OSAC Working with an SDO Process Description

This process begins after an OSAC Subcommittee (SC) has identified a need for a standard and has determined that such a document does not exist in published form. This project can range from a draft revision to an existing standard, a preliminary concept for a new standard (that has not been thoroughly developed) or a new draft document that is in a more mature state of development that is ready for a Standards Developing Organization's (SDO's) voluntary consensus standards development process.

SDO – 0   OSAC Subcommittee identifies the need for a standard within an OSAC priority area.

SDO – 25   SC determine whether the project is interdisciplinary by evaluating whether it could impact other subcommittees or committees. Examples might include documents which address overall quality requirements (such as what a quality system should include – proficiency testing, written protocols, validation of methods, etc.) or requirements for common elements – reporting conclusions and opinions, ensuring proper qualifications of associations, etc. If there is any potential that the project is interdisciplinary, send out an inquiry to all potentially impacted subcommittees. If all responses are negative (no impact to any other SC), then proceed to step SDO-100. If any responses are affirmative, proceed to SDO-40.

SDO – 40   The FSSB must approve the creation of any new "virtual" subcommittee (VSC) that spans across SACs, prior to their formation. If no, proceed to SDO-50. If yes, proceed to SDO-60. FSSB appoints the Chair of the VSC.

SDO – 50   Subcommittee that initiated/submitted the VSC proposal to the FSSB must determine next appropriate action, continue with the SDO process as single discipline document OR abandon the standard/idea.

SDO – 60   Form an interdisciplinary VSC and identify relevant SAC. VSC completes subcommittee tasks. Create an interdisciplinary virtual subcommittee (VSC) as follows:

- VSC must include equal representation from all impacted subcommittees and SAC's.
- All representatives are contributors and voting members, providing their input on behalf of their subcommittee.

SDO – 100   OSAC Subcommittee/VSC recommends that the standard be routed through the *OSAC Working with an SDO Process* and initiate KAVI PROJECT.

SDO – 200   SC/VSC identifies relevant SDO (working with their Quality Infrastructure Committee [QIC] liaison for assistance as needed) and initiates **QIC Form 6: SDO Process Request** form.

OSAC Working with an SDO Process Description

During this step, the subcommittee elects to develop a draft document or refine an existing draft (communicating their intent with the relevant SAC as appropriate, typically through the Priority Action Reports). The Subcommittee will route the draft standard and associated materials[1] through the Subcommittee review, any designated subject matter expert review(s), and may also elect to seek Level 1 comments[2] from OSAC Resource Committees through working group meetings, e-mail, and other venues.

SDO – 225   At this stage, the SC/VSC may elect to hold pitch meeting with Resource Committees.[3]

SDO – 250   SC/VSC submits materials to the Resource Committees for their review and comment (Level 2 comments, via Kavi) using the "add comment" feature.[4]

SDO – 300   SC/VSC completes *QIC Form 6: SDO Process Request* form. Subcommittee submits packet to begin approval routing via Kavi.

SDO – 400   SAC votes on whether to submit standard to an SDO. The vote should be recorded in meeting minutes or through a Kavi ballot. If no, proceed to SDO-425. If yes, proceed to SDO-450.

SDO – 425   SAC disapproves submission. SAC completes a *QIC Template B: Justification for Non-Approval,* and sends justification to SC/VSC. Proceed to SDO-475.

SDO – 450   SAC approves submission, packet is returned to subcommittee. Proceed to SDO-500.

SDO – 475   Requesting SC/VSC reviews non-approval form and determines appropriate next steps.

---

[1] For standards that are more mature, SC/VSC may also elect to complete and submit an accompanying *Registry Request Packet* at this time to include: 1) *QIC Form 1: Technical Merit Worksheet* 2) *QIC Form 3: Registry Request* 3) *QIC Form 4: Impact Worksheet* 4) *QIC Form 5: Harmonization Worksheet,* even though these forms are not required at this stage. (One benefit to completing the forms and performing the analysis is that it may help facilitate the development of the most robust, coherent, and unified draft standard possible, which may facilitate its chances of reaching the OSAC Registry.)

[2] Refer to *OSAC Member Comments Guide* for definition of comment levels.

[3] SC/VSC should work with their SAC on the SAC-specific direction on preferred level of Resource Committee engagement. Some SACs may prefer SC always pitch to resource committees at this stage.
[4] SC/VSC should work with their SAC on the SAC-specific direction on preferred level of Resource Committee engagement.

OSAC Working with an SDO Process Description

SDO – 500   SC/VSC assigns liaison (from within the SC/VSC) to coordinate with the SDO throughout the remainder of the SDO project duration. Liaison should ensure that any changes in the document (necessitated by the SDO balloting and comment adjudication process) are in-line with OSAC beliefs and able to be supported by the OSAC community.

SDO – 600   Follow the SDO's process required to develop a new work item or enter the standard or standard revision into the SDO's cycle. Submit latest OSAC draft to the SDO.

SDO – 700   SDO Comment Period Opens. OSAC Affairs posts link and, for nonpublic comment SDO, technical contact information in monthly OSAC Standards Bulletin and OSAC LinkedIn account to solicit OSAC member comments through the SDO. The OSAC Subcommittee and SAC that submitted the work item may collaborate to provide a collective OSAC response to the open comment period, and/or provide individual comments. Liaison should work closely with SDO to adjudicate any comments or concerns.

SDO – 800   SDO finalizes and publishes the standard.

SDO – 850   SC/VSC deliberates and discusses whether to submit the published standard to the Registry Approval Process. If no, proceed to SDO-1000. If yes, proceed to SDO-900.

SDO – 900   SC/VSC begins *OSAC Registry Approval Process.* For all documents that went through *OSAC Working with an SDO Process,* proceed to RA-100.

   Registry Request Packet includes:
   (1) *QIC Form 1: Technical Merit Worksheet*
   (2) *QIC Form 2: Standards Development Process Worksheet* (if applicable)
   (3) *QIC Form 3: Registry Request Form*
   (4) *QIC Form 4: Impact Worksheet*
   (5) *QIC Form 5: Harmonization Worksheet*.

SDO – 1000   All documents and records generated during the evaluation process must be retained, End