SAND2020-8790C

August 24, 2020: UPDATE
WG5 Augmentation &
ISO 35001 Implementation Guidance

Dr. L. Gribble, Mr. Gambill

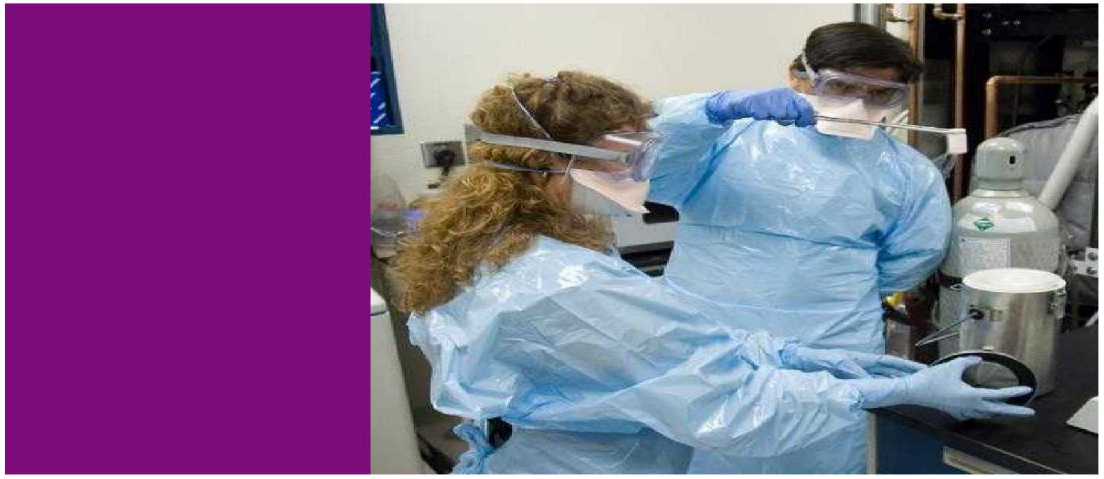
Sandia National Laboratories

Sandia National Laboratories is a multimission laboratory managed and operated by National Technology and Engineering Solutions of Sandia LLC, a wholly owned subsidiary of Honeywell International Inc. for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-NA0003525.
SAND XXXX-XXXX

Agenda Item #6

Augmenting WG5 with SMEs from developing countries

Background: ISO/TC212/WG5/N126



Progress Since November 2019: WG5 Augmentation

- Requested nominations from WG5 members and liaison organizations
- Most nominees presented by IFBA, and represent leadership of biosafety associations
- 30 nominations received
- 25 countries represented among the nominations, including:

Afghanistan
Azerbaijan
Bangladesh
Benin
Cameroon
Egypt
Georgia
Guinea
Indonesia
Ivory Coast
Kenya
Lebanon
Malaysia
Mali
Moldova
Morocco
Nigeria
Pakistan
Philippines
Senegal
South Africa
Tanzania
Thailand
Uganda
Vietnam

Path Forward: WG5 Augmentation

- Outreach to some, or all, of the nominees to gauge interest and ability to support WG5
- Internal consultation on selection of nominees. (There is no size limit on ISO Working Group members.)
- Consultation with associated groups on potential for sponsoring travel for nominees' involvement in future WG5 meetings.
- Final selection and notification to individuals

- Are there other considerations that should be included here?

Agenda Item #8

Implementation Guidance Form04 and CWA comparison document, including comment tables

Background: ISO/TC212/WG5/N127, N128.

Best Practice Implementation???

Progress Since November 2019: WG5 Augmentation

- Drafted FORM04 and submitted to CLSI for review and input.
- Assembled comparison table – aligning ISO 35001 with CWA 15792 and 16393
- Added commentary in comparison table indicating the similarities and differences between these products, and noting were WG5 may need to focus attention in order to cover essential topics not already addressed by CWA 16393
- Distributed FORM04 to WG5 with request for WG5 comments in advance of this meeting
- Received one completed set of comments back from EBSA

Comparison document outlines what benefit CWA 16393 may provide and where new development is most needed for ISO 35001 Implementation Guidance

Side by Side Document Comparison

- ISO 35001 (full standard text)
- CWA 16393 (full standard text)
- CWA 15793 (definitions only)

Include SNL GCBS' views on:

- How is ISO 35001 similar to or different than CWA 16393?
- Considerations for ISO 35001 Implementation Guidance, beyond CWA 16393

Path Forward: WG5 Augmentation

- Re-circulate FORM04 and comparison draft to WG5 with request for final comments by October 1, 2020
- Address comments in FORM04 by the November TC 212 virtual meeting
- Submit FORM04 for formal consideration in the November TC 212 meeting

- Are there other steps that should be included?

BACKGROUND

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 35001 development

35001 is principally based on CWA 15793

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

ISO 35001 establishes performance requirements for lab biorisk management

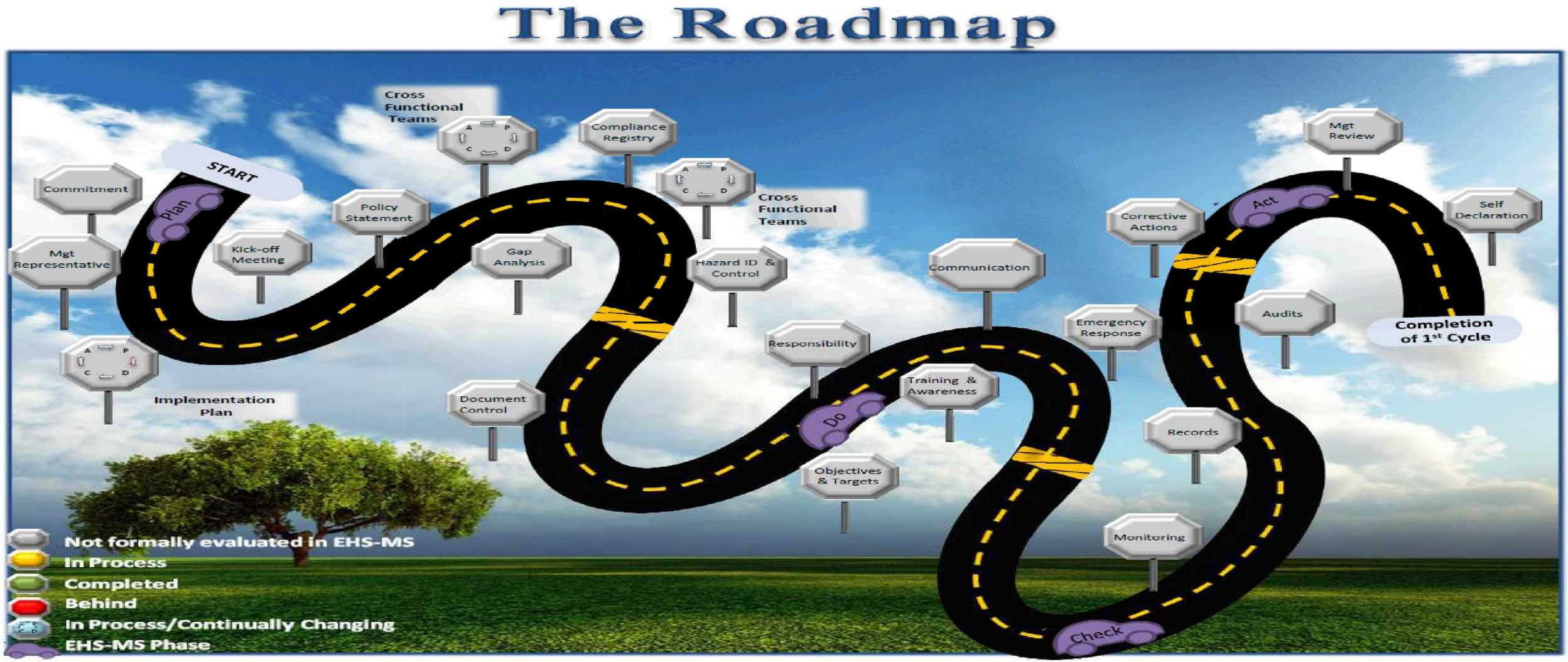
An informative implementation annex was approved in the initial scope, but deferred due to time constraints

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

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

Types of deliverables

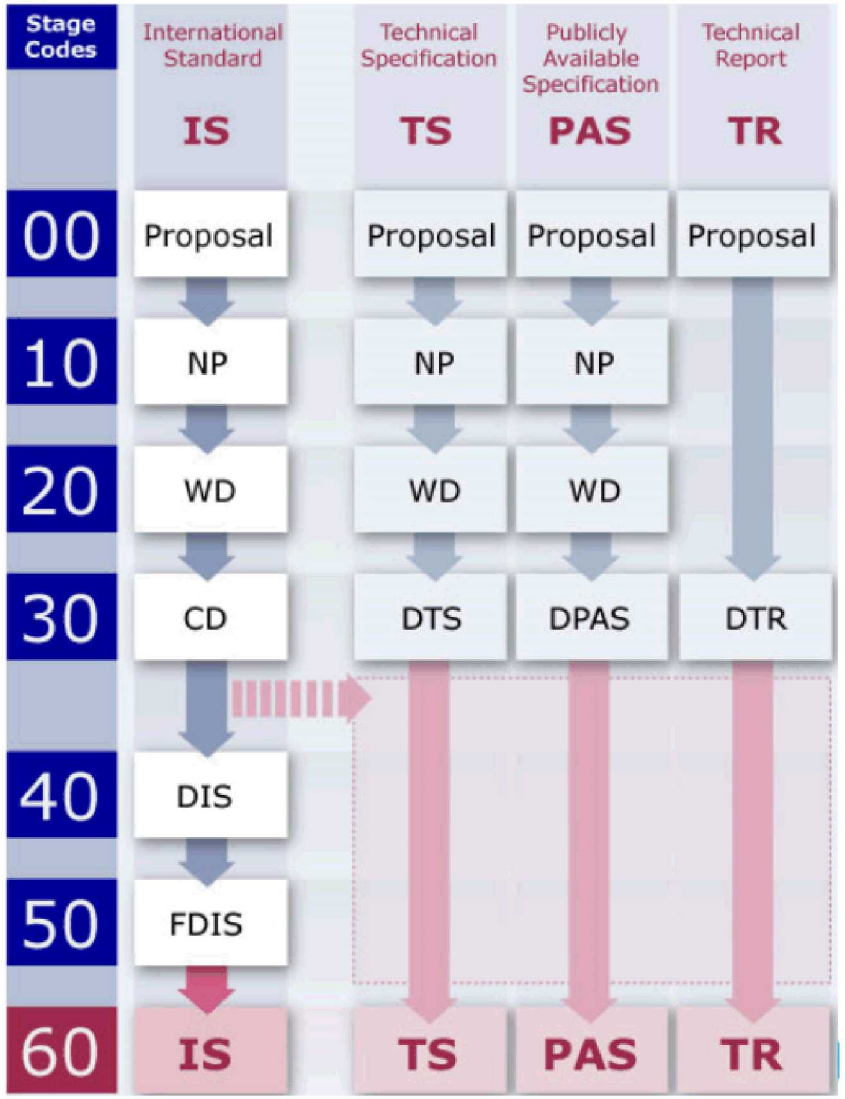
http://www.iso.org/iso/home/standards_development/deliverables-all.htm?type=standard

Can contain requirements

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

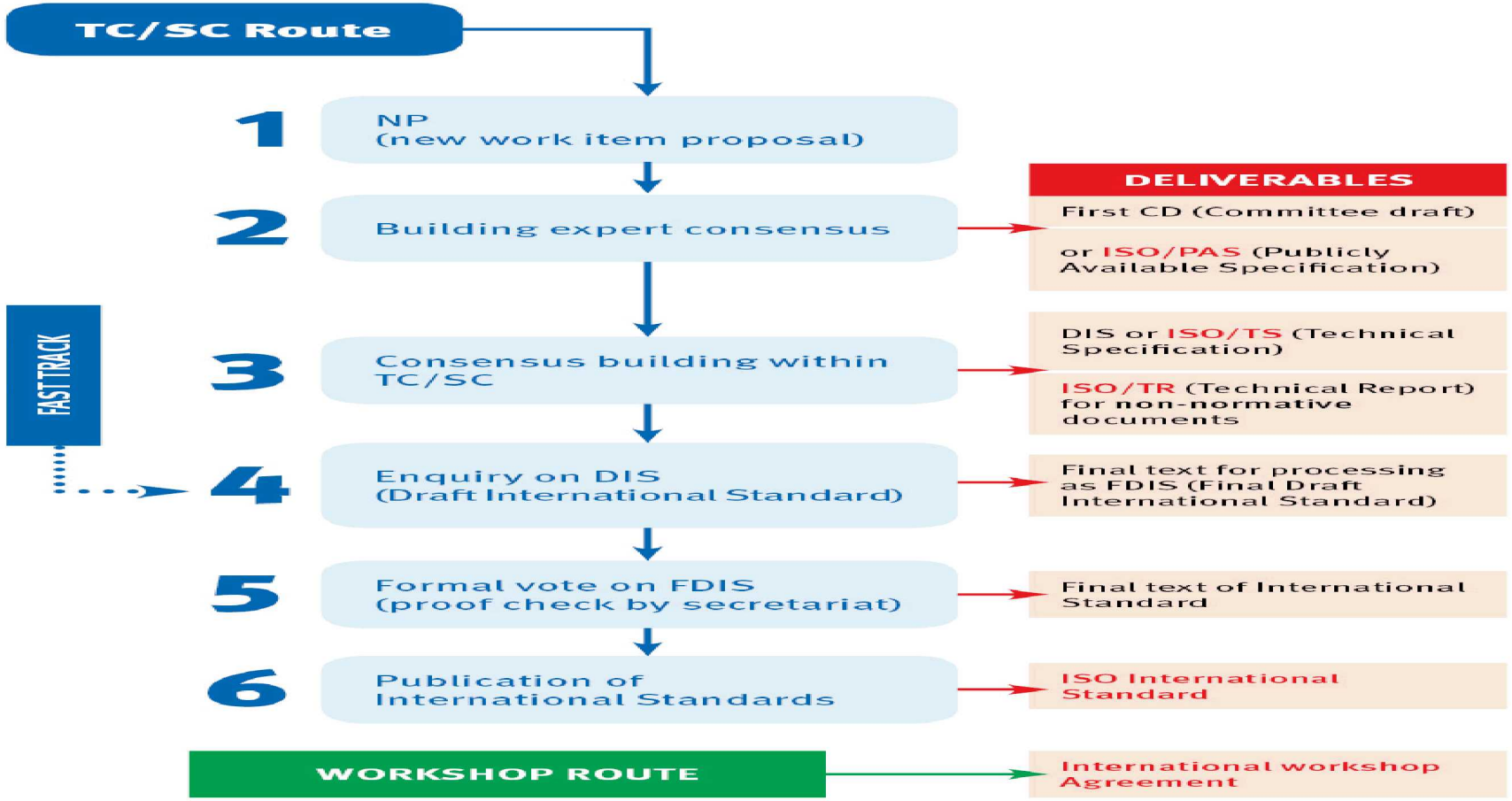
Informative only

- **ISO/TR**
  Technical Reports



Points sourced from ISO website

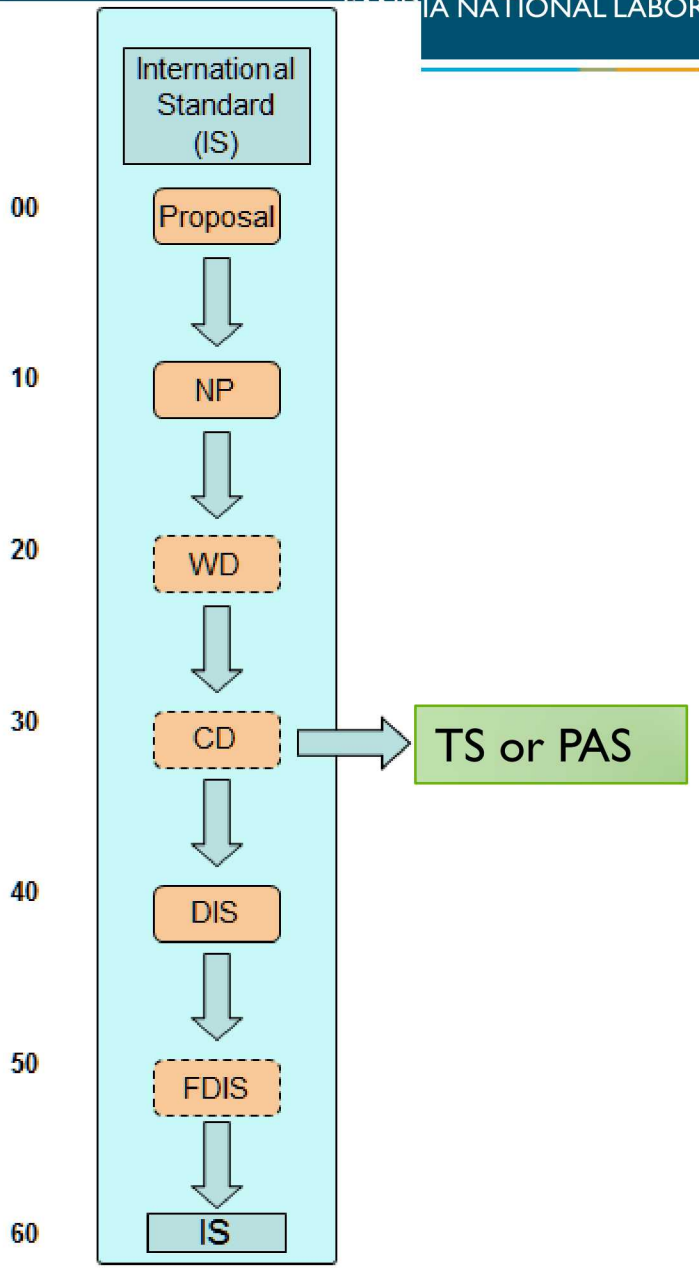
Process



Points sourced from ISO website

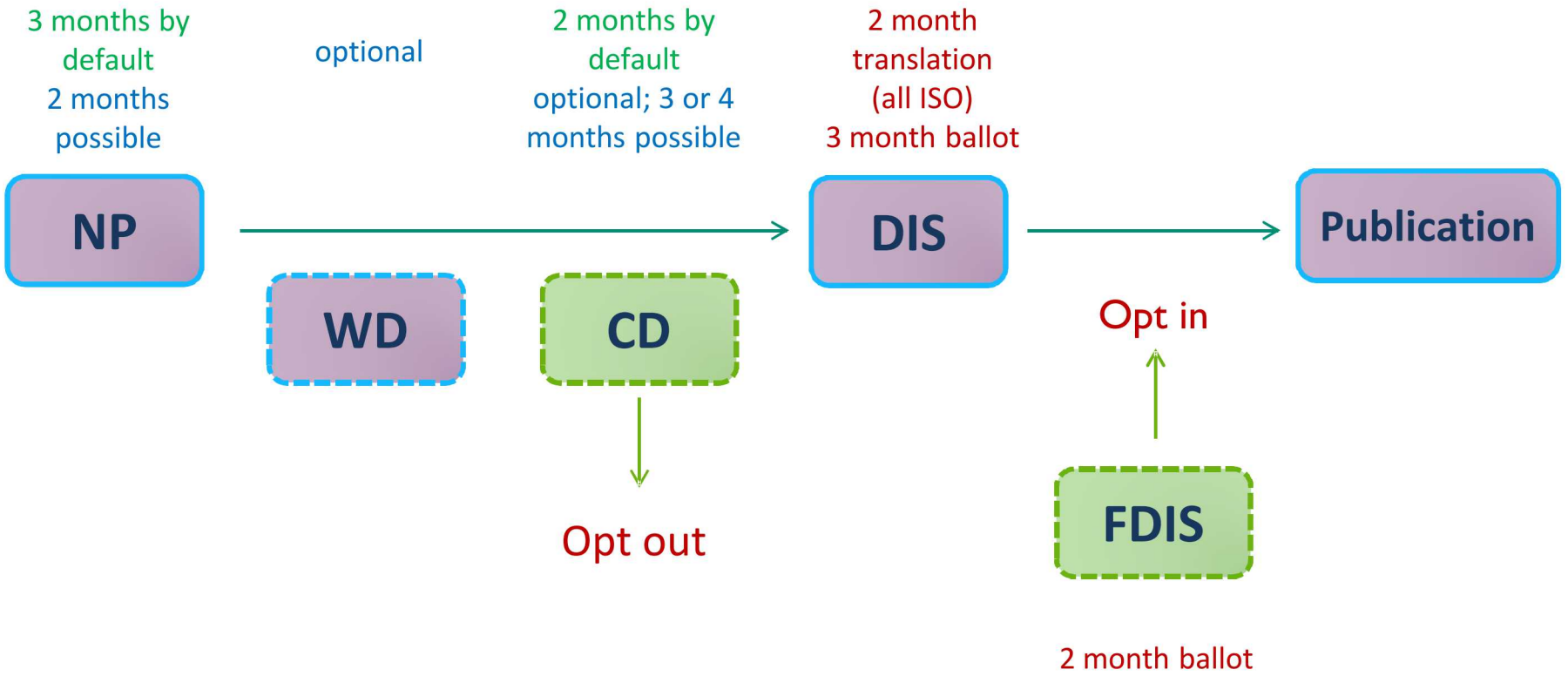
Main Stages of IS

- 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