

Pre-approval Process for Standard Revision

The members of the Standard Development Committee develop or revise the standard every year according to the following procedures.

1. Open feedback on the standards

1-1. Laboratory Medicine Foundation Homepage Q and A

Opinions and questions about the requirements for on-site inspection are received on the homepage of the Laboratory Medicine Foundation and the Standard Development Committee post responses to the questionnaires.

1-2. Feedback from Inspector/Surveyor or Users

The surveyor/inspector or users point out problems to the standard during the Outstanding Laboratory Accreditation On-site Inspection and submit suggestions for revision to the Laboratory Medicine Foundation.

1-3. Standard Development Guideline Workshops

Each year before the workshop, opinions from the workshop registrants on the standard requiring revision are collected and discussed during the workshop.

2. Statistics and analysis of on-site inspection scores for each standard

In November each year when on-site inspection is completed, the scores are analyzed by the inspection field and each standard. In other words, the score distribution is analyzed per each standard by evaluating the number and % of institution with perfect score, number and % of institution with partial deduction, and number and % of institution who received 0 points. Based on this statistical data, the necessity of revising the question is reviewed.

3. Standard Revision Process

3-1. Organizing Standard Development Working Committee

One or two laboratory Medicine medical specialists from different fields of inspection including Laboratory Management, Diagnostic Hematology, Clinical Chemistry, Diagnostic Immunology, Clinical Microbiology, Flow Cytometry, Cytogenetics, Molecular Diagnostic Testing, Transfusion Medicine, Histocompatibility, and Referral Medical Laboratory are recruited to form working committee. The multi-disciplinary and multi-institutional participants should have no known conflict of interest in standard revision.

3-2. Working committee members for each discipline input the standard revision draft into corresponding database based on the following:

- ① Various feedback received for each requirement
- ② Related domestic regulation
- ③ Domestic and international regulations and government guidelines
- ④ Journals, association guidelines
- ⑤ Other latest updated opinions

3-3. Standard Development Workshop

Through the Standard Development Committee Working Committee Workshop (also available online), revision proposals raised in each field of inspection are collected and reviewed by the entire committee members, and an agreement on the revision is prepared if validity and evidence of which the draft of the revision is based is sufficient and reasonable.

3-4. Standard Comparison Table of before and after revision

A comparison table of before and after revision is prepared based on the Standard Development Committee revision agreement. The comparison table can be distributed to other committees of laboratory foundation and the Korean Society of Laboratory Medicine Subcommittee members for their feedback and opinions.

4. Standards in consideration for revision are subjected to internal/external reviews for final approval as follows:

4-1. Inspection committee review

4-2. Operation committee of the Laboratory Medicine Foundation review

4-3. Korean Society

5. Standard Revision Approval

Standard revision for each year is finalized after the approval by the Board of Directors of the Korean Society for Laboratory Medicine.

6. Publication and Distribution of the Revised Standard

Reflecting the revisions approved by the board of directors, the next year's checklist (standard) is posted on the Laboratory Medicine Foundation homepage at <http://lmf.or.kr>. Feedback on the posted standard is also collected on the homepage and reviewed to be incorporated into next year's revision.

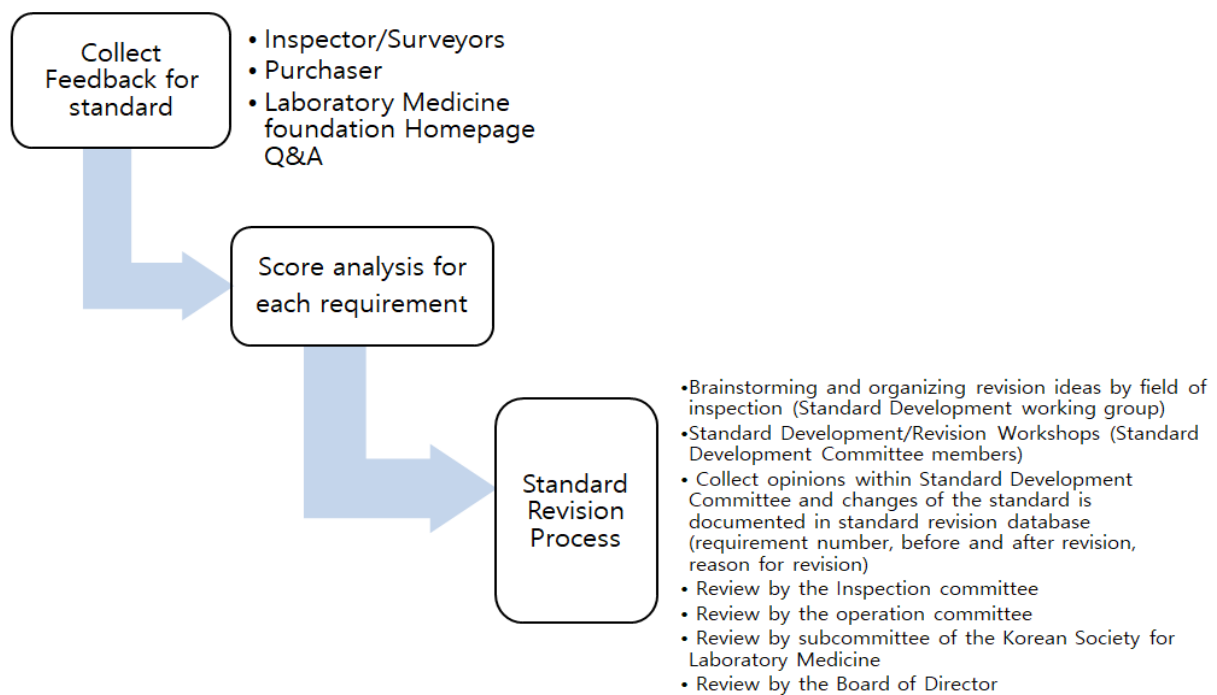


Figure 1. Process for Standard Development/Revision