

The background features abstract, overlapping green geometric shapes. On the left, a solid green triangle points downwards. On the right, a complex arrangement of semi-transparent green polygons in various shades (from light lime to dark forest green) creates a layered, architectural effect. A thin, light grey line extends from the bottom right towards the center of the page.

EN ISO 23908 revision

ISO/TC 84 Devices for administration of medicinal products and catheters

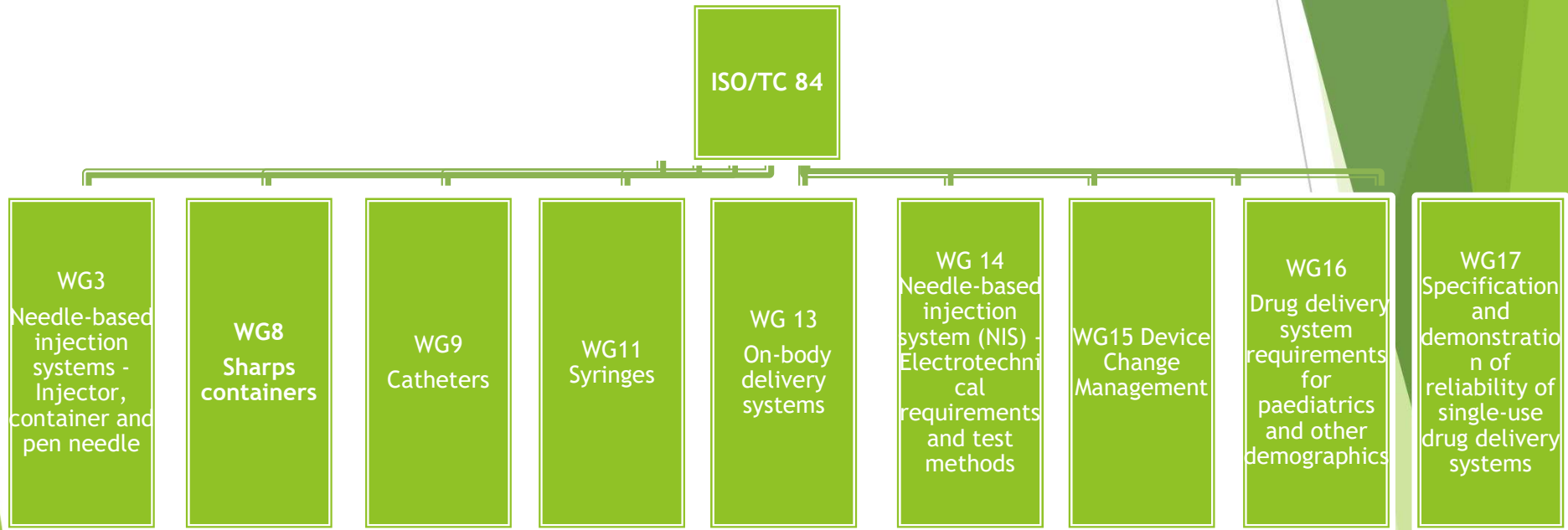
Scope

Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles and catheters.

Excluded:

- ✎ non catheter devices intended for diagnostic use;
- ✎ anaesthetic and respiratory equipment, including lung ventilators and oxygen therapy devices, covered by ISO/TC 12;
- ✎ cartridge systems for dental use, covered by ISO/TC 106;
- ✎ specific requirements for components and devices, including prefilled syringes, covered by ISO/TC 76.

ISO/TC 84 Devices for administration of medicinal products and catheters : Structure



ISO/TC 84 WG8 Sharps containers

- ✦ Responsible for maintenance of EN ISO 23907-1 (single use sharps container) and ISO 23907 (reusable sharps container) and EN ISO 23908, under ISO/TC 84 supervision.
- ✦ Highly experienced in testing methods for preventing the risk of unintended cuts and pricks, body fluid exposures and microbial contaminations
- ✦ WG8 is ready to support and develop EN ISO 23908 revision according ISO/TC 84 instructions



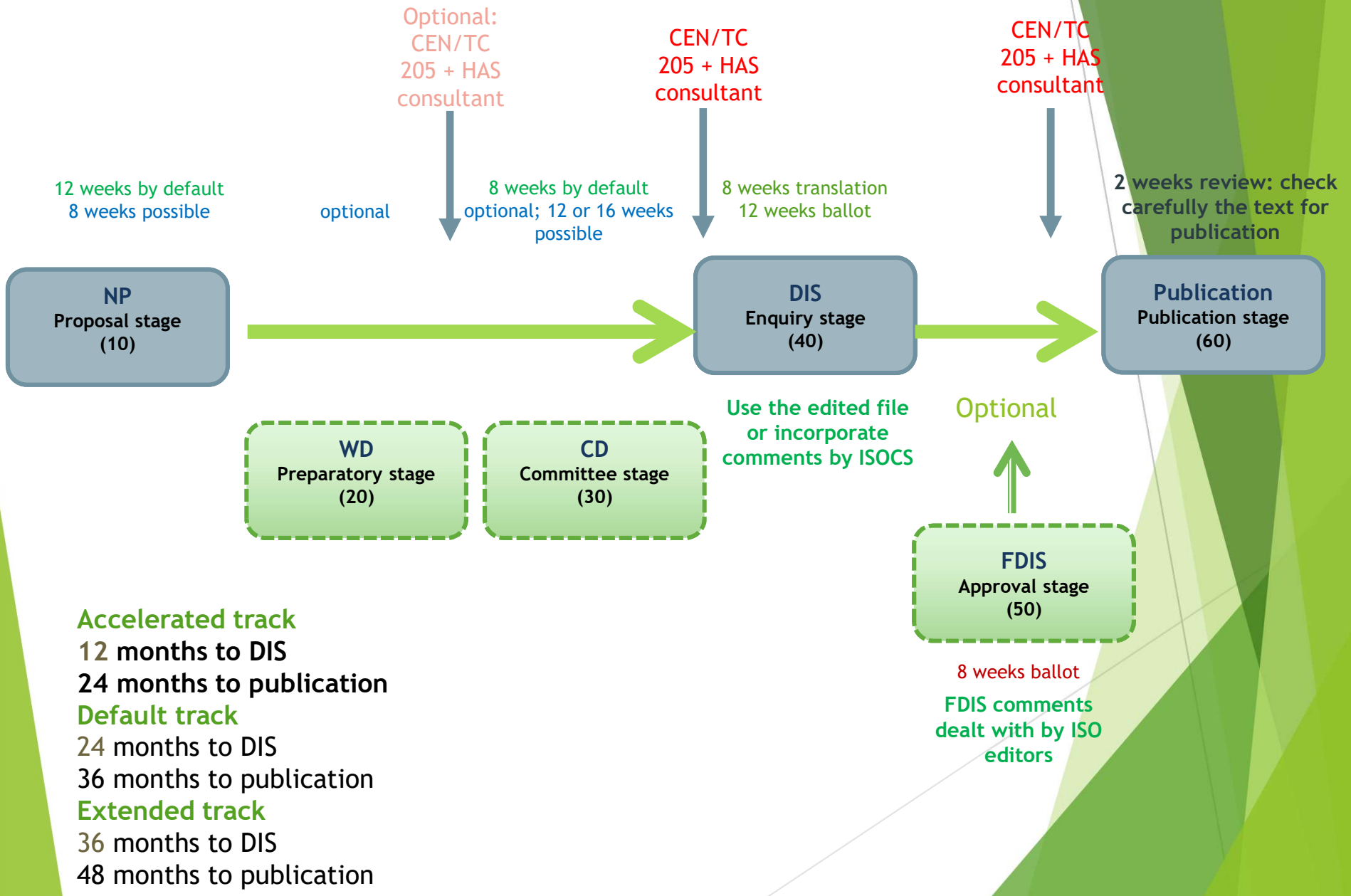


ISO Working groups

Participation:

- ✦ Participants are appointed by their national standardization bodies (NSB)
- ✦ The WG convenor may invite a single guest to a single meeting provided that s/he informs ISO before the meeting. ISO will inform the NSB of the guest.
- ✦ Call for experts will be organized to inform about EN ISO 23908 revision and seek for new participants

ISO STANDARD DRAFTING PROCESS



NWIP: ISO Form 4: for starting EN ISO 23908rev



International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации

FORM-4:
NEW-WORK-ITEM-PROPOSAL-(NP)

Circulation-date Click-here-to-enter-a-date.	Reference-number: Enter-Number (to-be-given-by-ISO-Central-Secretariat) ISO/TC-84-/SC-Enter-Number <input type="checkbox"/> → Proposal-for-a-new-PC N-Click-here-to-enter-text.
Closing-date-for-voting Click-here-to-enter-a-date.	
Proposer <input checked="" type="checkbox"/> → ISO-member-body: ISO/TC-84 <input type="checkbox"/> → Committee, liaison-or-other: Click-here-to-enter-text.	
Secretariat DS-Ms-Bibi-Nellemose bn@ds.dk	

A-proposal-for-a-new-work-item-within-the-scope-of-an-existing-committee-shall-be-submitted-to-the-secretariat-of-that-committee.

- Change of EN ISO 23908 current scope
- Justifications (Standardization request, alignment with ISO guidances...
- Impacts on market and current ISO standards
- Vienne Agreement with CEN/TC 205, cooperation with HAS consultant
- UN Sustainable Development Goals
- Proposed Standard Development Track (timeframe)
- Project leader

New Work Item proposal

Registering a new project is done only by correspondence (min 8 weeks ballot)

Accepted if:

2/3 majority of Participant ISO-members voting

- Minimum participation: **5** committees members
→ ISO/TC 84: 29 P-members and 28 O-members
- Experts must be **NAMED** to count towards the approval
- Minimum number of named experts must come from P-members **voting positively**

Possible milestones and perspectives

