ISO 13485:2003 Status Update

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BACKGROUND OF ISO 13485

- **ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes**, enables manufacturers to clearly demonstrate their compliance to quality and regulatory requirements, providing confidence to consumers and professionals worldwide.
- This standard is based on ISO 9001 for quality management systems, but with additional requirements specific to the medical devices industry.
- ISO 13485 is intended for use by organizations involved in the design, production, installation and servicing of medical devices, as well as in the design, development and provision of related services.
- It can also be used by internal and external parties, including certification bodies, in order to assess an organization's ability to meet the requirements.
- This standard is currently undergoing revision.

STAGES FOR STANDARDS DEVELOPMENT

Stages for Standards development

- There are six stages in any standards development.
  - Proposal stage (10)
  - Preparatory stage (20)
  - Committee stage (30)
  - Enquiry stage (40)
  - Approval stage (50)
  - Publication stage (60)

Stages for Standards development

Proposal stage (10)- Obligatory

- This 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. The electronic balloting portal should be used for the vote.
- The person being nominated as project leader is named on the Form.
- If there are possible complications around copyright, patents or conformity assessment, they should be raised at this early stage.
- This stage can be skipped for revisions and amendments to ISO standards that are already published

Stages for Standards development

Preparatory stage (20)- Optional

- 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 Convener (usually the Project leader).
- During this stage, experts continue to look out for issues around copyright, patents and conformity assessment.
- Successive WDs can be circulated until the experts are satisfied that they have developed the best solution they can. The draft is then forwarded to the WG's parent committee who will decide which stage to go to next (Committee stage or Enquiry stage).
- The ISO/TC platform can be used for sharing documents at this and other stages of standards development

Stages for Standards development

Committee stage (30)- Optional

- During this stage the draft from the working group is shared with the members of the parent committee.
- If the committee uses this stage, the committee draft (CD) is circulated to the members of the committee who then comment and vote using the Electronic Balloting Portal.
- Successive CDs can be circulated until consensus is reached on the technical content

Stages for Standards development

Enquiry stage (40)- Obligatory

- 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 DIS is approved if a two-thirds of the Full members of the TC/SC are in favor and not more than one-quarter of the total number of votes cast are negative
- If the DIS is approved, the project goes straight to publication. However, the committee leadership can decide to include the FDIS stage if needed.

Stages for Standards development

Approval stage (50)- Optional

- This stage will be automatically skipped if the DIS has been approved
- However, if the draft has been significantly revised following comments at the DIS stage (even if the DIS has been approved) committees can decide to carry out this stage.
- If this stage is used, 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 Full members of the TC/SC is in favor and not more than one-quarter of the total number of votes cast are negative.

Stages for Standards development

Publication stage (60)- Obligatory

- At this stage the secretary submits the final document for publication. Only editorial corrections are made to the final text.
- It is published by the ISO Central Secretariat as an International Standard.
- Committee secretaries and project leaders get a two-week sign off period before the standard is published

STATUS OF ISO 13485:2003

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- The ISO Technical Committee responsible for revising this standard is ISO/TC 210.
- Currently this is in 5th stage- Approval stage (FDIS stage).
- As on 29-10-2015, two months FDIS ballot has been initiated among ISO member countries.
- FDIS voting results expected to be known by end Dec 2015.
- Publication of new version is expected in early 2016.