Change Management in ISO QMS

Process and sustainability of good/best practices

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The strategic planning must be done now to maintain the credibility of these Standards.
History, Experience and Observations

- **1987**: Standard was based on traditional quality assurance standard used in Manufacturing sector.
- **1994**: Minor revision, without significant change.
- **2000**: Concept of eight quality management principles.
- **2004**: Minor revision, without significant change.
- **2015**: Significant Changes.
Issues Needing Change

- Lessons Learned
- Project Plan Review
- Validation
- Verification
- Comments Disposition Time
Best Practices...

- Mandatory entrance criteria for a new project to review and select key lessons for implementation
- Should not be allowed to enter into Committee Draft (CD) stage, without evidence of adherence
- Deviations to the above, to be signed by SC2 Chair, Secretary, Convener and Deputy, with risk assessment and mitigation plan developed by the convener
Best Practices…

- Initial overall project plan to be reviewed by SC2 Chair and agreed upon by all stakeholders
- Status review of the project plan during each opening and closing SC2/WG plenary
- No short-cuts in all the steps listed, allowed
- Delay communicated in advance to the ISO secretariat
Best Practices…

- Evidence: all input documents outlined in the design document were considered
- Verification results reviewed and joint consensus between SC2 Chair, Secretary, WG/TG Convener
Best Practices…

- Validation report taken seriously, every comment dispositioned adequately
- Response to national bodies how validation comments were dispositioned
- TC176/SC2 Chair and Secretary cannot make decision, without Validation WG/TG convener and co-convener agreement
Best Practices...

- Allow adequate time to disposition comments received during CD phase(s). Catch any shortages during Project Plan review.
- Include the validation comment dispositioning step in the project plan.
- No short-cuts allowed!!!
**Sustainability**

- **Convener training**
  - A checklist of items that must be met prior to starting the project

- **Ensure schedule adjustments are made, as needed**
  - In closing plenary, discuss moving forward strategy after time adjustments are made

- **Frequent communications**
  - **Internal**
    - All workgroups
    - ISO Secretariat
    - Any other dependent Standard(s)
  - **External**
    - Users
    - Media

- **Hold individuals accountable for deviations to the process**
US/Columbia Collaboration

- Partner on issues
- Periodic status meetings to discuss concerns/issues
- Consensus on methodology to address concerns/issues
- Joint discussion on pros/cons on suggestions/recommendations
- Provide support during internal WG/TG meetings
Change Management and implementation of best practices will be a continuous, rewarding journey for the QMS Family of Standards, ISO 9000, 9001, 9004