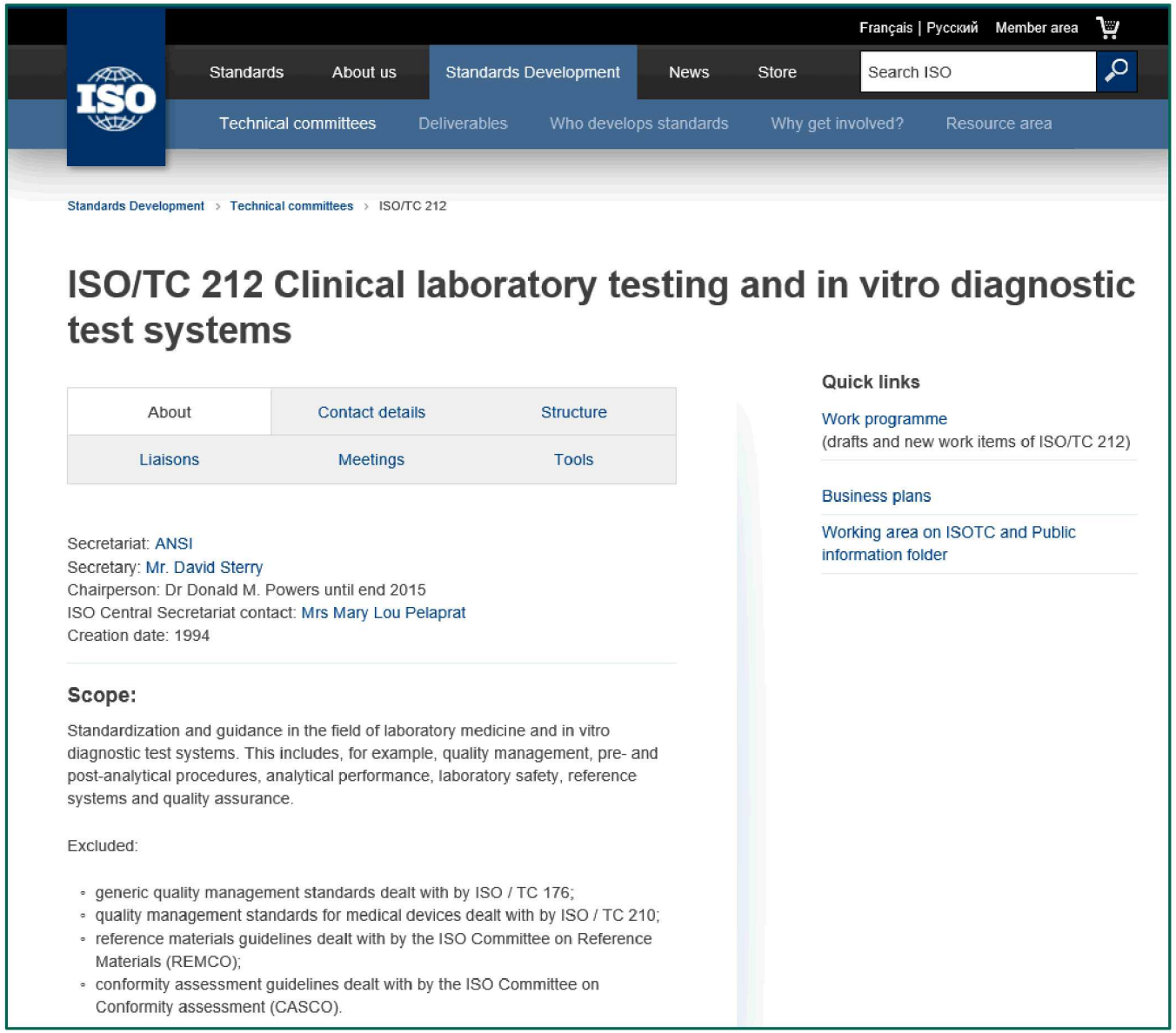
48 months to publication

Points sourced from ISO website



WG working space and resources

TC 212 Online – Finding information



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Technical committees Deliverables Who develops standards Why get involved? Resource area

Standards Development > Technical committees > ISO/TC 212

ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

About | Contact details | Structure

Liaisons | Meetings | Tools

Secretariat: ANSI
Secretary: Mr. David Sterry
Chairperson: Dr Donald M. Powers until end 2015
ISO Central Secretariat contact: Mrs Mary Lou Pelaprat
Creation date: 1994

Scope:

Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

Excluded:

- generic quality management standards dealt with by ISO / TC 176;
- quality management standards for medical devices dealt with by ISO / TC 210;
- reference materials guidelines dealt with by the ISO Committee on Reference Materials (REMCO);
- conformity assessment guidelines dealt with by the ISO Committee on Conformity assessment (CASCO).

Quick links

Work programme
(drafts and new work items of ISO/TC 212)

Business plans

Working area on ISOTC and Public information folder

TC 212 working area (e-Committees)

ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

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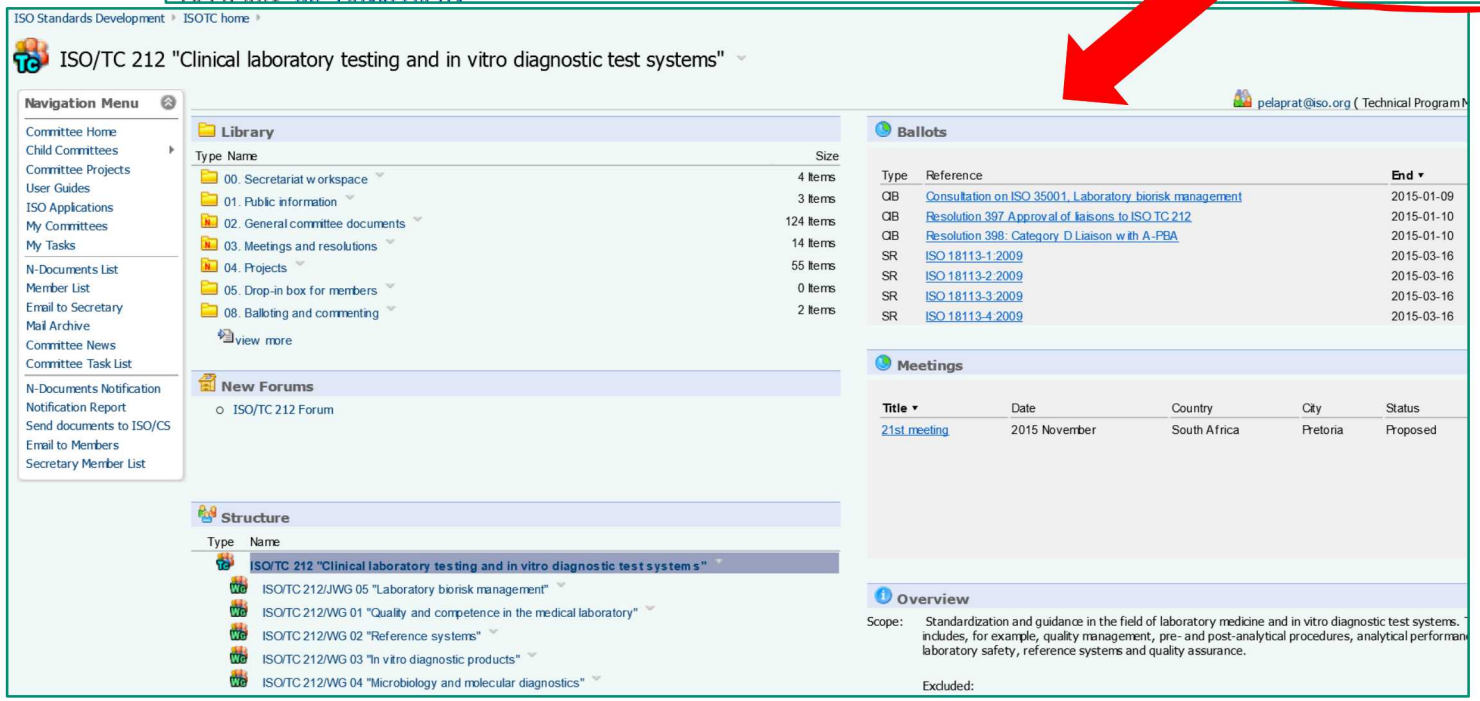
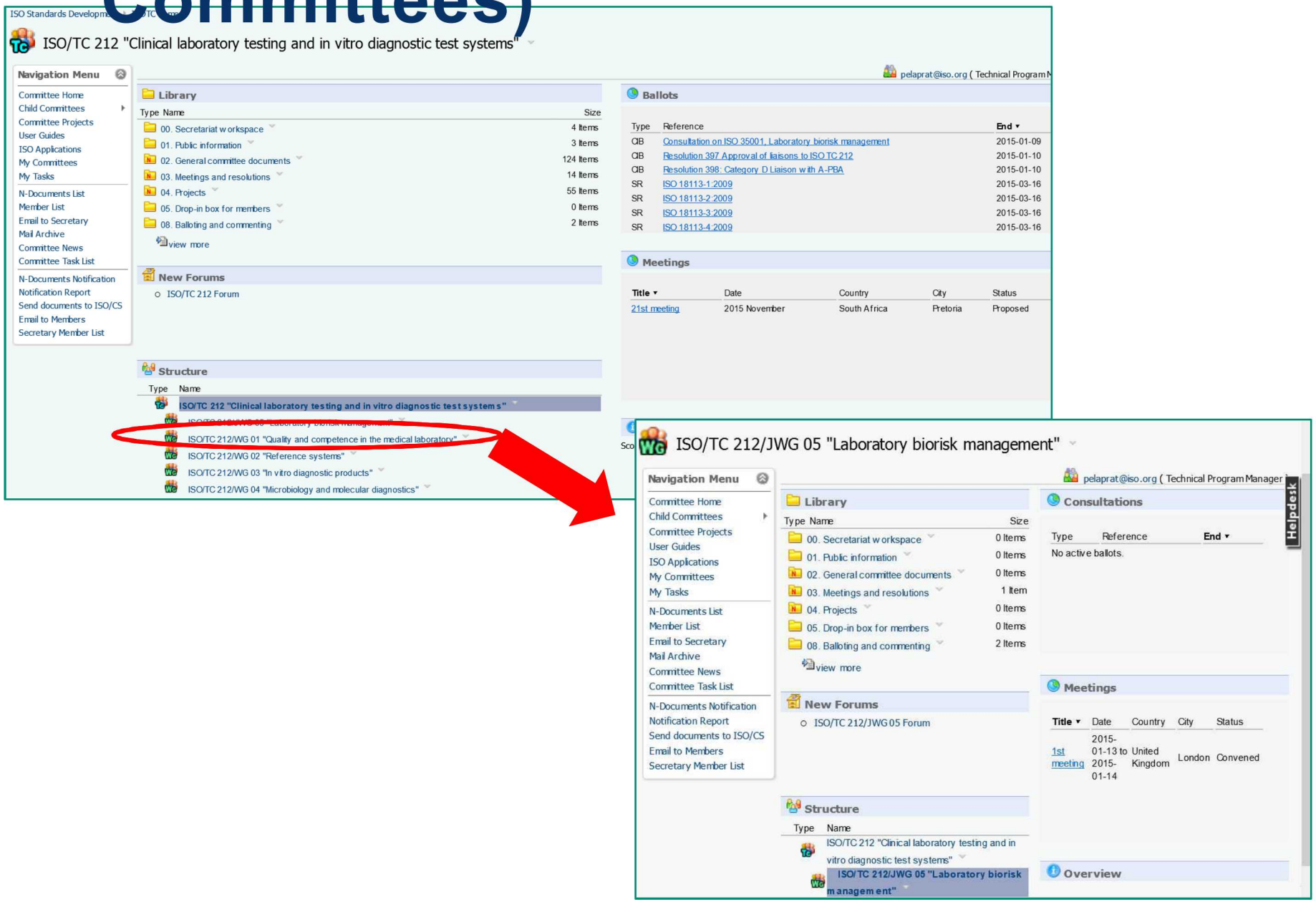


TC 212 working area (e-Committees)



Notifications – new documents

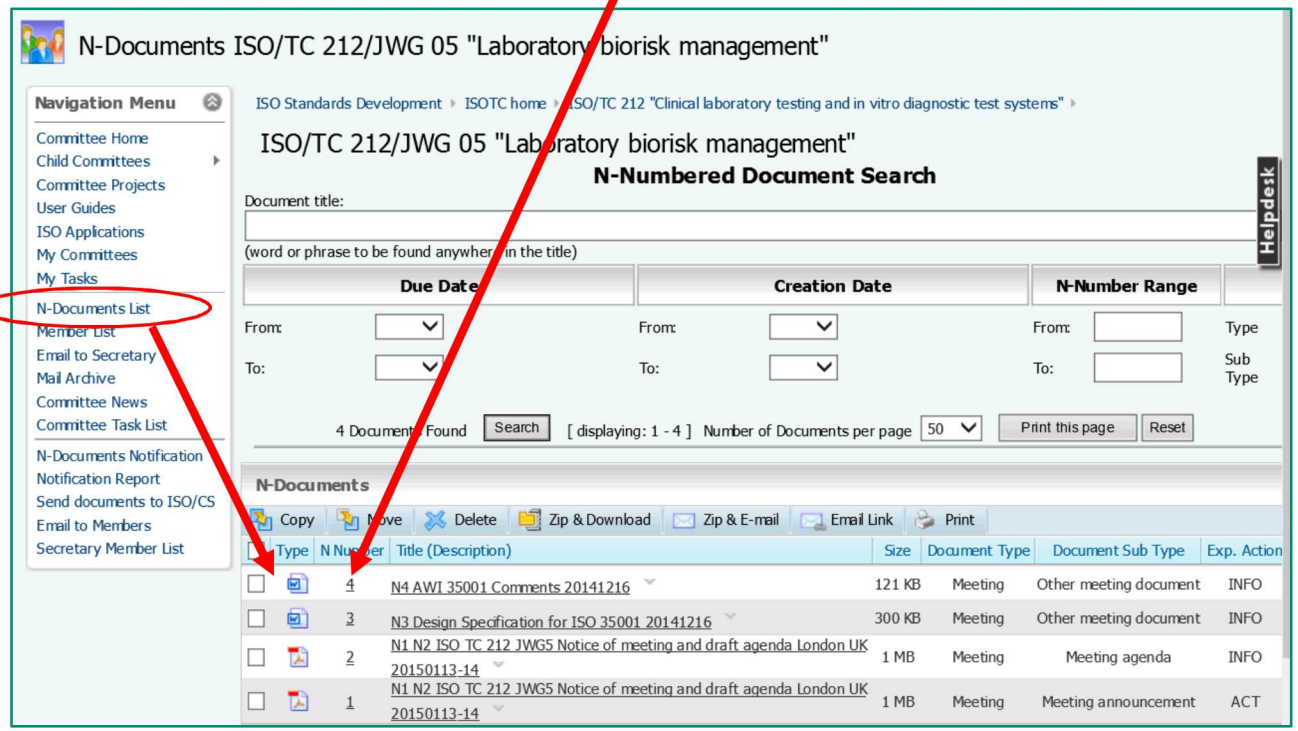
You will receive email notifications of new documents and any expected actions

N Number	Title (Description)	Exp. Action	Due Date	Version Date
4	N4 AWI 35001 Comments 20141216	INFO	None	2014-12-16
3	N3 Design Specification for ISO 35001 20141216	INFO	None	2014-12-16

Download all documents as ZIP : ZIP-File

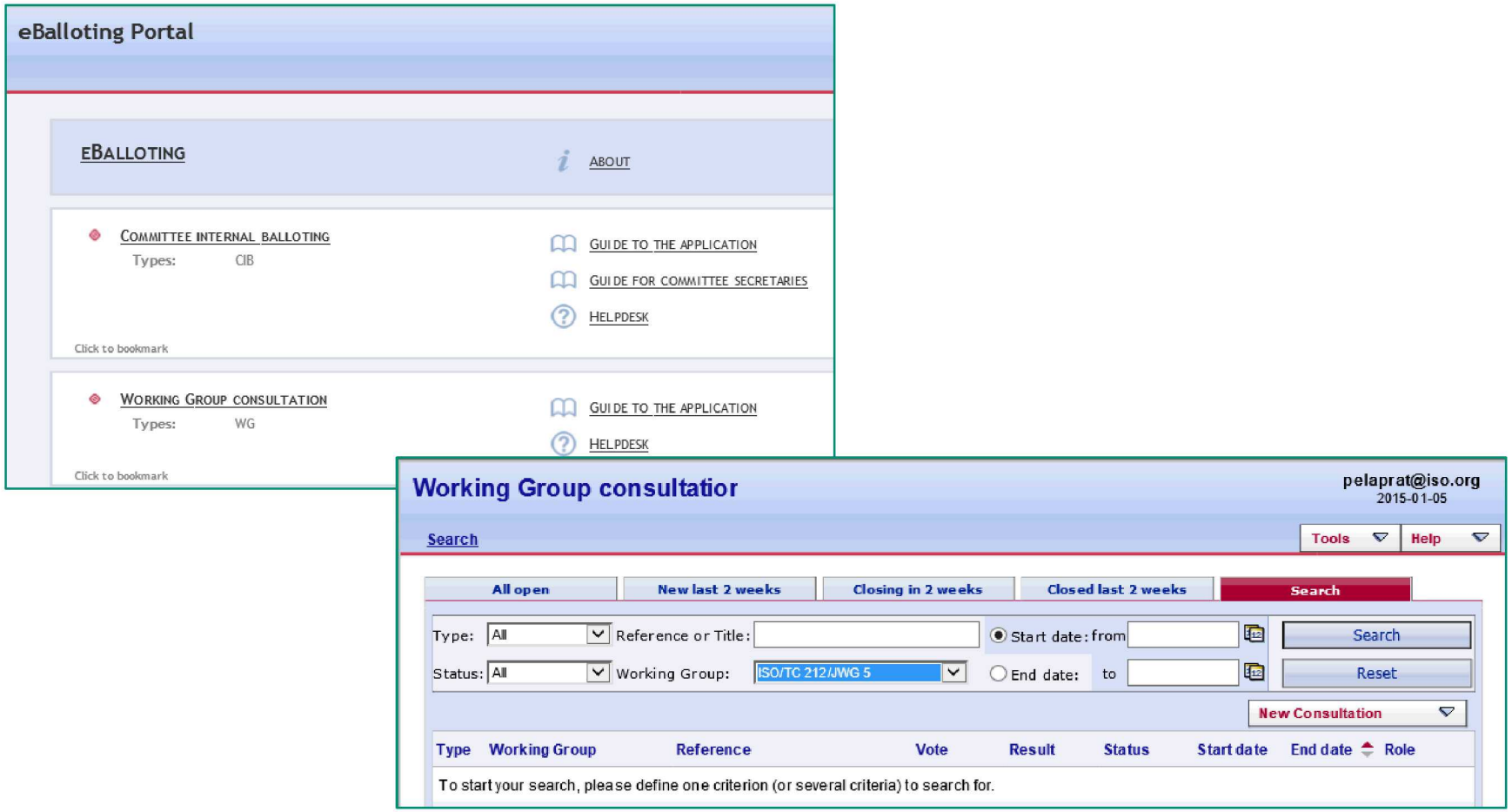
Access to ISO/TC 212/JWG 5 : Committee Homepage

*N-documents list



WG Consultation

- You will receive Email notifications of WG/JWG
- Access e-balloting using your Global Directory login



Using Webex for a WG meeting

- Remember – only call a physical meeting when it is necessary in order to discuss committee drafts or matters of substance that cannot be settled by other means.
- Webex phone/internet conferencing system: available free of charge to ISO members, committees and working groups for all ISO-related work.
- Contact webconferencing@iso.org to get a Webex account and see ISO Connect for instructions on how to use Webex:

https://connect.iso.org/display/it/Web+Conferencing+Resource+Page

Using Webex for a WG meeting

What do you need to organize an ISO web meeting?

- WebEx Account
- Computer
- Headset or Telephone (preferable)
- Host Meeting Link (https://iso-meetings.WebEx.com)
- Webcam (optional)
- Tranquil work area free from noise or other distractions (recommended)

Using Webex for a WG meeting

Before your first meeting

- Test your computer's ability to join a web meeting
- Test any other devices you plan to use
- Schedule a practice meeting with a willing participant:
  - Practice sharing applications or your desktop
  - Practice using the Webex control panel (list of participants, sending text messages, etc.)
- Follow the instructions given in First_Time_Organizers.pdf https://connect.iso.org/download/attachments/3178550/First_Time_Organizers.pdf?version=1&modificationDate=1383832285000&api=v2
- Follow the Tips for a successful meeting

Need help? send your request to webconferencing@iso.org